

**NFENTORA™**

fentanyl citrate

Buccal/Sublingual Effervescent Tablets

100 mcg, 200 mcg, 400 mcg, 600 mcg, and 800 mcg fentanyl

Opioid Analgesic

# Guide for Patients and Caregivers

Distributed by:  
Teva Canada Limited  
Toronto, Ontario M1B 2K9

Manufactured for:  
Teva Canada Innovation  
Montréal, Quebec H2Z 1S8

## IMPORTANT DRUG INFORMATION

- FENTORA is a prescription opioid (narcotic) cancer pain medicine containing fentanyl.
- FENTORA manages sudden bursts of pain described as “breakthrough pain” in cancer patients who are already taking other opioid pain medicines continuously for cancer pain.
- FENTORA is only to be used by patients with cancer who are already taking opioid (narcotic) pain medicines every day and are used to them (opioid tolerant).
- FENTORA should only be used in patients who have been taking other opioid pain medicines and their bodies have become used to them (“opioid-tolerant”). FENTORA should not be used by patients under 18 years of age.

## IMPORTANT SAFETY INFORMATION

- You should never give anyone your FENTORA. They could die from taking it. If a person has not been prescribed FENTORA, taking even one dose can cause a fatal overdose. This is especially true for children and for an adult who is not already taking opioids continuously.
- You may get life-threatening breathing problems while taking FENTORA. This is less likely to happen if you take it as prescribed by your doctor. Babies are at risk of life-threatening breathing problems if their mothers take opioids while pregnant or nursing.
- Keep FENTORA in a safe place away from children.
- Accidental use by a child is a medical emergency and can result in death. Get emergency help right away if a child takes FENTORA by accident. If possible, try to remove FENTORA from the child’s mouth.
- Taking FENTORA with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.

**For other important safety information, see the FENTORA Patient Medication Information: *Serious Warnings and Precautions***

## THE MOST IMPORTANT INFORMATION YOU SHOULD KNOW ABOUT USING FENTORA

This guide is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **FENTORA**.

**FENTORA**, which contains the drug fentanyl, is a tablet that you place between your gum and cheek or under the tongue.

**Fentanyl is a very strong opioid narcotic cancer pain medicine that can cause serious and life-threatening breathing problems.**

## Get emergency medical help immediately if you:

- have trouble breathing, or drowsiness with slow or shallow breathing
- have a slow heartbeat
- have extreme sleepiness
- have cold, clammy skin
- feel faint, dizzy, confused, or cannot think, walk, or talk normally
- have a seizure and/or hallucinations

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

## GENERAL INFORMATION

Your doctor prescribed FENTORA for you to treat breakthrough cancer pain. Using FENTORA has some risks because it contains fentanyl, an opioid (narcotic) pain medicine. Only obtain prescriptions for this medicine from the doctor in charge of your treatment. Do not seek prescriptions from other doctors unless you switch to another doctor for your cancer pain management.

**FENTORA can cause life-threatening breathing problems if mistakenly taken by a child or by people who are not used to taking opioid pain medicines every day.**

This booklet will help you learn more about FENTORA:

- Who should and should not use it
- How to correctly place FENTORA in your mouth
- How to dispose of unused units properly

You can get more information by consulting:

- A toll-free number [1-855-513-8382] to call if you have questions about FENTORA.
- Color-coded packaging that helps you and your pharmacist make sure you are getting the strength of FENTORA your doctor prescribed.



Read this booklet carefully before starting FENTORA. Also, read the Patient Medication Information that comes with each prescription for FENTORA as it contains updated information.

Ask the people who live with you to read this information. This booklet and the Patient Medication Information do not take the place of talking with your doctor about your breakthrough cancer pain. Ask your doctor or pharmacist any questions you have. Talk with them about any concerns you have.

## **FENTORA is for You and Only You**

- Never give FENTORA to anyone else, even if they have the same symptoms you have. It may harm them and even cause death.
- Keep FENTORA in a safe place away from children and from anyone else for whom it has not been prescribed.

## **Use FENTORA Exactly as Prescribed**

- Do not use FENTORA if your doctor did not prescribe it for you.
- FENTORA must be used only for the management of breakthrough cancer pain.
- Use FENTORA only if you are already taking other opioid pain medicines for your cancer pain every day and your body is used to these medicines (opioid tolerant). Your doctor will know if you are opioid tolerant. **Do not use FENTORA if you are not opioid tolerant.**
- Start taking FENTORA at the lowest dose of 100 micrograms (mcg). The dose goes up until you and your doctor find the right dose for you.
- Once your right dose has been selected, do not change your dose of FENTORA yourself. If you think you need more pain relief, talk with your doctor. Your doctor can decide if your dose of FENTORA needs to be changed.
- Do not take FENTORA more often than your doctor tells you.

## **Store FENTORA in a Safe, Secure Place**

- Keep FENTORA in a safe place, under lock, out of sight and reach of children and pets.
- Keep unused or expired FENTORA in a secure place to prevent theft, misuse or accidental exposure.
- Never take medicine in front of small children as they will want to copy you. Accidental ingestion by a child is dangerous and may result in death. If a child accidentally takes FENTORA, get emergency help right away.
- Accidental use by a child is a medical emergency and can result in death.
- Get emergency help right away if a child takes FENTORA by accident. If possible, try to remove FENTORA from the child's mouth.
- FENTORA is a controlled drug. It can be abused by people who abuse prescription medicines or street drugs.
- Keep FENTORA in a place where no one can easily reach it or steal it.

- FENTORA comes in a foil package. Do not open the package until ready to use. Once opened, use FENTORA right away.
- Follow the FENTORA administration guide (see below). Do not chew or swallow FENTORA. If you do, you will likely get less relief for your breakthrough cancer pain.
- Do not cut or split the FENTORA unit.

## FENTORA Administration Guide

### Opening the Blister Package

1. Do not open the blister until you are ready to use FENTORA.
2. Separate a single blister unit from the blister card by bending and tearing apart at the perforations.
3. Bend the blister unit along the line where indicated.
4. Peel back the blister backing to expose the tablet. **DO NOT attempt to push the tablet through the blister as this may cause damage to the tablet.**
5. Do not store the tablet once it has been removed from the blister package as this spoils the tablet and, more importantly, because this increases the risk of accidental exposure to the tablet.

### Tablet Administration

- Once the tablet is removed from the blister unit, you should **immediately** place the entire FENTORA tablet in the buccal cavity (above a rear molar, between the upper cheek and gum) or under your tongue. **You should not split the tablet.**
- **Do not split, suck, chew or swallow** FENTORA tablets as this will result in lower cancer pain relief.
- Leave the FENTORA tablet between the cheek and gum, or under the tongue, until it has dissolved, which usually takes approximately 14-25 minutes. After 30 minutes, if there is any FENTORA tablet left in your mouth, you may drink a glass of water.
- It is recommended that you switch sides of the mouth when administering subsequent doses of FENTORA.

## FENTORA Dosing Instructions

**To assist your doctor to find the right dose of FENTORA for you, and avoid the risk of overdosing, follow all instructions carefully.**

- **All patients MUST begin treatment using 100 mcg FENTORA.**
- You will be closely followed by your doctor and your dosage strength will be changed until you reach the right dose for you.
- **FENTORA should only be used ONCE for a breakthrough cancer pain episode. FENTORA should not be used again during the same episode.**
- During any episode of breakthrough cancer pain, if adequate cancer pain relief *is not achieved* after FENTORA, you may use a rescue medication (other than FENTORA, after 30 minutes) *as directed by your doctor.*

- **You MUST wait at least 4 hours before treating another episode of breakthrough cancer pain with FENTORA.**
- **Use of FENTORA should be limited to FOUR episodes of breakthrough cancer pain per day. If you experience more than four breakthrough cancer pain episodes per day, talk to your doctor.**

All unused tablets need to be returned to the pharmacy for proper disposal.

In case of drug overdose, contact a health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

## **Follow FENTORA Dosing Instructions Carefully**

- **FENTORA can cause life-threatening breathing problems which can lead to death.**
- **Call your doctor or get emergency medical help right away if you have any of the following symptoms:**
  - **Trouble breathing**
  - **Extreme sleepiness or drowsiness with slowed breathing**
  - **Slow, shallow breathing (little chest movement while breathing)**
  - **Faintness, dizziness, confusion, or other unusual symptoms**
  - **Inability to think, talk or walk normally**
  - **Seizure and hallucination**
  - **Abdominal pain, severe constipation, nausea**
  - **Agitation or restlessness, loss of muscle control or muscle twitching, tremor, diarrhea**
  - **Rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing (Allergic Reaction)**

## **FENTORA Serious Warnings and Precautions**

- **Do not use FENTORA unless you are regularly using another opioid pain medicine continuously for your cancer pain and your body is used to these medicines (this means you are opioid tolerant). You can ask your healthcare professional if you are opioid tolerant.**
- **Even if you take FENTORA as prescribed you are at a risk for opioid addiction, abuse and misuse. This can lead to overdose and death.**
- **You may get life-threatening breathing problems while taking FENTORA. This is less likely to happen if you take it as prescribed by your doctor. Babies are at risk of life-threatening breathing problems if their mothers take opioids while pregnant or nursing.**
- **You should never give anyone your FENTORA. They could die from taking it. If a person has not been prescribed FENTORA, taking even one dose can cause a fatal overdose. This is especially true for children and for an adult who is not already taking opioids continuously.**

- **In an emergency, try to remove FENTORA from the mouth.**
- **If you stop taking your regular opioid pain medicine for your cancer pain, you must stop using FENTORA. You may no longer be opioid-tolerant. Talk to your healthcare professional about how to treat your pain.**
- **You or a family member should call your doctor or get emergency medical help immediately if you have trouble breathing, drowsiness with slow breathing, slow shallow breathing (little chest movement with breathing) or feel faint, dizzy, confused, or have other unusual symptoms. These can be symptoms of an overdose with FENTORA. Your dose of FENTORA may be too high for you. These symptoms may lead to serious problems or death if not treated immediately. If you have any of the above symptoms, do not take another dose of FENTORA.**
- **Use FENTORA exactly as prescribed by your healthcare professional.**
  - **You must begin treatment with FENTORA at the lowest dose of 100 mcg.**
  - **You must not use more than ONE dose of FENTORA for each episode of breakthrough cancer pain.**
  - **You must wait at least 4 hours before treating a new episode of breakthrough pain with FENTORA.**
  - **You must not treat more than 4 episodes of breakthrough pain per day. Talk to your healthcare professional if you have more than 4 episodes of breakthrough cancer pain per day. The dose of your around-the-clock opioid pain medicine may need to be changed.**
- **Do not switch from FENTORA to other medicines that contain fentanyl without talking with your healthcare professional. The amount of fentanyl in a dose of FENTORA is not the same as the amount of fentanyl in other medicines that contain fentanyl. Your healthcare professional will prescribe a starting dose of FENTORA that may be different than other fentanyl containing medicines you may have been taking.**
- **If you took FENTORA while you were pregnant, whether for short or long periods of time or in small or large doses, your baby can suffer life-threatening withdrawal symptoms after birth. This can occur in the days after birth and for up to 4 weeks after delivery. If your baby has any of the following symptoms:**
  - **has changes in their breathing (such as weak, difficult or fast breathing)**
  - **is unusually difficult to comfort**
  - **has tremors (shakiness)**
  - **has increased stools, sneezing, yawning, vomiting, or fever**

**Seek immediate medical help for your baby.**

- **Keep FENTORA in a safe place away from children and pets. Do not use FENTORA in front of children.**
- **Taking FENTORA with other opioid medicines, benzodiazepines, alcohol, or other central nervous system depressants (including street drugs) can cause severe drowsiness, decreased awareness, breathing problems, coma, and death.**

## ANSWERS TO COMMON QUESTIONS ABOUT FENTORA

### Why has my doctor prescribed FENTORA?

Your doctor has prescribed FENTORA to treat your breakthrough cancer pain. The cancer pain medicine you take every day on a regular basis helps control your constant cancer pain. But you have also been feeling “flares” of intense pain that “breakthrough” the relief offered by your regular pain medicine. These flares are called “breakthrough pain” or BTP.

FENTORA is used specifically to treat BTP in patients with cancer who are already taking opioid (narcotic) pain medicine every day and are used to them (opioid tolerant).

### What is FENTORA?

FENTORA delivers fentanyl in a tablet that you place between your gum and cheek



or under the tongue to deliver relief of breakthrough cancer pain.



## What should I tell my doctor before I start taking FENTORA?

**Tell your doctor about all your medical and mental health problems.** Be sure to include:

- Trouble breathing or lung problems such as asthma, wheezing or being short of breath
- Head injury or brain problem
- Liver, lung or kidney problems
- Seizures (convulsions or fits)
- Slow heart rate or other heart problems
- Low blood pressure
- Mental problems including major depression, schizophrenia or hallucinations (seeing or hearing things that are not there)
- Past or present problems with alcohol for you or a family member
- Past or present problems with drug abuse or addiction, or a family history of a drug abuse problem or addiction problem
- Migraines
- Chronic or severe constipation
- Problems with your thyroid, adrenal or prostate gland
- Have any other medical conditions

**Tell your doctor if you are:**

- **Pregnant or planning to become pregnant.** FENTORA may harm your unborn baby.
- **Breastfeeding.** FENTORA passes through your breast milk and it can cause serious harm to your baby. You should not use FENTORA while breastfeeding.

**Pregnancy, nursing, labour and delivery:**

**Opioids can be transferred to your baby through breast milk, or while still in the womb. FENTORA can then cause life-threatening breathing problems in your unborn baby or nursing infant. Your doctor will determine if the benefits of using FENTORA outweigh the risks to your unborn baby or nursing infant.**

**If you are pregnant and are taking FENTORA, it is important that you don't stop taking your medication all of a sudden. If you do, it can cause a miscarriage or a still-birth. Your doctor will monitor and guide you on how to slowly stop taking FENTORA. This may help avoid serious harm to your unborn baby.**

**Tell your doctor about all the medicines you take.**

Include non-prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life-threatening medical problems when taken with FENTORA.

## How will my doctor know which FENTORA strength is right for me?

Your doctor or nurse will explain the step-by-step dosing instructions. These steps can help find out which strength of FENTORA is right for you.

## How often should I use FENTORA?

Use FENTORA exactly as your doctor tells you. Do not take FENTORA more often than **4 times** a day. Separate each dose by at least **4 hours**.

## Do I still use my regular medicine for persistent pain?

Keep using your regular opioid pain medicine. Your regular pain medicine is long acting. It controls your constant pain. FENTORA does not take the place of your regular pain medicine. Use FENTORA only for breakthrough cancer pain.

## Who should NOT take FENTORA?

- People who are **NOT** prescribed Fentora by their doctors.
- People who are NOT already taking other opioid pain medicines every day for constant cancer pain.
- People who have severe respiratory problems.
- People who are allergic to anything in FENTORA. The active ingredient is fentanyl citrate.
- People who are currently taking monoamine-oxidase (MAO) inhibitors (used for severe depression) or have done so in the past 2 weeks.
- People who have any heart problems.
- People who have bowel blockage or narrowing of the stomach or intestines.
- People who have severe pain in their abdomen.
- People who have a head injury.
- People who are at risk for seizures.
- People who suffer from alcoholism.
- People who are going to have, or recently had, a planned surgery.
- Women who are in labour.
- Women who are breastfeeding.

## How will my pharmacist know which FENTORA strength to give me?

FENTORA units come in 5 different color-coded boxes for the 5 different dosage strengths. The color-coded boxes help your pharmacist give you the strength of FENTORA your doctor prescribed. The units are in color-coded child-resistant foil packages. Every unit is marked with a number to identify the dose it delivers.

Dosage Strength	Engraving on the Tablet	Carton/Blister Package Colour
100 mcg	1	Blue
200 mcg	2	Orange
400 mcg	4	Sage green
600 mcg	6	Magenta (pink)
800 mcg	8	Yellow

## Can I eat or drink liquids while using FENTORA?

You can drink liquids after FENTORA has been in your mouth for 30 minutes but do not move the tablet(s) with your tongue/finger or eat any food until the tablet(s) has completely dissolved.

## What happens if I bite, chew or swallow the FENTORA unit?

**Do not bite, chew or swallow FENTORA units.** If you do, you will likely get less relief for your breakthrough cancer pain.

## What are the most common side effects of FENTORA?

The most common side effects of FENTORA are

- nausea
- vomiting
- dizziness, fainting
- low red blood cell coun,
- sleepiness
- swelling of the arms, hands, legs and feet
- headache
- constipation
- problems with vision
- itching
- sweating

FENTORA has other side effects. For a complete list, ask your doctor.

Talk with your doctor about any side effects that bother you or that do not go away.

You may develop a disorder of the adrenal gland called adrenal insufficiency. This means that your adrenal gland is not making enough of certain hormones. You may experience symptoms such as:

- nausea, vomiting
- feeling tired, weak or dizzy
- decreased appetite

You may be more likely to have problems with your adrenal gland if you have been taking opioids for longer than one month. Your doctor may do tests, give you another medication, and slowly take you off FENTORA.

FENTORA can cause Serotonin Syndrome, a rare but potentially life-threatening condition. It can cause serious changes in how your brain, muscles and digestive system work. You may develop Serotonin Syndrome if you take FENTORA with certain anti-depressants or migraine medications.

Serotonin Syndrome symptoms include:

- fever, sweating, shivering, diarrhea, nausea, vomiting;
- muscle shakes, jerks, twitches or stiffness, overactive reflexes, loss of coordination;
- fast heartbeat, changes in blood pressure;
- confusion, agitation, restlessness, hallucinations, mood changes, unconsciousness, and coma.

Sexual Function/Reproduction: Long term use of opioids may lead to a decrease in sex hormone levels. It may also lead to low libido (desire to have sex), erectile dysfunction or being infertile.

## **Will FENTORA make me sleepy?**

FENTORA can make you sleepy. Do not drive, operate machinery, or do other dangerous activities until you know how FENTORA affects you. Ask your doctor when it is okay to do those activities. In addition, other sedative drugs which may enhance the drowsiness caused by FENTORA.

## **Can I become addicted to FENTORA?**

FENTORA is an opioid medication. There is a chance of abuse or addiction with FENTORA.

If you are concerned, talk to your doctor or healthcare provider.

The chance of addiction is higher if you have ever been addicted to or abused other medications, street drugs, or alcohol, or have a history of mental health problems.

Opioid dependence and addiction: There are important differences between physical dependence and addiction. It is important that you talk to your doctor if you have questions or concerns about abuse, addiction or physical dependence.

## **Can I take other medicines while I am using FENTORA?**

- Tell your doctor about all your medicines. Include non-prescription medicines, vitamins, and herbal supplements.
- Some medicines may cause serious or life-threatening medical problems when taken with FENTORA.
- The dose of certain medicines and FENTORA may need to be changed if you use them together.
- Do not start any new medicines while using FENTORA until you talk with your doctor. Your doctor will tell you if it is safe to take other medicines while you are using FENTORA.
- Be very careful about taking other medicines that make you sleepy, such as other pain medicines or medicines for depression, sleep, nervousness, or allergies.

## **Can I drink alcohol while I am using FENTORA?**

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

## **If I'm feeling better, can I stop taking FENTORA**

If you have been taking FENTORA for more than a few days, you should not stop taking it all of a sudden. Your doctor will monitor and guide you on how to slowly stop taking FENTORA.

You should do it slowly to avoid uncomfortable symptoms such as having:

- body aches
- diarrhea
- goosebumps
- loss of appetite
- nausea
- feeling nervous or restless
- runny nose
- sneezing
- tremors or shivering
- stomach cramps
- rapid heart rate (tachycardia)
- having trouble sleeping
- an unusual increase in sweating
- heart palpitations
- an unexplained fever
- weakness
- yawning

By reducing or stopping your opioid treatment, your body will become less used to opioids. If you start treatment again, you will need to start at the lowest dose. You may overdose if you restart at the last dose you took before you slowly stopped taking FENTORA.

### **What if a child or adult accidentally takes FENTORA?**

**If a child or adult accidentally takes FENTORA, call 911 right away for emergency help. If possible, try to immediately remove the FENTORA tablet from the mouth.**

### **Where can I get more information on FENTORA?**

If you have any further questions on the use of FENTORA, ask your doctor or pharmacist, or call Teva Canada Innovation for more information at the following telephone number:

**1-855-513-8382**

### **How do I report suspected side effects?**

**It is important to report suspected side effects of all medications. A report should include as much information as possible on the medicine/s you are taking (including when you took the medicine, lot numbers and expiry dates), and the adverse event that occurred (when occurred, what occurred, how was it treated). Report the adverse reaction as soon as possible either to Teva Canada Limited at 1-800-268-4127 option 3 (English), E-fax: 1-416-335-4472 or to Health Canada.**

#### **Reporting Side Effects**

**You can report any suspected side effects associated with the use of health products to Health Canada by:**

- **Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or**
- **Calling toll-free at 1-866-234-2345.**

**NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.**

### **REFERENCES**

1. FENTORA Product Monograph. Teva Canada Innovation, March 05, 2018.