



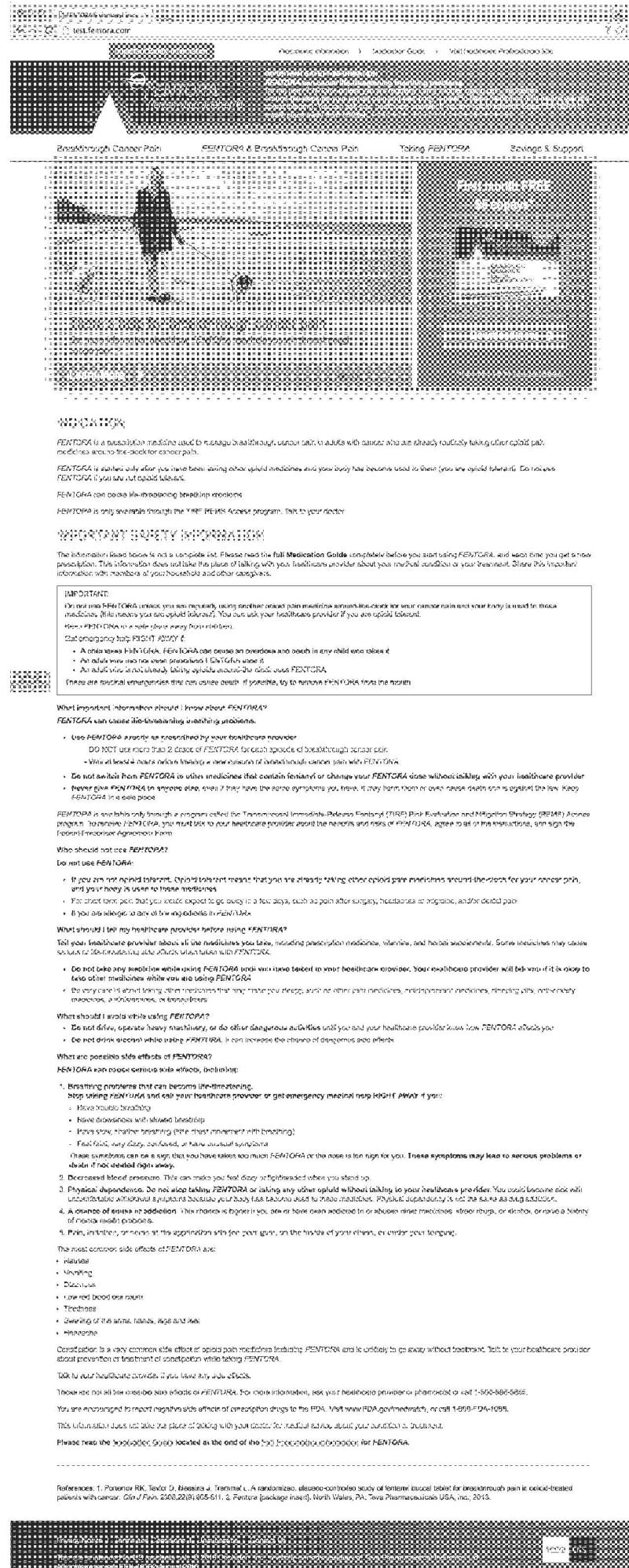
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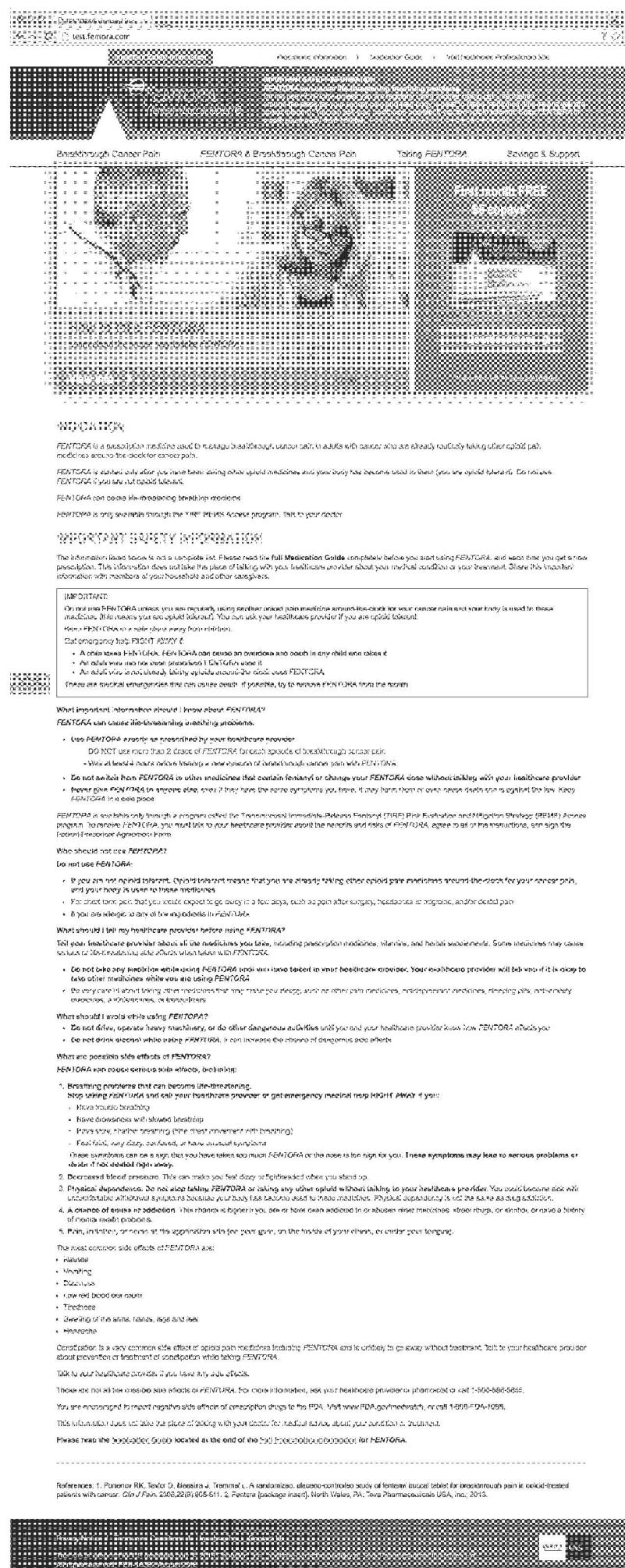
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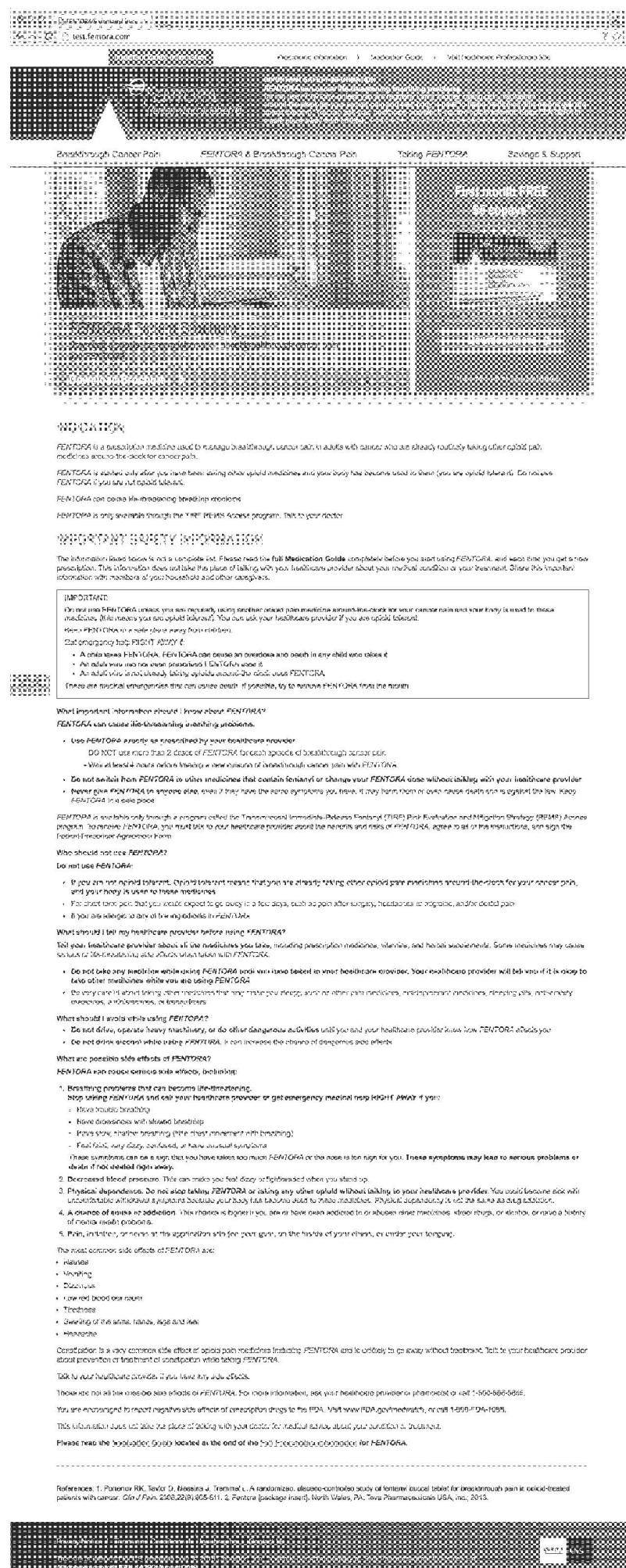












Pain

FENTORA® (fentanyl) is a prescription medicine used to manage breakthrough cancer pain in adults who cannot tolerate or are already routinely taking other opioid pain medicines, due to the risk for cancer pain.

FENTORA® is taken only after you have been taking other opioid medicines and your body has become used to them (you are opioid tolerant). Do not take **FENTORA®** if you are not opioid tolerant.

FENTORA® can cause life-threatening breathing problems.

FENTORA® is only available through the TEVA® FENTORA Access program. Talk to your doctor.

IMPORTANT SAFETY INFORMATION

The information below does not include the full Medication Guide. Please read the full Medication Guide completely before you start using **FENTORA®**, and each time you get a new prescription. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment. Share this important information with members of your household and other caregivers.

IMPORTANT:

Do not use **FENTORA®** unless you are regularly taking another opioid pain medicine around-the-clock for your cancer pain and your healthcare provider has told you to stop taking it. You must ask your healthcare provider if you are opioid tolerant. Read **FENTORA®** in a quiet place away from children.

Call emergency help RIGHT AWAY if:

- A child takes **FENTORA®**. **FENTORA®** can cause an overdose and death in any child who takes it.
- An adult who has never taken **FENTORA®** takes it.
- An adult who is not already taking opioid around-the-clock uses **FENTORA®**.

These are medical emergencies that can cause death. If possible, try to remove **FENTORA®** from the person.

What important information should I know about **FENTORA®?**

FENTORA® can cause life-threatening breathing problems.

- Use **FENTORA®** exactly as prescribed by your healthcare provider.
- DO NOT use more than 2 doses of **FENTORA®** for each episode of breakthrough cancer pain.
 - Wait at least 4 hours before taking a new dose if you have cancer pain with **FENTORA®**.
- Do not switch from **FENTORA®** to other medicines that contain fentanyl or change your **FENTORA®** dose without talking with your healthcare provider.
- Never give **FENTORA®** to anyone else, even if they have the same symptoms you have. It may harm them or even cause death and is against the law. Keep **FENTORA®** in a safe place.

FENTORA® is available only through a program called the Transmucosal Immediate-Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access Program. To receive **FENTORA®**, you must talk to your healthcare provider about the benefits and risks of **FENTORA®**, agree to all of the restrictions, and sign the Patient Agreement form.

Who should not use **FENTORA®?**

Do not use **FENTORA®:**

- If you are not opioid tolerant. Opioid tolerant means that you are already taking other opioid pain medicines around-the-clock for your cancer pain, and your body is used to these medicines.
- For short-term use, such as expected to go away in a few days, such as pain after surgery, headache or migraine, and dental pain.
- If you are allergic to any of the ingredients in **FENTORA®**.

What should I tell my healthcare provider before using **FENTORA®?**

Tell your healthcare provider about all the medicines you take, including prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious side effects when taken with **FENTORA®**.

- Do not take any medicine while using **FENTORA®** that was not taken to your healthcare provider. Your healthcare provider will be sure it is okay to take other medicines while you are using **FENTORA®**.
- Do not use **FENTORA®** when you feel tired, have low energy, and/or other pain medicines, antidepressant medicines, sleeping pills, nonsteroidal anti-inflammatories, a sedative, or tranquilizer.

What should I avoid while using **FENTORA®?**

- Do not drive, operate heavy machinery, or do other dangerous activities until you and your healthcare provider know how **FENTORA®** affects you.
- Do not drink alcohol while using **FENTORA®**. It can increase the chance of dangerous side effects.

What are possible side effects of **FENTORA®?**

FENTORA® can cause serious side effects, including:

- Breathing problems that can become life-threatening. Stop taking **FENTORA®** and call your healthcare provider or get emergency medical help **RIGHT AWAY** if you:
 - Have trouble breathing.
 - Have difficulty breathing with shallow breathing.
 - Have slow, shallow breathing ("the chest movement with breathing").
 - Feel "full," very dizzy, confused, or have unusual sensations.
 These symptoms can be a sign that you have taken too much **FENTORA®** or the dose is too high for you. These symptoms may lead to serious problems or death if not treated right away.
- Decreased appetite. This can make you feel dizzy or fatigued when you stand up.
- Physical dependence. Do not also take **FENTORA®** or taking any other opioid without telling to your healthcare provider. You could become sick with withdraw symptoms because your body has become used to these medicines. Physical dependency is not the same as drug addiction.
- A decrease in sex drive or erection. This change is temporary if you never had sex before or if you abuse other medicines, alcohol, drugs, or stimulants or have a history of sexual health problems.
- Pain, irritation, or rash at the application site for your gel, on the inside of your cheek, or under your tongue.

The most common side effects of **FENTORA®** are:

- Itching
- Nausea
- Drowsiness
- Low red blood cell count
- Tiredness
- Sweating of the arms, hands, legs and feet
- Hiccups

Constipation is a very common side effect of opioid pain medicines including **FENTORA®** and is unlikely to go away without treatment. Tell to your healthcare provider about prevention or treatment of constipation while taking **FENTORA®**.

Talk to your healthcare provider if you have any side effects.

These are not all the possible side effects of **FENTORA®**. For more information, ask your healthcare provider or pharmacist or call 1-800-666-6666. You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

This information does not take the place of talking with your doctor for medical advice about your condition or treatment.

Please read the **Medication Guide** located at the end of the **Product Information** for **FENTORA®**.

References: 1. Patten PK, Taitor D, Biesinger J, Trimble E. A randomized, double-blind study of transmucosal fentanyl citrate for breakthrough pain in opioid-treated patients with cancer. *Cancer*. 2003;92(8):185-191. 2. **FENTORA** (package insert). North Wales, PA: Teva Pharmaceuticals USA, Inc.; 2013.

[test.fentora.com](#)

FENTORA® (Fentanyl) is a prescription medicine used to manage breakthrough cancer pain in adults who cannot tolerate or are already routinely taking other opioid pain medicines around-the-clock for cancer pain.

FENTORA® is taken only after you have been taking other opioid medicines and your body has become used to them (you are opioid tolerant). Do not take FENTORA if you are not opioid tolerant.

FENTORA can cause life-threatening breathing problems.

FENTORA is only available through the TEVA PENTRA Access program. Talk to your doctor.

IMPORTANT SAFETY INFORMATION

The information below has to be a complete list. Please read the full Medication Guide completely before you start using FENTORA, and each time you get a new prescription. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment. Share this important information with members of your household and other caregivers.

IMPORTANT:

On rare occasions, you may suddenly begin another opioid pain medicine around-the-clock for your cancer pain and your body may not yet be used to it. You must ask your healthcare provider if you are opioid tolerant.

Read this Medication Guide every time you refill.

Call emergency help RIGHT AWAY if:

- A child takes FENTORA. FENTORA can cause an overdose and death in any child who takes it.
- An adult who has never taken FENTORA uses it.
- An adult who is not already taking opioid around-the-clock uses FENTORA.

These are medical emergencies that can cause death. If possible, try to remove FENTORA from the person.

What important information should I know about FENTORA?

FENTORA can cause life-threatening breathing problems.

- Use FENTORA exactly as prescribed by your healthcare provider.
- DO NOT use more than 2 doses of FENTORA for each episode of breakthrough cancer pain.
 - Wait at least 4 hours before taking a new dose if breakthrough cancer pain with FENTORA.
- Do not switch from FENTORA to other medicines that contain fentanyl or change your FENTORA dose without talking with your healthcare provider.
- Never give FENTORA to anyone else, even if they have the same symptoms you have. It may harm them or even cause death and is against the law. Keep FENTORA in a safe place.

FENTORA is available only through a program called the Transmucosal Immediate-Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access Program. To receive FENTORA, you must talk to your healthcare provider about the benefits and risks of FENTORA, agree to all of the restrictions, and sign the Patient Agreement form.

Who should not use FENTORA?

- If you are not opioid tolerant. Opioid tolerant means that you are already taking other opioid pain medicines around-the-clock for your cancer pain, and your body is used to these medicines.
- You expect to go away for a few days, such as pain after surgery, headache or migraine, and/or dental pain.
- If you are allergic to any of the ingredients in FENTORA.

What should I tell my healthcare provider before using FENTORA?

Tell your healthcare provider about all the medicines you take, including prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious side effects when taken with FENTORA.

- Do not take any medicine while using FENTORA and will have taken it to your healthcare provider. Your healthcare provider will be sure it is okay to take other medicines while you are using FENTORA.
- Do not stop taking other medicines that may raise your energy such as other pain medicines, antidepressant medicines, stimulant medicines, sleeping pills, nonsteroidal anti-inflammatories, or antihistamines.

When should I avoid using FENTORA?

- Do not drive, operate heavy machinery, or do other dangerous activities until you and your healthcare provider know how FENTORA affects you.
- Do not drink alcohol while using FENTORA. It can increase the chance of dangerous side effects.

What are possible side effects of FENTORA?

FENTORA can cause serious side effects, including:

- Breathing problems that can become life-threatening. Stop taking FENTORA and call your healthcare provider or get emergency medical help **RIGHT AWAY** if you:
 - Have trouble breathing.
 - Have difficulty breathing with slowed breathing.
 - Have slow, shallow breathing ("the chest movement with breathing").
 - Feel "foggy," very drowsy, confused, or have unusual sensations.
 These symptoms can be a sign that you have taken too much FENTORA or the dose is too high for you. These symptoms may lead to serious problems or death if not treated right away.
- Decreased blood pressure. This can make you feel dizzy or frightened when you stand up.
- Physical dependence. Do not also take FENTORA or taking any other opioid without talking to your healthcare provider. You could become sick with withdrawal symptoms because your body has become used to these medicines. Physical dependency is not the same as drug addiction.
- A decrease in sex drive or erection. This change is temporary if you never had sex before or if you abuse other medicines, alcohol, drugs, or certain other medicines.
- Pain, irritation, or infection at the application site for pentra gel, on the inside of your cheek, or under your tongue.

The most common side effects of FENTORA are:

- nausea
- vomiting
- dizziness
- low red blood cell count
- tiredness
- swelling of the arms, hands, legs and feet
- headache

Constipation is a very common side effect of opioid pain medicines including FENTORA and is unlikely to go away without treatment. Tell to your healthcare provider about prevention or treatment of constipation while taking FENTORA.

Talk to your healthcare provider if you have any side effects.

These are not all the possible side effects of FENTORA. For more information, ask your healthcare provider or pharmacist or call 1-800-666-6666.

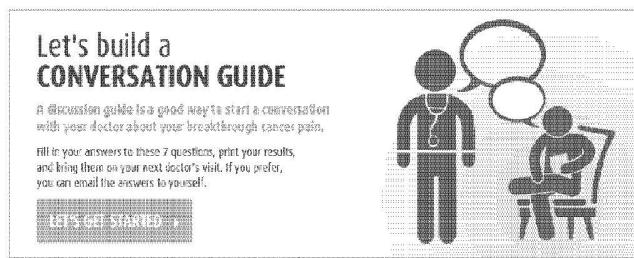
You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch, or call 1-800-FDA-1088.

This information does not take the place of talking with your doctor for medical advice about your condition or treatment.

Please read the [Medication Guide](#) located at the end of the [Patient Information](#) for FENTORA.

References: 1. Patten PK, Taitor D, Biesinger J, Trimble E. A randomized, double-blind study of transmucosal fentanyl citrate for breakthrough pain in opioid-treated patients with cancer. *Cancer Pain*. 2003;22(8):805-811. 2. Fentora (package insert). North Wales, PA: Teva Pharmaceuticals USA, Inc.; 2013.

Screen 01



Screen 02

Question 1 of 7

I've been taking my opioids around-the-clock and I'm still having pain.

True False

BACK **NEXT**

Screen 03

Question 1 of 7

I've been taking my opioids around-the-clock and I'm still having pain.

True False

BACK **NEXT**

Screen 04

Question 2 of 7

My most recent breakthrough pain episode occurred on:

Select a Date

BACK **NEXT**

Screen 05

Screen 06

Question 3 of 7

Screen 07

Question 3 of 7	
I experienced breakthrough pain on	
0	day(s) within the last 2 weeks.
1	
2	
3	
4	
5	
6	
7	
8	
9	
10	
11	
12	
13	
14	

Screen 08

Question 4 of 7

Screen 09

Question 4 of 7

On a scale of 0 to 10 (0 being "no pain" and 10 being "worst pain I ever felt")
I gave my most recent pain episode a _____ rating.

← BACK NEXT →

Screen 10

Question 5 of 7

The pain felt like (type in a description of how your pain felt,
or choose from one of the examples):

Example:

← BACK NEXT →

Screen 11

Choose a word

The pain felt like:

dull	aching
tugging	sharp
burning	throbbing
stabbing	shooting

pain felt,

← BACK NEXT →

Submit

Screen 12

Question 6 of 7

I took the prescribed dose of the medication

Medication name: at: Set time:

← BACK NEXT →

Screen 13

Choose a Time

Medication name: Set time:

04 : 08 AM PM

Set Time

← BACK NEXT →

Screen 14

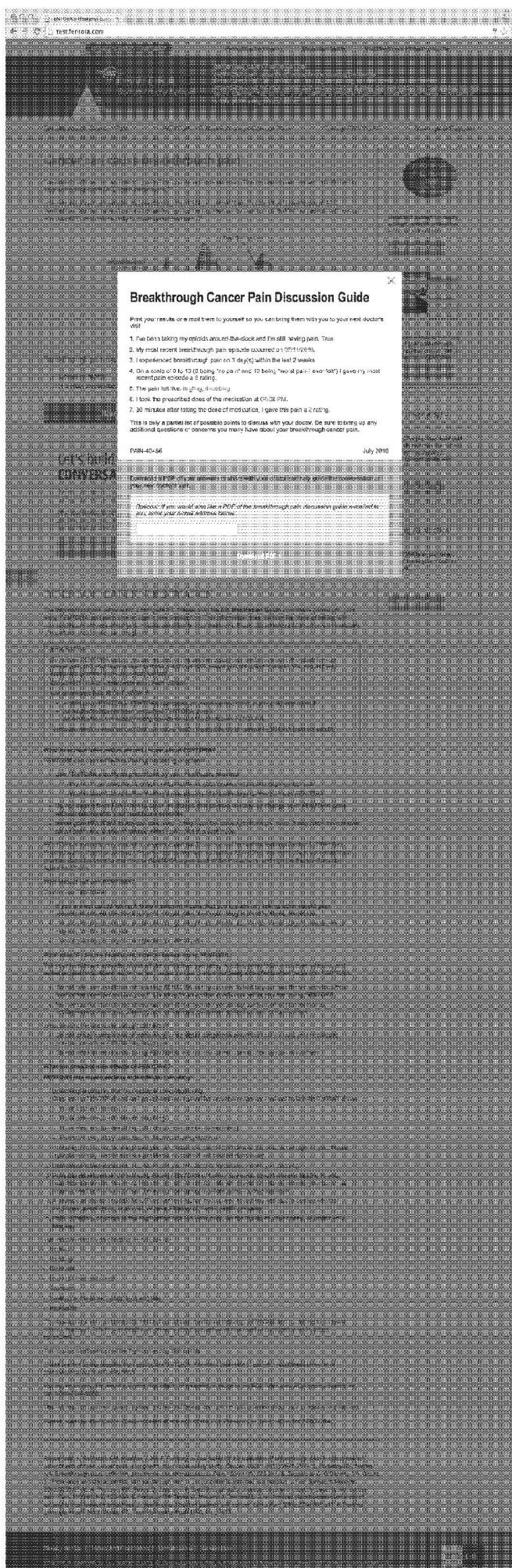
Screen 15

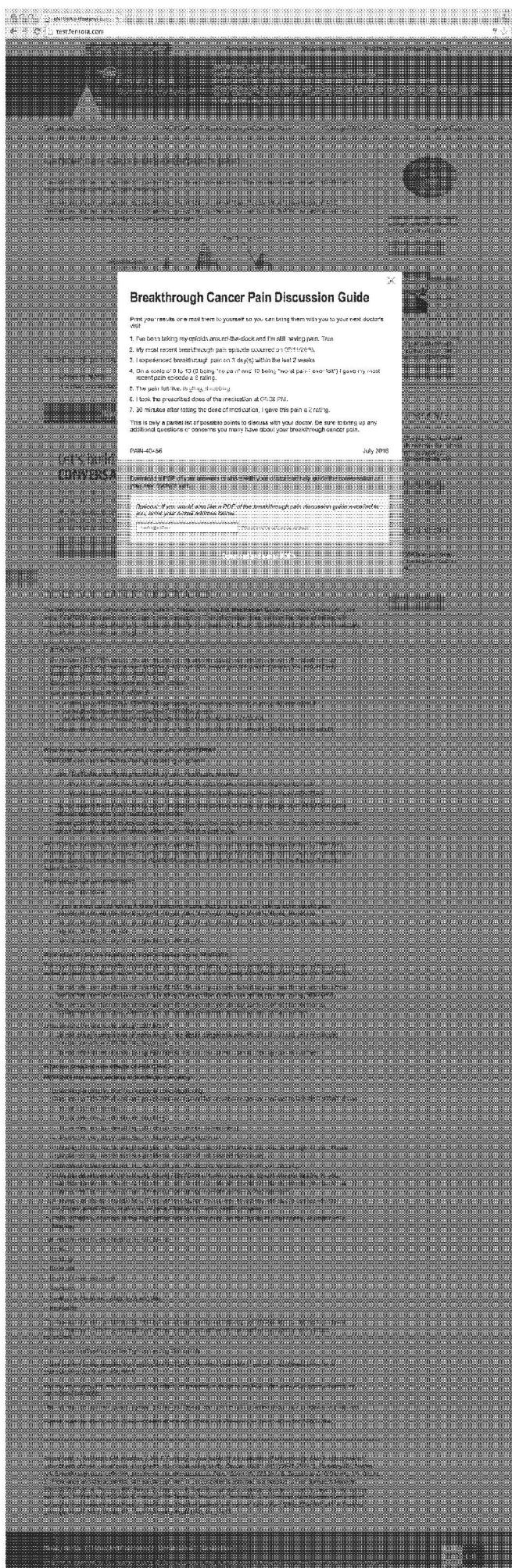
Question 7 of 7

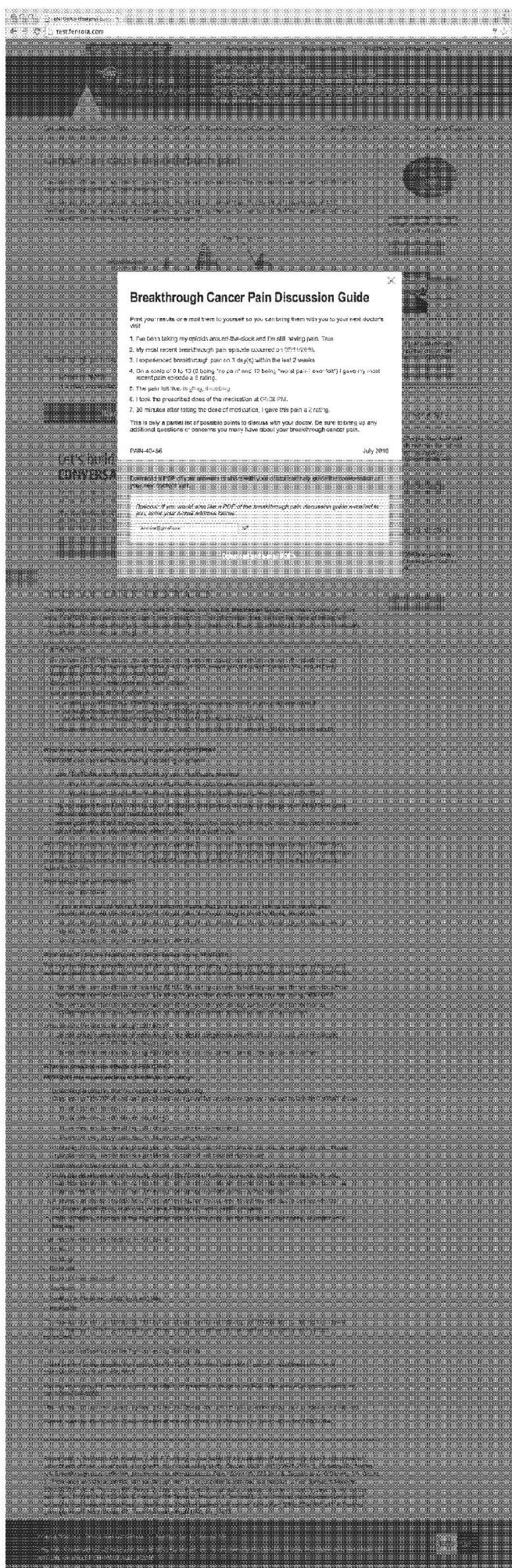
Screen 16

Your custom discussion guide has been created.

[START OVER](#) [VIEW MY GUIDE](#)







FENTORA®

Two options for FENTORA® administration: between the upper cheek and gum (the "all-in-one" or "ring" (solid) form)*

*Your doctor will determine which option is best for you. Administration after which the FENTORA® Disc can be used orally if required.



When starting treatment, FENTORA® Disc should always be placed in the buccal cavity above the nose/molar, before the upper teeth. Then gently press. Switch sides of your mouth for each dose.



Once your doctor tells you to take FENTORA® Disc under your tongue, you may have the option of taking it orally. Place the tablet under your tongue and let it dissolve.



Dedicated support for easy dosage, benefits verification, and prior authorization.



Download a brochure to keep track of your breakthrough cancer pain and learn about treatment with FENTORA®.

FENTORA® BTB

FENTORA® BTB provides relief that generally matches the pattern of breakthrough pain with opioid doses up to 10 mg morphine equivalents.²

IMPORTANT SAFETY INFORMATION

The "all-in-one" or "ring" form of FENTORA® Disc is the full Medication Guide complete "all-in-one" using FENTORA® Disc, and tell them you yes a new prescription. This medication does not work if taken orally. Your healthcare provider will prescribe medical assistance or your treatment. Share this important information with members of your household and close relatives.

I. OVERVIEW

Do not use FENTORA® Disc unless you are regularly using another opioid pain medication around-the-clock for your cancer pain. Your body is used to these medications (this means you are opioid tolerant). You can ask your healthcare provider if you are opioid tolerant.

II. IF YOU TAKE "ALL-IN-ONE" OR "RING" FORM FOR PAIN

A call to FENTORA® Disc, cause an overdose and death may occur if taken.

An adult can take one FENTORA® Disc at a time.

An adult can take one FENTORA® Disc at a time.

These are medical emergencies that can cause death. If feasible, try to remove FENTORA® from the mouth.

III. WHAT IS FENTORA® AND HOW IS IT USED?

FENTORA® can cause life-threatening breathing problems.

• Use FENTORA® Disc as prescribed by your healthcare provider.

• Do not use FENTORA® Disc if you are allergic to FENTORA® Disc.

• Do not switch from FENTORA® Disc to other medications that contain fentanyl or change your FENTORA® Disc without talking with your healthcare provider.

• If you are taking FENTORA® Disc, do not drink alcohol or drive a car. It can cause death and/or against the law. Keep FENTORA® Disc in a safe place.

FENTORA® Disc is available only through a program called the Transmucosal Immediate-Release Fentanyl (TRIF) Risk Evaluation and Mitigation System (REMS) Approval Program. To receive FENTORA®, you must first receive FENTORA® Disc from a participating physician and make a FENTORA® Disc Agreement Form, available online at www.teva.com/fentora.

IV. WHO SHOULD NOT USE FENTORA®?

Do not use FENTORA® Disc:

- If you are opioid tolerant. Opioid tolerant means that you are already taking other opioid pain medications around-the-clock for your cancer pain, and your body is used to these medications.
- If you are taking it, you are going to get very tired, says John Fentor, who is not an opioid-tolerant person.
- If you are allergic to any other ingredients in FENTORA® Disc.

V. WHAT SHOULD I TELL MY HEALTHCARE PROVIDER BEFORE USING FENTORA®?

Tell your healthcare provider about the medications you take, including prescription medications, vitamins, and herbal supplements. Some medications may cause serious side effects when taken with FENTORA® Disc.

- Do not take any medicine while using FENTORA® Disc until you have talked to your healthcare provider. Your healthcare provider will tell you if it is safe to take other medications while using FENTORA® Disc.
- Be very careful about taking other medicines that may make you sleepy, such as other pain medications, antihistamines, sedatives, sleeping pills, tranquilizers, muscle relaxants, tranquilizers, or tranquilizers.

VI. WHO SHOULD NOT USE FENTORA® DISCS?

- Do not drive, operate heavy machinery, or do other dangerous activities until you know how FENTORA® Disc affects you.
- Do not drink alcohol while using FENTORA® Disc. It can increase the chance of dangerous side effects.

VI. WHAT ARE SERIOUS SIDE EFFECTS OF FENTORA®?

FENTORA® Disc can cause serious side effects, including:

1. Breathing problems that can become life-threatening:
• Taking FENTORA® Disc can affect the way you breathe, causing you to stop breathing ("respiratory depression").
• Have trouble breathing.
• Have trouble swallowing.
• Have slow, shallow breathing (little chest movement with breathing).
• Feel lightheaded, confused, ... have unusual symptoms.
These symptoms can be a sign that you have taken too much FENTORA® Disc or the dose is too high for you. These symptoms may lead to serious problems or death if not treated right away.
2. Decreased blood pressure: This can make you feel dizzy or faint when you stand up.
3. Physical dependence: Do not stop taking FENTORA® Disc or taking any other opioid without talking to your healthcare provider. You could become ill with uncomfortable withdrawal symptoms because your body has become used to these medications. Physical dependence is not the same as drug addiction.
4. Signs of abuse or addiction: The chance is higher if you are already an addicted to or abused other medications, drugs, or alcohol, or have a history of mental health problems.
5. Skin irritation or some of the medication site (on your gum, on the insides of your cheek, or under your tongue).

VI. OTHER SIDE EFFECTS OF FENTORA®

- Nausea
- Vomiting
- Diarrhea
- Low red blood cell counts
- Tiredness
- Swelling of the arms, hands, legs and feet
- Rash

Coughing is a very common side effect of opioid pain medications including FENTORA® Disc and is related to physical well-being. Tell your healthcare provider if you have any side effects.

These are just a few possible side effects of FENTORA® Disc. For more information, call your healthcare provider or pharmacist or call 1-800-865-3855.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-332-1310.

This information does not take the place of talking with your doctor for medical advice about your condition or treatment.

Please read the Medication Guide located at the end of the full Prescribing Information for FENTORA®.

References: 1. Fentora [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc; 2013. 2. Portenoy RK, Taylor D, Messina J. Transmucosal, placebo-controlled study of fentanyl buccal solutol for breakthrough pain in opioid-treated patients with cancer. *Cancer Pain Symptom Suppl*. 2006;22(3):605-611.

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www.fentora.com

FENTORA® (fentanyl buccal tablet) ©

Purchasing Information

Medication Guide | Visit

IMPORTANT SAFETY INFORMATION

FENTORA® (fentanyl buccal tablet)
Do not use FENTORA if you have or are having breathing problems.
Do not use FENTORA if you are regularly using another pain and your body is used to it.
Ask your healthcare provider if you are having breathing problems, are regularly using another pain and your body is used to it.
Ask your healthcare provider if you are having breathing problems, are regularly using another pain and your body is used to it.

Reinforcement

A Savings & Support

In order to receive FENTORA® (fentanyl buccal tablet) ©, you must complete a **Reimbursement Assistance Program Consent Form**, then fax the form to 1-877-4FENTORA (1-877-436-8672).

First month FREE*

\$5 copays*

LOAD FORM >

On-call reimbursement support
Call 1-877-4FENTORA (1-877-436-8672)
(Open Monday - Friday 6 AM - 7 PM CT)

Indicates required fields

Name: _____
Phone Number: _____
Confirm e-mail: _____

I understand and agree to the To am not eligible for coverage for the healthcare program.
I am of age or older.
and understand the Local Code.

I understand that I may choose to stop receiving further communications from FENTORA by following the instructions listed on the communication or by contacting:

DOWNLOAD

ANT SAFETY IN

Important: This information is not a complete guide to all the full Medication Guide complete information about FENTORA, and each time you take FENTORA this information does not take the place of what your healthcare provider about FENTORA and how to use it.

Important Note:
Do not use FENTORA unless you are regularly taking opioid pain medicine around the clock for your cancer pain and your body is used to it. If you are not, this means you are opioid naïve. You can talk to your healthcare provider if you are opioid naïve.
Keep FENTORA in a safe place away from children.

Get emergency help RIGHT AWAY if:

- A child takes FENTORA. FENTORA can cause an overdose and death in any child who takes it.
- An adult who has not been prescribed FENTORA uses it.
- An adult who is not already taking opioids around-the-clock uses FENTORA.

These are medical emergencies that can cause death. If possible, try to remove FENTORA from the mouth.

What important information should I know about FENTORA?

FENTORA can cause life-threatening breathing problems.

Use FENTORA exactly as prescribed by your healthcare provider.

- DO NOT use more than 2 doses of FENTORA for each episode of breakthrough cancer pain.
- Take FENTORA at least 4 hours before treat-
- through cancer pain with FENTORA.
- switch from FENTORA to another opioid or change your
- FENTORA to anyone else.
- A in a safe place.
- available only through a pro-
- scribe FENTORA, you must
- rive Agreement Form.
- not use FENTORA?
- ENTORA:
- do not tolerate Opioid
- and your body is used to these medicines
- For short periods that you expect to go away in a few days, such as pain after surgery, headaches or migraine, and/or dental pain.
- If you are allergic to any of the ingredients in FENTORA

What should I tell my healthcare provider before using FENTORA?

Tell your healthcare provider about all the medicines you take, including prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life-threatening side effects when taken with FENTORA.

Do not take any medicines while using FENTORA until you have talked to your healthcare provider. Your healthcare provider will tell you if it is okay to take other medicines while you are using FENTORA.

Be very careful taking other medicines that may make you sleepy, such as other pain medicines, antidepressant medicines, sleeping pills, anti-anxiety medicines, and substances that stimulate you.

What should I avoid while using FENTORA?

- Do not drive, operate heavy machinery, or do other dangerous activities until you and your healthcare provider know how FENTORA affects you.
- Do not drink alcohol while using FENTORA. It increases the chance of dangerous side effects.

What are possible side effects of FENTORA?

FENTORA can cause serious side effects, including:

- Breathing problems that can become life-threatening. Stop taking FENTORA and call your healthcare provider or get emergency medical help RIGHT AWAY if you:
 - have trouble breathing
 - feel lightheaded with slowed breathing
 - have slow, shallow breathing (little or no breathing)
 - feel faint, very dizzy, confused, or have unusual symptoms
- These symptoms can be a sign that you have taken too much FENTORA or the dose is too high for you. These symptoms may lead to serious problems or death if they are not treated right away.
- Decreased blood pressure. This can make you feel dizzy or light-headed when you stand up.
- Physical dependence. Do not stop taking FENTORA or taking any other opioid without talking to your healthcare provider. You could become sick with uncontrollable withdrawal symptoms because your body has become used to these medicines. Physical dependency is not the same as drug addiction.
- A chance of abuse or addiction. This chance is higher if you are, or have been addicted to, or abused other medicines, street drugs, or alcohol, or have a history of mental health problems.
- Pain, irritation, or sores at the application site (on your gum, on the inside of your cheek, or under your tongue).

The most common side effects of FENTORA are:

- Nausea
- od cough
- the arms, hands, legs and feet
- a very common side effect ion or treatment of constipation
- healthcare provider if you have:
 - all the possible side effects
- fusing FENTORA and is unli
- alment. Talk to your healthca

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch, or call 1-800-FDA-1088.

This information does not take the place of talking with your doctor for medical advice about your condition or treatment.

Please read the located at the end of the Full Prescribing Information for FENTORA.

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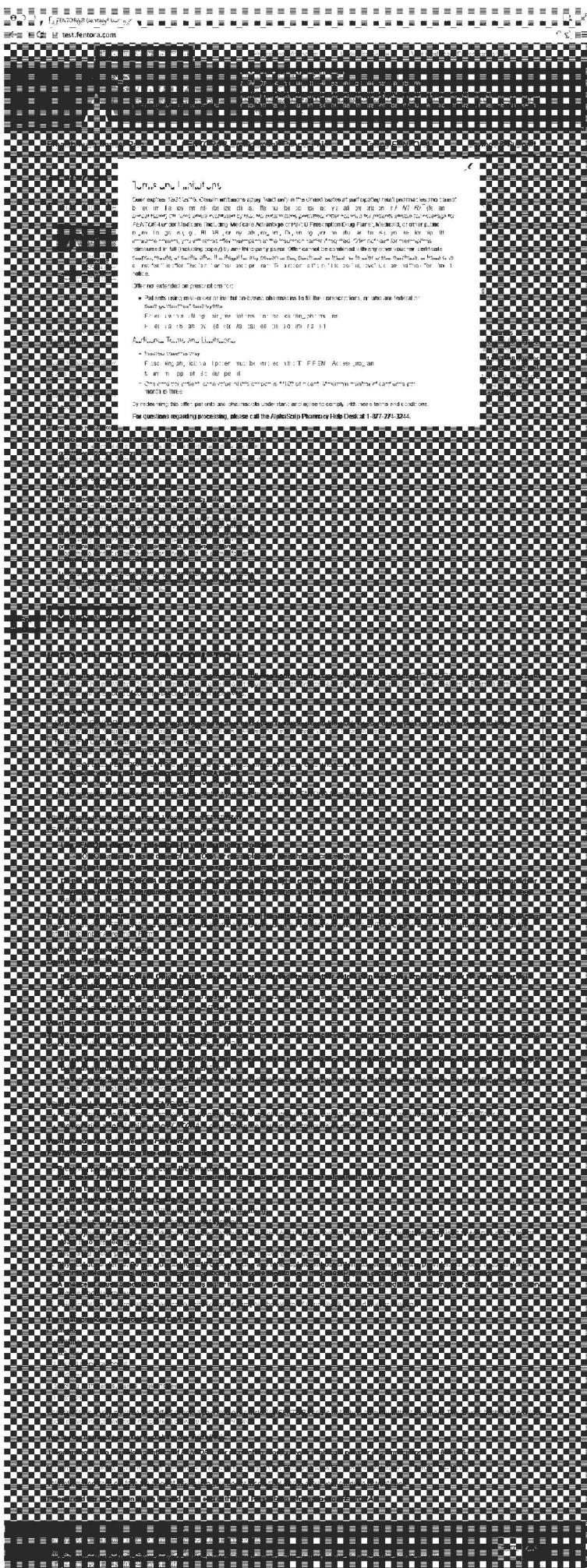
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P-29463 00019





IMPORTANT SAFETY INFORMATION
FENTORA® (fentanyl buccal tablet) for breakthrough cancer pain
DO NOT USE FENTORA IF YOU HAVE AN OPIOID TOLERANCE

Breakthrough Cancer Pain **FENTORA® & Breakthrough Cancer Pain** **Taking FENTORA** **Savings & Support**

Your **FENTORA® Savings Card** is below!

Print this card and present it to your pharmacist when you get your next prescription. With the card, you may be eligible to receive your first month of **FENTORA FREE**, and \$0 copays. Void where prohibited by law.

If you'd like to print the card now, you can [download it here](#).

IMPORTANT SAFETY INFORMATION

The information listed below is not a complete list. Please read the **full Medication Guide** completely before you start using **FENTORA**, and each time you get a new prescription. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment. Share this important information with members of your household and other caregivers.

INFORMATION:

Do not use FENTORA unless you are regularly taking another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines (this means you are opioid tolerant). You can ask your healthcare provider if you are opioid tolerant.

Keep **FENTORA** in a safe place away from children.

Get emergency help **RIGHT AWAY** if:

- A child takes **FENTORA**. **FENTORA** can cause an overdose and death in any child who takes it.
- An adult who has not been previously **FENTORA** uses it.
- An adult who is not already taking opioid around-the-clock uses **FENTORA**.

These are medical emergencies that can cause death. If possible, try to remove **FENTORA** from the mouth.

What important information should I know about **FENTORA?**

FENTORA can cause life-threatening breathing problems.

Use **FENTORA exactly as prescribed by your healthcare provider**

- DO NOT** use more than 2 doses of **FENTORA** for each episode of breakthrough cancer pain.
- Wait at least 4 hours before taking a new episode of breakthrough cancer pain with **FENTORA**.
- Do not switch from **FENTORA** to other medicines that contain fentanyl or change your **FENTORA** dose without talking with your healthcare provider.**
- Never give **FENTORA** to anyone else, even if they may have the same symptoms you have. It may harm them or even cause death. It is illegal to keep **FENTORA** in a safe place.**

FENTORA is available only through a program called the Transmucosal Immediate-Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access program. To receive **FENTORA**, you must talk to your healthcare provider about the benefits and risks of **FENTORA**, agree to all of the instructions, and sign the Patient/Prescriber Agreement Form.

Who should not use **FENTORA?**

Do not use **FENTORA:**

- If you are not opioid tolerant. **Opioid tolerant** means that you are already taking other opioid pain medicines around-the-clock for your cancer pain, and your body is used to those medicines.
- For short-term pain that you would expect to go away in a few days, such as pain after surgery, headache or migraine, or ear-related pain.
- If you are allergic to any of the ingredients in **FENTORA**.

What should I tell my healthcare provider before using **FENTORA?**

Tell your healthcare provider about all the medicines you take, including prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life threatening side effects when taken with **FENTORA.**

- Do not take any medicine while using **FENTORA** until you have talked to your healthcare provider. Your healthcare provider will tell you if it is okay to take other medicines while you are using **FENTORA**.**
- Be very careful about taking other medicines that may make you sleepy, such as other pain medicines, sedatives, hypnotics, sleeping aids, anti-anxiety medicines, antihistamines, or tranquilizers.

What should I avoid while using **FENTORA?**

- Do not drive, operate heavy machinery, or do other dangerous activities** until you and your healthcare provider know how **FENTORA** affects you.
- Do not drink alcohol** while using **FENTORA**. It can increase the chance of dangerous side effects.

What are possible side effects of **FENTORA?**

FENTORA can cause serious side effects, including:

- Breathing problems that can become life threatening.** Stop taking **FENTORA** and call your healthcare provider or get emergency medical help **RIGHT AWAY** if you:
 - I have trouble breathing
 - I have drowsiness with slowed breathing
 - I have slow, shallow breathing (no chest movement with breathing)
 - I feel tired, very dizzy, confused, or have unusual symptoms
 These symptoms can be a sign that you have taken too much **FENTORA** or the dose is too high for you. These symptoms may lead to serious problems or death if not treated right away.
- Decreased blood pressure.** This can make you feel dizzy or light-headed when you stand up.
- Physical dependence.** Do not stop taking **FENTORA** or taking any other opioid without talking to your healthcare provider. You could become sick with uncomfortable withdrawal symptoms because your body has become used to these medicines. Physical dependence is not the same as drug addiction.
- A desire or strong need to take **FENTORA**.** This desire or strong need can be linked to or related to other medicines (e.g., street drugs or alcohol), or have a history of mental health problems.
- Pain, irritation, or sores at the application site (on your skin, or the inside of your cheek or under your tongue).**

The most common side effects of **FENTORA are:**

- Nausea
- Vomiting
- Dizziness
- Low red blood cell count
- Tiredness
- Swelling of the arms, hands, legs and feet
- Headache

Dependence is a very common side effect of opioid pain medicines including **FENTORA and is unlikely to go away without treatment. Tell to your healthcare provider about prevention or treatment of constipation while taking **FENTORA**.**

Talk to your healthcare provider if you have any side effects.

These are not all the possible side effects of **FENTORA. For more information, ask your healthcare provider or pharmacist or call 1-800-295-6362.**

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.FDA.gov/medwatch](#), or call 1-800-FDA-1088.

This information does not take the place of talking with your doctor for medical advice about your condition or treatment.

Please read the **Medication Guide located at the end of the **Full Prescribing Information for **FENTORA****.**

References: 1. Fentora [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; 2012. 2. Portenoy RK, Taylor D, Messina J, Tramer L. A randomized, placebo-controlled study of fentanyl buccal tablet for breakthrough pain in opioid-treated patients with cancer. *Cancer* 2006;102(9):859-861.

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Breakthrough Cancer Pain

FENTORA & Breakthrough Cancer Pain

Taking FENTORA

Savings & Support

IMPORTANT SAFETY INFORMATION

FENTORA can cause life-threatening breathing problems. Do not use **FENTORA** unless you are "regularly taking another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines" (this means you are opioid tolerant). You can ask your healthcare provider if you are opioid tolerant.

Healthcare professionals: submit your request to teva.us/submitinfo for free access.

To request information about **FENTORA, contact us at 1-800-956-5655 or visit www.tevapharm.com.**

Important Safety Information

The information above is not a complete set. Please read the **full Medication Guide** completely before you start using **FENTORA**, and each time you get a new prescription. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment. Share this important information with members of your household and other caregivers.

IMPORTANT

Do not use **FENTORA** unless you are "regularly taking another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines" (this means you are opioid tolerant). You can ask your healthcare provider if you are opioid tolerant.

Keep **FENTORA** in a safe place away from children. Get emergency help **RIGHT AWAY** if:

- A child takes **FENTORA**. **FENTORA** can cause an overdose and death in any child who takes it.
- An adult who has not been prescribed **FENTORA** uses it.
- An adult who is not already taking opioids around the clock uses **FENTORA**.

These are medical emergencies that can cause death. If possible, try to remove **FENTORA** from the mouth.

What important information should I know about **FENTORA?**

FENTORA can cause life-threatening breathing problems.

Use **FENTORA exactly as prescribed by your healthcare provider**

- DO NOT use more than 2 doses of **FENTORA** for each episode of breakthrough cancer pain.
- Wait at least 4 hours before taking a new episode of breakthrough cancer pain with **FENTORA**.
- Do not switch from **FENTORA** to other medicines that contain fentanyl or change your **FENTORA** dose without talking with your healthcare provider.
- Never give **FENTORA** to anyone else, even if they have the same symptoms you have. It may harm them or even cause death and is against the law. Keep **FENTORA** in a safe place.

FENTORA is available only through a program called the Transmucosal Immediate-Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy (REMS) Access program. To receive **FENTORA**, you must talk to your healthcare provider about its benefits and risks of **FENTORA**, agree to all of the instructions, and sign the Patient/Prescriber Agreement Form.

Who should not use **FENTORA?**

Do not use **FENTORA:**

- If you are not opioid tolerant. Opioid tolerant means that you are already taking other opioid pain medicines around-the-clock for your cancer pain, and your body is used to **these medicines**.
- For short-term pain that you would expect to go away in a few days, such as pain after surgery, headaches or migraine, and/or dental pain.
- If you are allergic to any of the ingredients in **FENTORA**.

What should I tell my healthcare provider before using **FENTORA?**

Tell your healthcare provider about all the medicines you take, including prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life-threatening side effects when taken with **FENTORA**.

- Do not take any medicine while using **FENTORA** until you have talked to your healthcare provider. Your healthcare provider will tell you it is okay to take other medicines while you are using **FENTORA**.
- Be very careful about taking other medicines that may make you sleepy, such as other pain medicines, antihistamines, sedatives, sleeping pills, anti-anxiety medications, anti-inflammatories, or tranquilizers.

What should I avoid while using **FENTORA?**

Do not drive, operate heavy machinery, or do other dangerous activities until you and your healthcare provider know how **FENTORA affects you.**

Do not drink alcohol while using **FENTORA. It can increase the chance of dangerous side effects.**

What are possible side effects of **FENTORA?**

FENTORA can cause serious side effects, including:

1. Breathing problems that can become life-threatening. Stop taking **FENTORA** and call your healthcare provider or get emergency medical help **RIGHT AWAY** if you:
 - Have trouble breathing
 - Have difficulty breathing with slowed breathing
 - Have slow, shallow breathing (no chest movement with breathing)
 - Feel tired, very dizzy, confused, or have unusual symptoms
 These symptoms can be a sign that you have taken too much **FENTORA** or the dose is too high for you. These symptoms may lead to serious problems or death if not treated right away.
2. Decreased blood pressure. This can make you feel dizzy or light-headed when you stand up.
3. Physical dependence. Do not stop taking **FENTORA** or taking any other opioid without talking to your healthcare provider. You could become sick with uncomfortable withdrawal symptoms because your body has become used to these medicines. Physical dependence is not the same as drug addiction.
4. Abuse or misuse of medication. This behavior is typical if you are not taking **FENTORA** as directed or if you abuse other medicines (e.g., street drugs or alcohol), or have a history of mental health problems.
5. Pain, irritation, or sores at the application site (on your skin, on the inside of your cheek, or under your tongue).

The most common side effects of **FENTORA** are:

- Nausea
- Vomiting
- Constipation
- Low red blood cell count
- Tiredness
- Swelling of the arms, hands, legs and feet
- Headache

Dependence is a very common side effect of opioid pain medicines including **FENTORA** and is unlikely to go away without treatment. Tell your healthcare provider about prevention or treatment of constipation while taking **FENTORA**.

Talk to your healthcare provider if you have any side effects.

These are not all the possible side effects of **FENTORA**. For more information, ask your healthcare provider or pharmacist or call 1-800-956-5655.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch, or call 1-800-FDA-1088.

This information does not take the place of talking with your doctor for medical advice about your condition or treatment.

Please read the **Medication Guide** located at the end of the **Full Prescribing Information for **FENTORA****.

Useful Numbers

Reimbursement Assistance Hotline:
1-877-4-FENTORA
1-877-436-3672

Patient Assistance Program (tevacares):
1-877-237-4691

Teva US Medical Information:
1-800-956-5655

Dedicated support for copay savings, benefit verification, and prior authorization.

Download a brochure to keep track of your breakthrough cancer pain and learn about treatment with **FENTORA**.

FENTORA & BTP

Taking **FENTORA**

FENTORA is an oral tablet placed inside your mouth to dissolve.

References: 1. Fentora [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; 2012. 2. Portenoy RK, Taylor D, Messina J, Trermer L. A randomized, placebo-controlled study of fentanyl buccal tablet for breakthrough pain in opioid-treated patients with cancer. *Cancer* 2006;102(9):859-861.

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IMPORTANT SAFETY INFORMATION

FENTORA® (fentanyl buccal tablet) is a prescription opioid pain medicine. FENTORA® is used to treat breakthrough cancer pain in adults who are already taking other opioid pain medicines around-the-clock for their cancer pain.

To remove your address from the e-mail list for FENTORA, enter your e-mail address and click the "Unsubscribe" button.

E-mail:

IMPORTANT SAFETY INFORMATION

The information listed below is not a complete list. Please read the full Medication Guide completely before you start using FENTORA, and each time you get a new prescription. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment. Share this important information with members of your household and other caregivers.

IMPORTANT:

Do not use FENTORA unless you are regularly using another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines (this means you are opioid tolerant). You can ask your healthcare provider if you are opioid tolerant.

Keep FENTORA in a safe place away from children.
 Get emergency help RIGHT AWAY if:

- A child takes FENTORA. FENTORA can cause an overdose and death in any child who takes it.
- An adult who has not been prescribed FENTORA uses it.
- An adult who is not already taking opioids around-the-clock uses FENTORA.

These are medical emergencies that can cause death. If possible, try to remove FENTORA from the mouth.

What important information should I know about FENTORA?

FENTORA can cause life-threatening breathing problems.

- Use FENTORA exactly as prescribed by your healthcare provider.
- DO NOT use more than 2 doses of FENTORA for each episode of breakthrough cancer pain.
- Wait at least 4 hours before starting a new episode of breakthrough cancer pain with FENTORA.
- Do not switch from FENTORA to other medicines that contain fentanyl or change your FENTORA dose without talking with your healthcare provider.
- Never give FENTORA to anyone else, even if they have the same symptoms you have. It may harm them or even cause death and it against the law. Keep FENTORA in a safe place.

FENTORA is available only through a program called the Transmucosal Immediate-Release Fentanyl (TRIF) Risk Evaluation and Mitigation Strategy (REMS) Access program. To receive FENTORA, you must talk to your healthcare provider about the benefits and risks of FENTORA, agree to all of the instructions, and sign the Patient-Rescuer Agreement Form.

Who should not use FENTORA?

Do not use FENTORA if:

- If you are not opioid tolerant. Opioid tolerant means that you are already taking other opioid pain medicines around-the-clock for your cancer pain, and your body is used to these medicines.
- For short-term pain that you would expect to go away in a few days, such as pain after surgery, headaches or migraines, and dental pain.
- If you are allergic to any of the ingredients in FENTORA.

What should I tell my healthcare provider before using FENTORA?

Tell your healthcare provider about all the medicines you take, including prescription medicines, vitamins, and herb supplements. Some medicines may cause serious or life-threatening side effects when taken with FENTORA.

- Do not take any medicines while using FENTORA until you have talked to your healthcare provider. Your healthcare provider will tell you if it is okay to take other medicines while you are using FENTORA.
- Be very careful about taking other medicines that may make you sleepy, such as other pain medicines, sedatives, tranquilizers, medicines, sleeping pills, anti-anxiety medicines, antihistamines, or tranquilizers.

What should I avoid while using FENTORA?

- Do not drive, operate heavy machinery, or do other dangerous activities until you and your healthcare provider know how FENTORA affects you.
- Do not drink alcohol while using FENTORA. It can increase the chance of dangerous side effects.

What are possible side effects of FENTORA?

FENTORA can cause serious side effects, including:

- Breathing problems that can become life-threatening. Stop taking FENTORA and call your healthcare provider or get emergency medical help RIGHT AWAY if you:
 - Have trouble breathing
 - Have drowsiness with slowed breathing
 - Have slow shallow breathing (little chest movement with breathing)
 - Feel faint, very dizzy, confused, or have unusual symptoms
- These symptoms can be a sign that you have taken too much FENTORA or the dose is too high for you. These symptoms may lead to serious problems or death if not treated right away.
- Decreased blood pressure. This can make you feel dizzy or lightheaded when you stand up.
- Physical dependence. Do not stop taking FENTORA or taking any other opioid without talking to your healthcare provider. You could become sick with uncomfortable withdrawal symptoms because your body has become used to these medicines. Physical dependency is not the same as drug addiction.
- A change of abuse or addiction. This change is higher if you are or have been addicted to or abused other medicines, street drugs, or alcohol, or have a history of mental health problems.
- Pain, irritation, or sores at the application site (on your gum, on the inside of your cheek, or under your tongue).

The most common side effects of FENTORA are:

- Nausea
- Vomiting
- Dizziness
- Low red blood cell count
- Tiredness
- Swelling of the arms, hands, legs and feet
- Headache

Constipation is a very common side effect of opioid pain medicines including FENTORA and is unlikely to go away without treatment. Talk to your healthcare provider about prevention or treatment of constipation while taking FENTORA.

Talk to your healthcare provider if you have any side effects.

These are not all the possible side effects of FENTORA. For more information, ask your healthcare provider or pharmacist or call 1-800-956-5655.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch, or call 1-800-FDA-1088.

This information does not take the place of talking with your doctor for medical advice about your condition or treatment.

Please read the Medication Guide located at the end of the Full Prescribing Information for FENTORA.

References: 1. Fentora [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; 2013. 2. Tepasne J, Tepasne L. A randomized, placebo-controlled study of fentanyl buccal tablet for breakthrough pain in opioid-treated patients with cancer. *Clin J Pain*. 2006;22(8):805-811.

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IMPORTANT SAFETY INFORMATION

FENTORA® (fentanyl buccal tablet) for breakthrough cancer pain. FENTORA® is a prescription opioid pain medicine. It is used to treat breakthrough cancer pain in adults who are already taking other opioid pain medicines around-the-clock for their cancer pain. FENTORA® is not for use in children under 18 years of age. FENTORA® is not for use in patients who are not opioid tolerant. FENTORA® is not for use in patients who are not already taking other opioid pain medicines around-the-clock for their cancer pain.

To remove your address from the e-mail list for FENTORA, enter your e-mail address and click the "Unsubscribe" button.

E-mail: we don't have the address you entered in our database.

UNSUBSCRIBE

IMPORTANT SAFETY INFORMATION

The information listed below is not a complete list. Please read the full Medication Guide completely before you start using FENTORA, and each time you get a new prescription. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment. Share this important information with members of your household and other caregivers.

IMPORTANT:

Do not use FENTORA unless you are regularly using another opioid pain medicine around-the-clock for your cancer pain and your body is used to these medicines (this means you are opioid tolerant). You can ask your healthcare provider if you are opioid tolerant.

Keep FENTORA in a safe place away from children.

Get emergency help RIGHT AWAY if:

- A child takes FENTORA. FENTORA can cause an overdose and death in any child who takes it.
- An adult who has not been prescribed FENTORA uses it.
- An adult who is not already taking opioids around-the-clock uses FENTORA.

These are medical emergencies that can cause death. If possible, try to remove FENTORA from the mouth.

What important information should I know about FENTORA?

FENTORA can cause life-threatening breathing problems.

- Use FENTORA exactly as prescribed by your healthcare provider.
- DO NOT use more than 2 doses of FENTORA for each episode of breakthrough cancer pain.
- Wait at least 4 hours before starting a new episode of breakthrough cancer pain with FENTORA.
- Do not switch from FENTORA to other medicines that contain fentanyl or change your FENTORA dose without talking with your healthcare provider.
- Never give FENTORA to anyone else, even if they have the same symptoms you have. It may harm them or even cause death and it against the law. Keep FENTORA in a safe place.

FENTORA is available only through a program called the Transmucosal Immediate-Release Fentanyl (TRIF) Risk Evaluation and Mitigation Strategy (REMS) Access program. To receive FENTORA, you must talk to your healthcare provider about the benefits and risks of FENTORA, agree to all of the instructions, and sign the Patient-Rescuer Agreement Form.

Who should not use FENTORA?

Do not use FENTORA:

- If you are not opioid tolerant. Opioid tolerant means that you are already taking other opioid pain medicines around-the-clock for your cancer pain, and your body is used to these medicines.
- For short-term pain that you would expect to go away in a few days, such as pain after surgery, headaches or migraines, and dental pain.
- If you are allergic to any of the ingredients in FENTORA.

What should I tell my healthcare provider before using FENTORA?

Tell your healthcare provider about all the medicines you take, including prescription medicines, vitamins, and dietary supplements. Some medicines may cause serious or life-threatening side effects when taken with FENTORA.

- Do not take any medicines while using FENTORA until you have talked to your healthcare provider. Your healthcare provider will tell you if it is okay to take other medicines while you are using FENTORA.
- Be very careful about taking other medicines that may make you sleepy, such as other pain medicines, sedatives, tranquilizers, medicines, sleeping pills, anti-anxiety medicines, antihistamines, or tranquilizers.

What should I avoid while using FENTORA?

- Do not drive, operate heavy machinery, or do other dangerous activities until you and your healthcare provider know how FENTORA affects you.
- Do not drink alcohol while using FENTORA. It can increase the chance of dangerous side effects.

What are possible side effects of FENTORA?

FENTORA can cause serious side effects, including:

- Breathing problems that can become life-threatening. Stop taking FENTORA and call your healthcare provider or get emergency medical help RIGHT AWAY if you:
 - Have trouble breathing
 - Have drowsiness with slowed breathing
 - Have slow shallow breathing (little chest movement with breathing)
 - Feel faint, very dizzy, confused, or have unusual symptoms
- These symptoms can be a sign that you have taken too much FENTORA or the dose is too high for you. These symptoms may lead to serious problems or death if not treated right away.
- Decreased blood pressure. This can make you feel dizzy or lightheaded when you stand up.
- Physical dependence. Do not stop taking FENTORA or taking any other opioid without talking to your healthcare provider. You could become sick with uncontrollable withdrawal symptoms because your body has become used to these medicines. Physical dependency is not the same as drug addiction.
- A change in abuse or addiction. This change is bigger if you are or have been addicted to or abused other medicines, street drugs, or alcohol, or have a history of mental health problems.
- Pain, irritation, or sores at the application site (on your gum, on the inside of your cheek, or under your tongue).

The most common side effects of FENTORA are:

- Nausea
- Vomiting
- Dizziness
- Low red blood cell count
- Tiredness
- Swelling of the arms, hands, legs and feet
- Headache

Constipation is a very common side effect of opioid pain medicines including FENTORA and is unlikely to go away without treatment. Talk to your healthcare provider about prevention or treatment of constipation while taking FENTORA.

Talk to your healthcare provider if you have any side effects.

These are not all the possible side effects of FENTORA. For more information, ask your healthcare provider or pharmacist or call 1-800-956-5655.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch, or call 1-800-FDA-1088.

This information does not take the place of talking with your doctor for medical advice about your condition or treatment.

Please read the Medication Guide located at the end of the Full Prescribing Information for FENTORA.

References: 1. Fentora [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; 2013. 2. Trenerry RK, Taylor D, Massina J, Trenerry L. A randomized, placebo-controlled study of fentanyl buccal tablet for breakthrough pain in opioid-treated patients with cancer. *Clin J Pain*. 2006;22(8):605-611.

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FENTORA
In the Mouth of Your Mouth

IMPORTANT SAFETY INFORMATION
FENTORA can cause life-threatening breathing problems.
Do not use **FENTORA** unless you are regularly using another opioid pain medicine
around-the-clock for your cancer pain and your body is used to those medicines (this means you are opioid tolerant). You can ask your healthcare provider if you are opioid tolerant. **FENTORA** is a safe place after taking **FENTORA**.

Breakthrough Cancer Pain **FENTORA & Breakthrough Cancer Pain** **Taking FENTORA** **Savings & Support**

You have been removed from our e-mail list.

IMPORTANT SAFETY INFORMATION

The information listed below is not a complete list. Please read the full **Medication Guide** completely before you start using **FENTORA**, and each time you get a new prescription. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment. Share this important information with members of your household and other caregivers.

IMPORTANT:

Do not use **FENTORA** unless you are regularly using another opioid pain medicine around-the-clock for your cancer pain and your body is used to those medicines (this means you are opioid tolerant). You can ask your healthcare provider if you are opioid tolerant.

Keep **FENTORA** in a safe place away from children.

Get emergency help **RIGHT AWAY**:

- > A child takes **FENTORA**. **FENTORA** can cause an overdose and death in any child who takes it.
- > An adult who has not been prescribed **FENTORA** uses it.
- > An adult who is not already taking opioids around-the-clock uses **FENTORA**.

These are medical emergencies that can cause death. If possible, try to remove **FENTORA** from the mouth.

What important information should I know about **FENTORA**?
FENTORA can cause life-threatening breathing problems.

- Use **FENTORA** exactly as prescribed by your healthcare provider
- Do NOT use more than 2 doses of **FENTORA** for each episode of breakthrough cancer pain
- Wait at least 4 hours before treating a new episode of breakthrough cancer pain with **FENTORA**
- Do not switch from **FENTORA** to other medicines that contain fentanyl or change your **FENTORA** dose without talking with your healthcare provider
- Never give **FENTORA** to anyone else, even if they have the same symptoms you have. It may harm them or even cause death and is against the law. Keep **FENTORA** in a safe place

FENTORA is available only through a program called the Transmucosal Immediate-Release Fentanyl (TRIF) Risk Evaluation and Mitigation Strategy (RaMS) Access program. To receive **FENTORA**, you must talk to your healthcare provider about the benefits and risks of **FENTORA**, agree to all of the instructions, and sign the Patient-Prescriber Agreement Form.

Who should not use **FENTORA**?
Do not use **FENTORA**:

- > If you are not opioid tolerant. Opioid tolerant means that you are already taking other opioid pain medicines around-the-clock for your cancer pain, and your body is used to those medicines
- > For non-cancer pain that you would expect to go away in a few days, such as pain after surgery, headaches or migraines, and/or dental pain
- > If you are allergic to any of the ingredients in **FENTORA**

What should I tell my healthcare provider before using **FENTORA**?
Tell your healthcare provider about all the medicines you take, including prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life-threatening side effects when taken with **FENTORA**.

- Do not take any medicine while using **FENTORA** until you have talked to your healthcare provider. Your healthcare provider will tell you if it is okay to take other medicines while you are using **FENTORA**
- Be very careful about taking other medicines that may make you sleepy, such as other pain medicines, antidepressant medicines, sleeping pills, anti-anxiety medicines, antihistamines, or tranquilizers

What should I avoid while using **FENTORA**?
- Do not drive, operate heavy machinery, or do other dangerous activities until you and your healthcare provider know how **FENTORA** affects you

What are possible side effects of **FENTORA**?
FENTORA can cause serious side effects, including:

1. Breathing problems that can become life-threatening.
Stop taking **FENTORA** and call your healthcare provider or get emergency medical help **RIGHT AWAY** if you:
 - Have trouble breathing
 - Have drowsiness with slowed breathing
 - Have slow, shallow breathing (little chest movement with breathing)
 - Feel faint, very dizzy, confused, or have unusual symptoms
 These symptoms can be a sign that you have taken too much **FENTORA** or the dose is too high for you. These symptoms may lead to serious problems or death if not treated right away.
2. Decreased blood pressure. This can make you feel dizzy or lightheaded when you stand up.
3. Physical dependence. Do not stop taking **FENTORA** or taking any other opioid without talking to your healthcare provider. You could become sick with uncomfortable withdrawal symptoms because your body has become used to these medicines. Physical dependency is not the same as drug addiction.
4. A chance of abuse or addiction. This chance is higher if you ever or have been addicted to or abused other medicines, street drugs, or alcohol, or have a history of mental health problems.
5. Pain, irritation, or sores at the application site (on your gum, on the inside of your cheek, or under your tongue).

The most common side effects of **FENTORA** are:

- Nausea
- Vomiting
- Dizziness
- Low red blood cell count
- Tiredness
- Swelling of the arms, hands, legs and feet
- Headache

Constipation is a very common side effect of opioid pain medicines including **FENTORA** and is unlikely to go away without treatment. Talk to your healthcare provider about prevention or treatment of constipation while taking **FENTORA**.

Talk to your healthcare provider if you have any side effects.

These are not all the possible side effects of **FENTORA**. For more information, ask your healthcare provider or pharmacist or call 1-800-895-8955.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch, or call 1-800-FDA-1088.

This information does not take the place of talking with your doctor for medical advice about your condition or treatment.

Please read the **Medication Guide** located at the end of the **Full Prescribing Information** for **FENTORA**.

References: 1. Fentora [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; 2013. 2. Portenoy RK, Taylor D, Massia J, Tramuel L. A randomized, placebo-controlled study of fentanyl buccal tablet for breakthrough pain in opioid-treated patients with cancer. *Clin J Pain*. 2006;22(9):895-911.

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