MEDICATION GUIDE

ACTIQ® (AK-tik) CII
(fentanyl citrate) oral transmucosal lozenge
200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg, 1600 mcg

IMPORTANT:

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

Keep ACTIQ in a safe place away from children.

Get emergency medical help right away if:

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

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

Read this Medication Guide completely before you start using ACTIQ 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 healthcare provider about your medical condition or your treatment. Share this important information with members of your household and other caregivers.

What is the most important information I should know about ACTIQ?

ACTIQ can cause life-threatening breathing problems which can lead to death:

Do not use ACTIQ if you are not opioid tolerant.

1. If you stop taking your around-the-clock opioid pain medicine for your cancer pain, **you must stop** using ACTIQ. You may no longer be opioid tolerant. Talk to your healthcare provider about how to treat your pain.
2. **Use ACTIQ exactly as prescribed by your healthcare provider.**
   - You must not use more than 1 unit of ACTIQ at a time and no more than 2 units of ACTIQ during each episode of breakthrough cancer pain.
   - You must wait at least 4 hours before treating a new episode of breakthrough pain. **See the Medication Guide section "How should I use ACTIQ?" and the Patient Instructions for Use at the end of this Medication Guide about how to use ACTIQ the right way.**
3. **Do not switch from ACTIQ to other medicines that contain fentanyl without talking with your healthcare provider.** The amount of fentanyl in a dose of ACTIQ is not the same as the amount of fentanyl in other medicines that contain fentanyl. Your healthcare provider will prescribe a starting dose of ACTIQ that may be different than other fentanyl containing medicines you may have been taking.
4. **Do not** use ACTIQ for short-term pain that you would expect to go away in a few days, such as:
   - pain after surgery
   - headache or migraine
   - dental pain
5. N**ever give ACTIQ to anyone else,** even if they have the same symptoms you have. It may harm them or even cause death.

ACTIQ is a federally controlled substance (CII) because it is a strong opioid (narcotic) pain medicine that can be misused by people who abuse prescription medicines or street drugs.

- **Prevent theft, misuse or abuse. Keep ACTIQ in a safe place** to protect it from being stolen. ACTIQ can be a target for people who abuse opioid (narcotic) medicines or street drugs.
- **Selling or giving away this medicine is against the law.**

ACTIQ is available only through a program called the ACTIQ REMS program. To receive ACTIQ, you must:
- talk to your healthcare provider
- understand the benefits and risks of ACTIQ
- agree to all of the instructions
- sign the Patient-Prescriber Agreement form

What is ACTIQ?
- ACTIQ is a prescription medicine that contains the medicine fentanyl.
- ACTIQ is used to manage breakthrough pain in adults (16 years of age and older) with cancer who are already routinely taking other opioid pain medicines around-the-clock for cancer pain.
- ACTIQ is started only after you have been taking other opioid pain medicines and your body has become used to them (you are opioid tolerant). Do not use ACTIQ if you are not opioid tolerant.
- ACTIQ is a lozenge (attached to a handle) that you place between your cheek and lower gum and suck on to dissolve.
- You must stay under your healthcare provider's care while using ACTIQ.
- ACTIQ is only:
  - available through the ACTIQ REMS program
  - given to people who are opioid tolerant

It is not known if ACTIQ is safe and effective in children under 16 years of age.

Who should not use ACTIQ?

Do not use ACTIQ:

- **if you are not opioid tolerant. Opioid tolerant means that you are already taking other opioid pain medicines around-the-clock for at least one week or longer 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
  - headache or migraine
  - dental pain
- if you are allergic to any of the ingredients in ACTIQ. See the end of this Medication Guide for a complete list of ingredients in ACTIQ.

What should I tell my healthcare provider before using ACTIQ?

Before using ACTIQ, tell your healthcare provider if you:

- have trouble breathing or lung problems such as asthma, wheezing, or shortness of breath
- have or had a head injury or brain problem
- have liver or kidney problems
- have seizures
- have a slow heart rate or other heart problems
- have low blood pressure
- have mental problems including major depression, schizophrenia or hallucinations (seeing or hearing things that are not there)
- have a past or present drinking problem (alcoholism), or a family history of drinking problems
- have a past or present drug abuse or addiction problem, or a family history of a drug abuse problem or addiction problem
- have diabetes. Each ACTIQ unit contains about ½ teaspoon (2 grams) of sugar.
- have any other medical conditions
- are pregnant or plan to become pregnant. ACTIQ may cause serious harm to your unborn baby.
- are breastfeeding or plan to breastfeed. ACTIQ passes into your breast milk. It can cause serious harm to your baby. You should not use ACTIQ while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may cause serious or life-threatening side effects when taken with ACTIQ. Sometimes, the doses of certain medicines and ACTIQ may need to be changed if used together.

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

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use ACTIQ?

Before you can begin to use ACTIQ:

- Your healthcare provider will explain the ACTIQ REMS program to you.
- You will sign the ACTIQ REMS program Patient-Prescriber Agreement form.
- ACTIQ is only available at pharmacies that are part of the ACTIQ REMS program. Your healthcare provider will let you know the pharmacy closest to your home where you can have your ACTIQ prescription filled.

Using ACTIQ:

- **Use ACTIQ exactly as prescribed. Do not use ACTIQ more often than prescribed.**
- Your healthcare provider will change the dose until you and your healthcare provider find the right dose for you.
- **See the detailed Patient Instructions for Use at the end of this Medication Guide for information about how to use ACTIQ the right way.**

- Finish the ACTIQ unit completely in 15 minutes to get the most relief. If you finish ACTIQ too quickly, you will swallow more of the medicine and get less relief.
- **Do not bite or chew ACTIQ. You will get less relief for your breakthrough cancer pain.**
- You may drink some water before using ACTIQ but you should not drink or eat anything while using ACTIQ.
- You must not use more than 2 units of ACTIQ during each episode of breakthrough cancer pain:
  - Use **1** unit for an episode of breakthrough cancer pain. Finish the unit over 15 minutes.
  - If your breakthrough cancer pain is not relieved 15 minutes after you finished the ACTIQ unit, use **only 1** more unit of ACTIQ at this time.
  - If your breakthrough pain does not get better after the second unit of ACTIQ, call your healthcare provider for instructions. **Do not use another unit of ACTIQ at this time.**
- Wait at least **4** hours before treating a new episode of breakthrough cancer pain with ACTIQ.
- It is important for you to keep taking your around-the-clock opioid pain medicine while using ACTIQ.
- Talk to your healthcare provider if your dose of ACTIQ does not relieve your breakthrough cancer pain. Your healthcare provider will decide if your dose of ACTIQ needs to be changed.
- Talk to your healthcare provider 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.
- If you begin to feel dizzy, sick to your stomach, or very sleepy before ACTIQ is completely dissolved, remove ACTIQ from your mouth.
- If you use too much ACTIQ or overdose, you or your caregiver should call for emergency medical help or have someone take you to the nearest hospital emergency room right away.

What should I avoid while using ACTIQ?

- **Do not drive, operate heavy machinery, or do other dangerous activities** until you know how ACTIQ affects you. ACTIQ can make you sleepy. Ask your healthcare provider when it is okay to do these activities.
- **Do not drink alcohol while using ACTIQ.** It can increase your chance of getting dangerous side effects.

What are the possible side effects of ACTIQ?
ACTIQ can cause serious side effects, including:

1. **Breathing problems that can become life-threatening.** See "**What is the most important information I should know about ACTIQ?"**
   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 other unusual symptoms

   These symptoms can be a sign that you have used too much ACTIQ or the dose is too high for you. **These symptoms may lead to serious problems or death if not treated right away. If you have any of these symptoms, do not use any more ACTIQ until you have talked to your healthcare provider.**
2. **Decreased blood pressure.** This can make you feel dizzy or lightheaded if you get up too fast from sitting or lying down.
3. **Physical dependence. Do not stop taking ACTIQ or 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 are or have ever been addicted to or abused other medicines, street drugs, or alcohol, or if you have a history of mental health problems.

The most common side effects of ACTIQ are:

- nausea
- vomiting
- dizziness

- sleepiness
- weakness
- headache
- anxiety
- confusion
- depression
- rash
- trouble sleeping

Constipation (not often enough or hard bowel movements) is a very common side effect of pain medicines (opioids) including ACTIQ and is unlikely to go away without treatment. Talk to your healthcare provider about dietary changes, and the use of laxatives (medicines to treat constipation) and stool softeners to prevent or treat constipation while taking ACTIQ.

ACTIQ contains sugar. Cavities and tooth decay can happen in people taking ACTIQ. When taking ACTIQ, you should talk to your dentist about proper care of your teeth.

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of ACTIQ. For more information, ask your healthcare provider or pharmacist.

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

How should I store ACTIQ?

- **Always keep ACTIQ in a safe place away from children and from anyone for whom it has not been prescribed.** Protect ACTIQ from theft.
    - You can use the ACTIQ Child Safety Kit to help you store ACTIQ and your other medicines out of the reach of children. It is very important that you use the items in the ACTIQ Child Safety Kit to help protect the children in your home or visiting your home.
    - If you were not offered a Child Safety Kit when you received your medicine, call Cephalon, Inc., at 1-800-896-5855 or visit www.actiq.com to request one.

The ACTIQ Child Safety Kit contains important information on the safe storage and handling of ACTIQ.

The Child Safety Kit includes:

- **A child-resistant lock that** you use to secure the storage space where you keep ACTIQ (See Figure 1).

Figure 1

- **A portable locking pouch** for you to keep a small supply of ACTIQ nearby. The rest of your ACTIQ must be kept in a locked storage space.
    - Keep this pouch secured with its lock and keep it out of the reach and sight of children (See Figure 2).

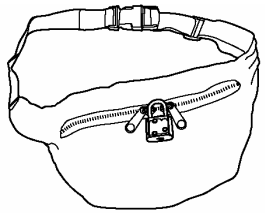

Figure 2

- **A child-resistant temporary storage bottle** (See Figure 3).

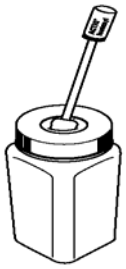

Figure 3

- Store ACTIQ at room temperature, 59°F to 86°F (15°C to 30°C) until ready to use.
- Do not freeze ACTIQ.
- **Keep ACTIQ in the original sealed child-resistant blister package. Do not open the blister package until you are ready to use ACTIQ.**
- Keep ACTIQ dry.

How should I dispose of ACTIQ units when they are no longer needed?

Disposing of ACTIQ units after use:

Partially used ACTIQ units may contain enough medicine to be harmful or fatal to a child or other adults who have not been prescribed ACTIQ. **You must properly dispose of the ACTIQ handle right away after use even if there is little or no medicine left on it.**

After you have finished the ACTIQ unit and the medicine is totally gone, throw the handle away in a place that is out of the reach of children.

If **any** medicine remains on the used ACTIQ unit after you have finished:

- Place the used ACTIQ unit under hot running water until the medicine is gone, and then throw the handle away out of the reach of children and pets (See Figure 4).

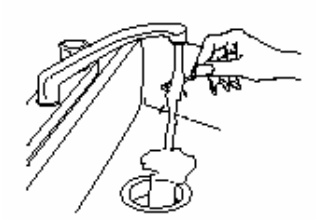

Figure 4

<u>Temporary Storage of Used ACTIQ Units</u>:

- If you did not finish the entire ACTIQ unit and you cannot dissolve the medicine under hot running water right away, put the used ACTIQ unit in the temporary storage bottle that you received in the ACTIQ Child Safety Kit. Push the used ACTIQ unit into the opening on the top until it falls completely into the bottle. **Never leave unused or partially used ACTIQ units where children or pets can get to them** (See Figure 5).

Figure 5

<u>Disposing of Used ACTIQ Units from the Temporary Storage Bottle</u>:

You must dispose of all used ACTIQ units in the temporary storage bottle **at least one time each day**, as follows:

1. To open the temporary storage bottle, push down on the cap until you are able to twist the cap to the left to remove it (See Figure 6).

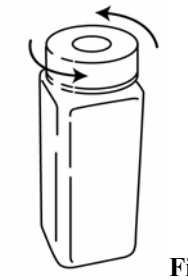

Figure 6

2. Remove one ACTIQ unit from the temporary storage bottle. Hold the ACTIQ by its handle over the toilet bowl.
3. Using wire-cutting pliers, cut the medicine end off so that it falls into the toilet.
4. Throw the handle away in a place that is out of the reach of children.
5. Repeat these 3 steps for each ACTIQ handle that is in the storage bottle. There should not be more than 4 handles in the temporary storage bottle for 1 day.
6. Flush the toilet twice.

Do not flush entire unused ACTIQ units, ACTIQ handles, or blister packages down the toilet.

Disposing of unopened ACTIQ units: Dispose of any unopened ACTIQ units remaining from a prescription as soon as they are no longer needed, as follows:

1. Remove all ACTIQ from the locked storage space (See Figure 7).

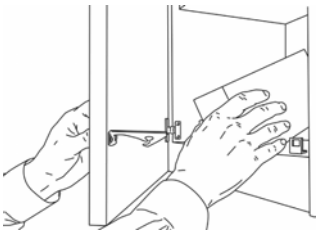

Figure 7

2. Remove one ACTIQ unit from its blister package by using scissors to cut off the marked end and then peel back the blister backing (See Figures 8A and 8B).

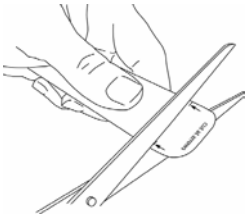

Figure 8A

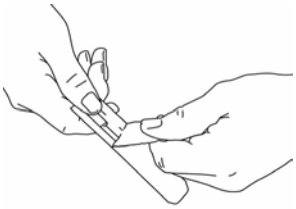

Figure 8B

3. Hold ACTIQ by its handle over the toilet bowl. Use wire-cutting pliers to cut the medicine end off so that it falls into the toilet (See Figures 9A and 9B).

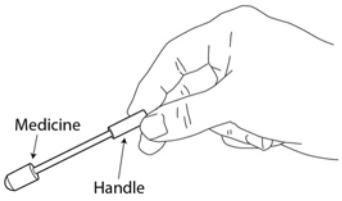

Figure 9A

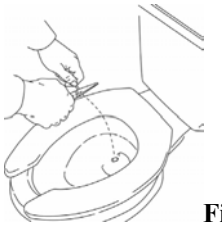

Figure 9B

4. Throw the handle away in a place that is out of the reach of children (See Figure 10).

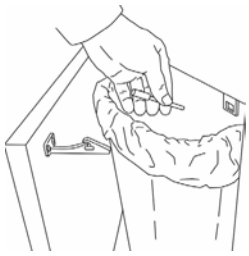

Figure 10

5. Repeat steps 1 through 4 for each ACTIQ unit.

6. Flush the toilet twice after the medicine ends from 5 ACTIQ units have been cut off (See Figure 11). Do not flush more than 5 ACTIQ units at a time.

Figure 11

- Do not flush entire unused ACTIQ units, ACTIQ handles, or blister packages down the toilet.

If you need help with disposal of ACTIQ, call Cephalon, Inc., at 1-800-896-5855, or call your local Drug Enforcement Agency (DEA) office.

General information about ACTIQ

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

This Medication Guide summarizes the most important information about ACTIQ. If you would like more information, talk with your healthcare provider or pharmacist. You can ask your pharmacist or healthcare provider for information about ACTIQ that is written for healthcare professionals. You can also call the ACTIQ REMS program at 1-888-688-6885 or visit actiqandfentorarems.com.

What are the ingredients of ACTIQ?

Active Ingredient: fentanyl citrate
Inactive Ingredients: sugar, citric acid, dibasic sodium phosphate, artificial berry flavor, magnesium stearate, modified food starch and confectioner's sugar.

Patient Instructions for Use

Before you use ACTIQ, it is important that you read the Medication Guide and these Patient Instructions for Use. Be sure that you read, understand, and follow these Patient Instructions for Use so that you use ACTIQ the right way. Ask your healthcare provider or pharmacist if you have any questions about the right way to use ACTIQ.

When you get an episode of breakthrough cancer pain, use the dose of ACTIQ prescribed by your healthcare provider as follows:

- You may drink some water before using ACTIQ but you should not drink or eat anything while using ACTIQ.
- Each unit of ACTIQ is sealed in its own blister package (See Figure12). **Do not open the blister package until you are ready to use ACTIQ.**

Figure 12

- When you are ready to use ACTIQ, cut open the package using scissors. Peel back the blister backing, and remove the ACTIQ unit (See Figures 13A and 13B). The end of the unit printed with "ACTIQ" and the strength number of the unit ("200", "400", "600", "800", "1200", or "1600") is the medicine end that is to be placed in your mouth. Hold the ACTIQ unit by the handle (See Figure 14).

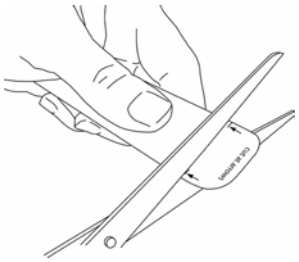

Figure13A

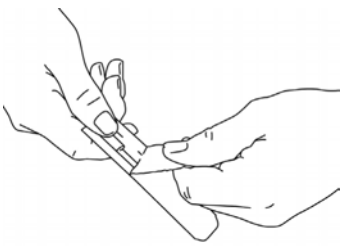

Figure 13B

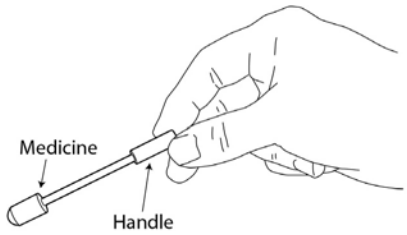

Figure 14

1. Place the medicine end of the ACTIQ unit in your mouth between your cheeks and gums and actively suck on the medicine.
2. Move the medicine end of the ACTIQ unit around in your mouth, especially along the inside of your cheeks (See Figure 15).

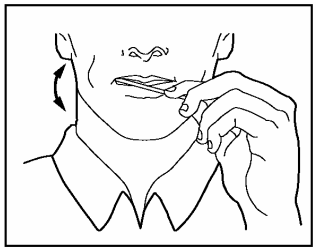

Figure 15

3. Twirl the handle often.
4. Finish the ACTIQ unit completely over 15 minutes to get the most relief. If you finish ACTIQ too quickly, you will swallow more of the medicine and get less relief.
5. **Do not bite or chew ACTIQ. You will get less relief for your breakthrough cancer pain.**

- If you cannot finish all of the medicine on the ACTIQ unit and cannot dissolve the medicine under hot tap water right away, immediately put the ACTIQ unit in the temporary storage bottle for safe keeping (See Figure 16).
  - Push the ACTIQ unit into the opening on the top until it falls completely into the bottle. You must properly dispose of the ACTIQ unit as soon as you can.

Figure 16

See "**How should I dispose of ACTIQ units when they are no longer needed?**" for proper disposal of ACTIQ.

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

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