

Medication Guide

FENTORA[®] (fen-tor-a)
(fentanyl buccal tablet)

CII

100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg, 800 mcg

IMPORTANT:

1. Do not use *FENTORA* unless you are regularly using other opioid pain medicines around-the-clock for your constant cancer pain and your body is used to these medicines.
2. Keep *FENTORA* in a safe place away from children. Accidental use by a child is a medical emergency and can result in death. If a child accidentally takes *FENTORA*, get emergency help right away.

Read the Medication Guide that comes with *FENTORA* before you start taking it and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or your treatment. Share this important information with members of your household.

What is the most important information I should know about *FENTORA*?

1. *FENTORA* can cause life-threatening breathing problems which can lead to death:
 - if you are not regularly using other opioid pain medicines around-the-clock for your constant cancer pain and your body is not used to these medicines. This means that you are not opioid tolerant.
 - if you do not use it exactly as prescribed by your doctor.
2. Your doctor will prescribe a starting dose of *FENTORA* that is different than other fentanyl containing medicines you may have been taking. Do not substitute *FENTORA* for other fentanyl medicines, including Actiq[®], without talking with your doctor.

What is *FENTORA*?

- *FENTORA* is a prescription medicine that contains the medicine fentanyl. *FENTORA* is a federally controlled substance (CII) because it is a strong opioid pain medicine that can be abused by people who abuse prescription medicines or street drugs.
- *FENTORA* is used to treat breakthrough pain in adult patients with cancer (18 years of age and older) who are regularly using other opioid pain medicines around-the-clock for their constant cancer pain. *FENTORA* is started only after you have been taking other opioid pain medicines and your body has gotten used to them (you are opioid tolerant). **DO NOT USE *FENTORA* if you are not opioid tolerant.**

- You must stay under your doctor's care while taking *FENTORA*.
- ***FENTORA* must not be used for the treatment of short-term pain from injuries, surgery, and headaches, including migraines.**
- ***FENTORA* should be placed in the mouth, against your gum and allowed to dissolve.** You may feel a gentle bubbling sensation between your cheek and gum as the tablet dissolves. *FENTORA* is not meant to be chewed or swallowed.
- **Prevent theft and misuse. Keep *FENTORA* in a safe place** to protect it from being stolen since it can be a target for people who abuse narcotic medicines or street drugs.
- **Never give *FENTORA* to anyone else,** even if they have the same symptoms you have. It may harm them and even cause death.
- **Selling or giving away this medicine is against the law.**

Who should not take *FENTORA*?

Do Not Take *FENTORA*:

- if you are not regularly using other opioid pain medicines around-the-clock for your constant cancer pain.
- **for the treatment of short-term pain from injuries, surgery, and headaches, including migraines.**
- **if you are allergic to anything in *FENTORA*.** The active ingredient is fentanyl. See the end of this Medication Guide for a complete list of ingredients in *FENTORA*.

What should I tell my doctor before starting *FENTORA*?

Tell your doctor about all of your medical and mental problems, especially the ones listed below:

- Trouble breathing or lung problems such as asthma, wheezing, or shortness of breath
- A head injury or brain problem
- Liver or kidney problems
- Seizures (convulsions or fits)
- Slow heart rate or other heart problems
- Low blood pressure
- Mental problems including major depression or hallucinations (seeing or hearing things that are not there)
- A past or present drinking problem or alcoholism, or a family history of this problem
- A past or present drug abuse or addiction problem, or a family history of this problem

Tell your doctor if you are:

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

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal and dietary supplements. Some medicines may cause serious or life-threatening medical problems when taken with *FENTORA*. Sometimes, the doses of certain medicines and *FENTORA* need to be changed if used together.

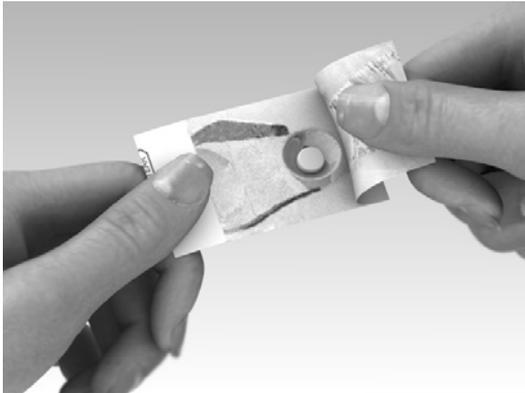
Do not take any medicine while using *FENTORA* until you have talked to your doctor. Your doctor will tell you if it is safe to take other medicines while you are using *FENTORA*. Be especially careful about taking other medicines that make you sleepy such as other pain medicines, anti-depressant medicines,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

Know the medicines you take. Keep a list of them to show your doctor and pharmacist.

How should I use *FENTORA*?

- **Use *FENTORA* exactly as prescribed by your doctor.** Do not use *FENTORA* more often than prescribed.
 - **Use 1 dose of *FENTORA* for an episode of breakthrough cancer pain.** When the amount of *FENTORA* is being adjusted by your doctor, a dose may include more than 1 tablet.
 - **If your breakthrough cancer pain is not relieved after 30 minutes, use ONLY 1 more dose of *FENTORA* at this time.**
 - **Wait at least 4 more hours before using *FENTORA* again for another episode of breakthrough cancer pain.**
 - **Remember you must continue taking your regularly used around-the-clock opioid medicine while taking *FENTORA*.**
- **Talk to your doctor if your dose of *FENTORA* does not relieve your breakthrough cancer pain.** Your doctor will decide if your dose of *FENTORA* needs to be changed.
- **Talk to your doctor 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 adjusted.
- *FENTORA* comes packaged in a blister card. **Do not open the blister until ready to use.** Separate one of the blister units from the blister card by tearing apart at

the perforations. Bend the blister unit along the line where indicated. Peel back foil on blister pack to expose tablet.



- **DO NOT push the tablet through the foil on the blister pack** because this could damage the tablet.
- **Once removed from the blister pack, *FENTORA* must be used right away.**
- **Place a *FENTORA* tablet in your mouth above a rear molar tooth between the upper cheek and gum and leave in place until the tablet is dissolved. This generally takes between 14 to 25 minutes. After 30 minutes if there is any tablet left, swallow it with a glass of water.** If you cannot take the medicine in this manner, tell your doctor who will advise you what to do. Do not split the tablet.



- **Do not bite, chew or suck *FENTORA* tablets.** If you do so, you will swallow more of the medicine and get less relief for your breakthrough cancer pain.
- Do not split the *FENTORA* tablet. The *FENTORA* tablet should be used whole.
- If you begin to feel dizzy, sick to your stomach, or very sleepy before the tablet is completely dissolved, rinse your mouth with water and spit the remaining pieces of the tablet into a sink or toilet right away. Rinse the sink or flush the toilet to dispose of any remaining tablet pieces.
-
- **If you take too much *FENTORA* or overdose, call 911 for emergency help.**

What should I avoid while taking *FENTORA*?

- **Do not drive, operate heavy machinery, or do other dangerous activities** until you know how *FENTORA* affects how alert you are. *FENTORA* can make you sleepy. Ask your doctor when it is okay to do these activities.
- **Do not drink alcohol while using *FENTORA*.** It can increase your chance of getting dangerous side effects.
- **Do not take any medicine while using *FENTORA* until you have talked to your doctor.** Your doctor will tell you if it is safe to take other medicines while you are using *FENTORA*. Be especially careful about taking other medicines that make you sleepy such as other pain medicines, anti-depressant medicines, sleeping pills, anxiety medicines, antihistamines, or tranquilizers.

What are the possible or reasonably likely SIDE EFFECTS of *FENTORA*?

- *FENTORA* can cause serious breathing problems that can become life-threatening, especially if used the wrong way. See “What is the most important information I should know about *FENTORA*?”

Call your doctor or get emergency medical help right away if you:

- have trouble breathing
- have extreme drowsiness with slowed breathing
- have slow, shallow breathing (little chest movement with breathing)
- feel faint, very dizzy, confused, or have unusual symptoms

The above symptoms mean that you have taken too much (overdose) *FENTORA* or the dose is too high for you. **These symptoms may lead to serious problems or death if not treated right away. Do not take another dose of *FENTORA*.**

- *FENTORA* can cause pain or sores at the application site (on your gum or the inside of your cheek). Tell your doctor if this is a problem for you.
- *FENTORA* can cause your blood pressure to drop. This can make you feel dizzy if you get up too fast from sitting or lying down.
- *FENTORA* can cause physical dependence. Do not stop taking *FENTORA* or any other opioid without talking to your doctor. 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.
- **There is a chance of abuse or addiction with *FENTORA*.** The chance is higher if you are or have been addicted to or abused other medications, street drugs, or alcohol, or if you have a history of mental problems.
- **The most common side effects of *FENTORA*** are nausea, vomiting, dizziness, sleepiness, headache, and constipation. Constipation (not often enough or hard bowel movements) is a very common side effect of pain medicines (opioids) including *FENTORA* and is unlikely to go away without treatment. Talk to your

doctor about dietary changes, and the use of laxatives (medicines to treat constipation) and stool softeners to prevent or treat constipation while taking *FENTORA*.

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

These are not all the possible side effects of *FENTORA*. For a complete list, ask your doctor.

Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

How should I store *FENTORA*?

- **Keep *FENTORA* in a safe and secure place away from children and from anyone for whom it has not been prescribed. Accidental use by a child is a medical emergency and can result in death. If a child accidentally takes *FENTORA*, get emergency help right away.**
- ***FENTORA* is supplied in single sealed child-resistant blister packages.**
- Do NOT remove *FENTORA* from its blister packaging for storage in a temporary container, such as a pillbox.
- Store *FENTORA* at room temperature, 59° to 86°F (15° to 30°C) until ready to use.
- **Always keep *FENTORA* in a secure place to protect from theft.**

How should I dispose of unopened *FENTORA* tablets when they are no longer needed?

- Dispose of any unopened *FENTORA* tablets remaining from a prescription as soon as they are no longer needed.
- **To dispose of unused *FENTORA*, remove *FENTORA* tablets from blister packages and flush down the toilet. Do not flush the *FENTORA* blister packages or cartons down the toilet.**
- If you need help with disposal of *FENTORA*, call Cephalon, Inc., at 1-800-896-5855.

General Information About the Safe and Effective Use of *FENTORA*

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Use *FENTORA* only for the purpose for which it was prescribed. Do not give *FENTORA* to other people, even if they have the same symptoms you have. ***FENTORA* can harm other people and even cause death. Sharing *FENTORA* is against the law.**

This Medication Guide summarizes the most important information about *FENTORA*. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about *FENTORA* that is written for healthcare professionals. You can also call Cephalon, Inc., at 1-800-896-5855.

What are the ingredients of *FENTORA*?

Active Ingredient: fentanyl citrate

Inactive Ingredients: mannitol, sodium starch glycolate, sodium bicarbonate, sodium carbonate, citric acid, and magnesium stearate.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Rx Only.

**Cephalon, Inc.
FRAZER, PA 19355, USA**

Reference Number 074000106.XX
October 2007

U.S. Patent Nos. 6,200,604 and 6,974,590
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Place pharmacy label here.

IMPORTANT:
Safe use of this product requires that the patient and/or caregiver read the enclosed Medication Guide for important warnings and directions.

28 Buccal Tablets (4 tablets X 7 cards)

NDC 63459-541-28

FENTORA® 
(fentanyl buccal tablet)

equivalent to **100 mcg** fentanyl base

**To the Pharmacist:
Before dispensing:**

- PATIENTS RECEIVING FENTORA MUST BE TOLERANT TO AROUND-THE-CLOCK OPIOID THERAPY**
- DO NOT SUBSTITUTE FENTORA FOR OTHER FENTANYL PRODUCTS**
- Counsel the patient about the use of this product including maximum dosing during a single breakthrough pain episode
- Instruct patients to read the enclosed FENTORA Medication Guide

WARNING: Keep out of the reach of children
PATIENTS MUST BE TOLERANT TO AROUND-THE-CLOCK OPIOID THERAPY
DO NOT SUBSTITUTE FENTORA FOR OTHER FENTANYL PRODUCTS
FENTORA can be harmful or fatal if given to someone for whom it was not prescribed

FOR BUCCAL ADMINISTRATION. DO NOT CHEW OR SWALLOW TABLET WHOLE.

NDC 63459-541-28

Rx only

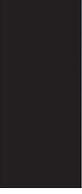
28 Buccal Tablets

FENTORA® 
(fentanyl buccal tablet)

equivalent to **100 mcg** fentanyl base

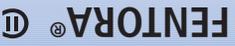
Each tablet contains fentanyl citrate equivalent to 100 mcg fentanyl base.
Store at 20°-25°C (68°-77°F) with excursions permitted between 15° and 30°C (59° to 86°F) until ready to use.
(See USP Controlled Room Temperature.)

For buccal administration.
Usual Dosage: See package insert.

LOT
EXP

FENTORA® 
(fentanyl buccal tablet)
equivalent to **100 mcg** fentanyl base

NDC 63459-541-28
Rx only
28 Buccal Tablets

28 Buccal Tablets (4 tablets X 7 cards)
NDC 63459-541-28
Rx only
FENTORA® 
(fentanyl buccal tablet)
equivalent to **100 mcg** fentanyl base
For information about this product call: 1-800-896-5855
U.S. Patent Nos. 6,200,604 and 6,974,590
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Item # 073000146.03 Printed in USA
Cephalon, Inc.
Frazier, PA 19355

28 Buccal Tablets (4 tablets X 7 cards)
NDC 63459-541-28
FENTORA® 
(fentanyl buccal tablet)
equivalent to **100 mcg** fentanyl base
WARNING: Keep out of the reach of children
PATIENTS MUST BE TOLERANT TO AROUND-THE-CLOCK OPIOID THERAPY
DO NOT SUBSTITUTE FENTORA FOR OTHER FENTANYL PRODUCTS
FENTORA can be harmful or fatal if given to someone for whom it was not prescribed
FOR BUCCAL ADMINISTRATION. DO NOT CHEW OR SWALLOW TABLET WHOLE.
Read enclosed FENTORA Medication Guide for important warnings and directions.

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Place pharmacy label here.

IMPORTANT:
Safe use of this product requires that the patient and/or caregiver read the enclosed Medication Guide for important warnings and directions.

28 Buccal Tablets (4 tablets X 7 cards)

NDC 63459-542-28

FENTORA® 
(fentanyl buccal tablet)

equivalent to **200 mcg** fentanyl base

**To the Pharmacist:
Before dispensing:**

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- DO NOT SUBSTITUTE FENTORA FOR OTHER FENTANYL PRODUCTS**
- Counsel the patient about the use of this product including maximum dosing during a single breakthrough pain episode
- Instruct patients to read the enclosed FENTORA Medication Guide

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FENTORA can be harmful or fatal if given to someone for whom it was not prescribed

FOR BUCCAL ADMINISTRATION. DO NOT CHEW OR SWALLOW TABLET WHOLE.

NDC 63459-542-28

Rx only

28 Buccal Tablets

FENTORA® 
(fentanyl buccal tablet)

equivalent to **200 mcg** fentanyl base

Each tablet contains fentanyl citrate equivalent to 200 mcg fentanyl base.
Store at 20°-25°C (68°-77°F) with excursions permitted between 15° and 30°C (59° to 86°F) until ready to use.
(See USP Controlled Room Temperature.)

For buccal administration.
Usual Dosage: See package insert.

LOT
EXP

FENTORA® 
(fentanyl buccal tablet)
equivalent to **200 mcg** fentanyl base

NDC 63459-542-28
Rx only
28 Buccal Tablets

28 Buccal Tablets (4 tablets X 7 cards)
NDC 63459-542-28
Rx only
FENTORA® 
(fentanyl buccal tablet)
equivalent to **200 mcg** fentanyl base
For information about this product call: 1-800-896-5855
U.S. Patent Nos. 6,200,604 and 6,974,590
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Cephalon
Frazier, PA 19355

! WARNING: Keep out of the reach of children
PATIENTS MUST BE TOLERANT TO AROUND-THE-CLOCK OPIOID THERAPY
DO NOT SUBSTITUTE FENTORA FOR OTHER FENTANYL PRODUCTS
FENTORA can be harmful or fatal if given to someone for whom it was not prescribed
FOR BUCCAL ADMINISTRATION. DO NOT CHEW OR SWALLOW TABLET WHOLE.
Read enclosed FENTORA Medication Guide for important warnings and directions.

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Cephalon

28 Buccal Tablets (4 tablets X 7 cards)
NDC 63459-542-28
FENTORA® 
(fentanyl buccal tablet)
equivalent to **200 mcg** fentanyl base


073000147.03

Place pharmacy label here.

IMPORTANT:
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28 Buccal Tablets (4 tablets X 7 cards)

NDC 63459-543-28

FENTORA® 
(fentanyl buccal tablet)

equivalent to **300 mcg** fentanyl base

**To the Pharmacist:
Before dispensing:**

- PATIENTS RECEIVING FENTORA MUST BE TOLERANT TO AROUND-THE-CLOCK OPIOID THERAPY**
- DO NOT SUBSTITUTE FENTORA FOR OTHER FENTANYL PRODUCTS**
- Counsel the patient about the use of this product including maximum dosing during a single breakthrough pain episode
- Instruct patients to read the enclosed FENTORA Medication Guide

 **WARNING: Keep out of the reach of children**
PATIENTS MUST BE TOLERANT TO AROUND-THE-CLOCK OPIOID THERAPY
DO NOT SUBSTITUTE FENTORA FOR OTHER FENTANYL PRODUCTS
FENTORA can be harmful or fatal if given to someone for whom it was not prescribed

FOR BUCCAL ADMINISTRATION. DO NOT CHEW OR SWALLOW TABLET WHOLE.

NDC 63459-543-28

Rx only

28 Buccal Tablets

FENTORA® 
(fentanyl buccal tablet)

equivalent to **300 mcg** fentanyl base

Each tablet contains fentanyl citrate equivalent to 300 mcg fentanyl base.
Store at 20°-25°C (68°-77°F) with excursions permitted between 15° and 30°C (59° to 86°F) until ready to use.
(See USP Controlled Room Temperature.)

For buccal administration.
Usual Dosage: See package insert.

FENTORA® 
(fentanyl buccal tablet)

equivalent to **300 mcg** fentanyl base

LOT
EXP


NDC 63459-543-28
Rx only
28 Buccal Tablets

For information about this product call: 1-800-896-5855
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Frazier, PA 19355



equivalent to **300 mcg** fentanyl base

(fentanyl buccal tablet)

FENTORA® 

28 Buccal Tablets (4 tablets X 7 cards)
NDC 63459-543-28
Rx only

 Cephalon



FOR BUCCAL ADMINISTRATION. DO NOT CHEW OR SWALLOW TABLET WHOLE.
Read enclosed FENTORA Medication Guide for important warnings and directions.

 **WARNING: Keep out of the reach of children**
PATIENTS MUST BE TOLERANT TO AROUND-THE-CLOCK OPIOID THERAPY
DO NOT SUBSTITUTE FENTORA FOR OTHER FENTANYL PRODUCTS
FENTORA can be harmful or fatal if given to someone for whom it was not prescribed

equivalent to **300 mcg** fentanyl base

(fentanyl buccal tablet)

FENTORA® 

28 Buccal Tablets (4 tablets X 7 cards)
NDC 63459-543-28



073000163.02

Place pharmacy label here.

IMPORTANT:
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28 Buccal Tablets (4 tablets X 7 cards)

NDC 63459-544-28

FENTORA® 
(fentanyl buccal tablet)

equivalent to **400 mcg** fentanyl base

**To the Pharmacist:
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FOR BUCCAL ADMINISTRATION. DO NOT CHEW OR SWALLOW TABLET WHOLE.

NDC 63459-544-28

Rx only

28 Buccal Tablets

FENTORA® 
(fentanyl buccal tablet)

equivalent to **400 mcg** fentanyl base

Each tablet contains fentanyl citrate equivalent to 400 mcg fentanyl base.
Store at 20°-25°C (68°-77°F) with excursions permitted between 15° and 30°C (59° to 86°F) until ready to use.
(See USP Controlled Room Temperature.)

For buccal administration.
Usual Dosage: See package insert.

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EXP

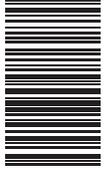
FENTORA® 
(fentanyl buccal tablet)
equivalent to **400 mcg** fentanyl base

NDC 63459-544-28
Rx only
28 Buccal Tablets

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(fentanyl buccal tablet)
equivalent to **400 mcg** fentanyl base
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Frazier, PA 19355

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NDC 63459-544-28
FENTORA® 
(fentanyl buccal tablet)
equivalent to **400 mcg** fentanyl base

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IMPORTANT:
Safe use of this product requires that the patient and/or caregiver read the enclosed Medication Guide for important warnings and directions.

28 Buccal Tablets (4 tablets X 7 cards)
NDC 63459-546-28

FENTORA® 
(fentanyl buccal tablet)

equivalent to **600 mcg** fentanyl base

**To the Pharmacist:
Before dispensing:**

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- Instruct patients to read the enclosed FENTORA Medication Guide

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NDC 63459-546-28
Rx only

28 Buccal Tablets

FENTORA® 
(fentanyl buccal tablet)

equivalent to **600 mcg** fentanyl base

Each tablet contains fentanyl citrate equivalent to 600 mcg fentanyl base.
Store at 20°-25°C (68°-77°F) with excursions permitted between 15° and 30°C (59° to 86°F) until ready to use.
(See USP Controlled Room Temperature.)

For buccal administration.
Usual Dosage: See package insert.

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FENTORA® 
(fentanyl buccal tablet)
equivalent to **600 mcg** fentanyl base

NDC 63459-546-28
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28 Buccal Tablets (4 tablets X 7 cards)
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Rx only
FENTORA® 
(fentanyl buccal tablet)
equivalent to **600 mcg** fentanyl base
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Cephalon, Inc.
Frazier, PA 19355

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NDC 63459-546-28
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(fentanyl buccal tablet)
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Cephalon


073000149.03

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28 Buccal Tablets (4 tablets X 7 cards)
NDC 63459-548-28

FENTORA® 
(fentanyl buccal tablet)

equivalent to **800 mcg** fentanyl base

**To the Pharmacist:
Before dispensing:**

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- Counsel the patient about the use of this product including maximum dosing during a single breakthrough pain episode
- Instruct patients to read the enclosed FENTORA Medication Guide

! WARNING: Keep out of the reach of children
PATIENTS MUST BE TOLERANT TO AROUND-THE-CLOCK OPIOID THERAPY
DO NOT SUBSTITUTE FENTORA FOR OTHER FENTANYL PRODUCTS
FENTORA can be harmful or fatal if given to someone for whom it was not prescribed

FOR BUCCAL ADMINISTRATION. DO NOT CHEW OR SWALLOW TABLET WHOLE.

NDC 63459-548-28
Rx only

28 Buccal Tablets

FENTORA® 
(fentanyl buccal tablet)

equivalent to **800 mcg** fentanyl base

Each tablet contains fentanyl citrate equivalent to 800 mcg fentanyl base.
Store at 20°-25°C (68°-77°F) with excursions permitted between 15° and 30°C (59° to 86°F) until ready to use.
(See USP Controlled Room Temperature.)

For buccal administration.
Usual Dosage: See package insert.

LOT
EXP

FENTORA® 
(fentanyl buccal tablet)
equivalent to **800 mcg** fentanyl base

NDC 63459-548-28
Rx only
28 Buccal Tablets

28 Buccal Tablets (4 tablets X 7 cards)
NDC 63459-548-28
Rx only
FENTORA® 
(fentanyl buccal tablet)
equivalent to **800 mcg** fentanyl base
For information about this product call: 1-800-896-5855
U.S. Patent Nos. 6,200,604 and 6,974,590
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Frazier, PA 19355

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Read enclosed FENTORA Medication Guide for important warnings and directions.

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