

- 16 Inform female patients that if they become pregnant or plan to become pregnant during treatment with ACTIQ, they should ask their doctor about the effects that ACTIQ (or any medicine) may have on them and their unborn children.

17.2 Dental Care

Because each ACTIQ unit contains approximately 2 grams of sugar (hydrated dextrans), frequent consumption may increase the risk of dental decay. The occurrence of dry mouth associated with the use of opioid medications (such as fentanyl) may add to this risk.

Post-marketing reports of dental decay have been received in patients taking ACTIQ [see *Adverse Reactions* (6.2)]. In some of these patients, dental decay occurred despite reported routine oral hygiene. As dental decay in cancer patients may be multi-factorial, patients using ACTIQ should consult their dentist to ensure appropriate oral hygiene.

17.3 Diabetic Patients

Advise diabetic patients that ACTIQ contains approximately 2 grams of sugar per unit.

17.4 ACTIQ Child Safety Kit

Provide patients and their caregivers with an ACTIQ Child Safety Kit, which contains educational materials and safe interim storage containers to help patients store ACTIQ and other medicines out of the reach of children. To obtain a supply of Child Safety Kits, health care professionals can call Cephalon, Inc., at 1-800-896-5855.

17.5 Disposal of Used ACTIQ Units

Patients must be instructed to dispose of completely used and partially used ACTIQ units.

- 1) After consumption of the unit is complete and the matrix is totally dissolved, throw away the handle in a trash container that is out of the reach of children.
- 2) If any of the drug matrix remains on the handle, place the handle under hot running tap water until all of the drug matrix is dissolved, and then dispose of the handle in a place that is out of the reach of children.
- 3) Dispose of handles in the child-resistant container (as described in steps 1 and 2) at least once a day.

If the patient does not entirely consume the unit and the remaining drug cannot be immediately dissolved under hot running water, the patient or caregiver must temporarily store the ACTIQ unit in the specially provided child-resistant container out of the reach of children until proper disposal is possible.

17.6 Disposal of Unopened ACTIQ Units When No Longer Needed

Patients and members of their household must be advised to dispose of any unopened units remaining from a prescription as soon as they are no longer needed.

To dispose of the unused ACTIQ units:

- 1) Remove the ACTIQ unit from its blister package using scissors, and hold the ACTIQ by its handle over the toilet bowl.
- 2) Using wire-cutting pliers cut off the drug matrix end so that it falls into the toilet.
- 3) Dispose of the handle in a place that is out of the reach of children.
- 4) Repeat steps 1, 2, and 3 for each ACTIQ unit. Flush the toilet twice after 5 units have been cut and deposited into the toilet.

Do not flush the entire ACTIQ units, ACTIQ handles, blister packages, or cartons down the toilet. Dispose of the handle where children cannot reach it [see *How Supplied/Storage And Handling* (16.1)].

Detailed instructions for the proper storage, administration, disposal, and important instructions for managing an overdose of ACTIQ are provided in the ACTIQ *Medication Guide*. Encourage patients to read this information in its entirety and give them an opportunity to have their questions answered.

In the event that a caregiver requires additional assistance in disposing of excess unusable units that remain in the home after a patient has expired,

instruct them to call the toll-free number for Cephalon, Inc., (1-800-896-5855) or seek assistance from their local DEA office.

Medication Guide

Actiq® (AK-tik) CII

(oral transmucosal fentanyl citrate)

200 mcg, 400 mcg, 600 mcg, 800 mcg, 1200 mcg, 1600 mcg



WARNING:

1. **Do not use *Actiq* 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. **You MUST keep *Actiq* in a safe place out of the reach of children.** Accidental ingestion by a child is a medical emergency and can result in death. **Death has been reported in children who have accidentally taken *Actiq*. If a child accidentally takes *Actiq*, get emergency help right away.**

Read the Medication Guide that comes with *Actiq* 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 *Actiq*?

1. ***Actiq* 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 *Actiq* that is different than other fentanyl containing medicines you may have been taking. Do not substitute *Actiq* for other fentanyl medicines without talking with your doctor.**
3. **Use no more than 2 units of *Actiq* per episode of breakthrough cancer pain. You must wait at least 4 hours before using *Actiq* again for another episode of breakthrough cancer pain.**

What is *Actiq*?

- *Actiq* is a prescription medicine that contains the medicine fentanyl. ***Actiq* 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.**
- ***Actiq* is to be used only to treat breakthrough pain in adult patients with cancer (16 years of age and older)**

who are regularly using other opioid pain medicines around-the-clock for their constant cancer pain. *Actiq* 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 *Actiq* if you are not opioid tolerant.** Please talk with your doctor about whether or not you are opioid tolerant.

- You must stay under your doctor's care while taking *Actiq*.
- ***Actiq* must not be used for the treatment of short-term pain from injuries, surgery, or headaches, including migraines.**
- **Prevent theft and misuse. Keep *Actiq* 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 *Actiq* 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 *Actiq*?

Do Not Take *Actiq*:

- 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, or headaches, including migraines,** or for pain that will go away in a few days, such as pain from doctor or dentist visits, or any short-lasting pain.
- **if you are allergic to anything in *Actiq*.** The active ingredient in *Actiq* is fentanyl. See the end of this Medication Guide for a complete list of ingredients in *Actiq*.

What should I tell my doctor before I start taking *Actiq*?

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
- If you are diabetic. Each *Actiq* unit contains about ½ teaspoon (2 grams) of sugar.

Tell your doctor if you are:

- **pregnant or planning to become pregnant.** *Actiq* may harm your unborn baby.

- **breast feeding.** Fentanyl passes through your breast milk and it can cause serious harm to your baby. **You should not use *Actiq* while breast feeding.**

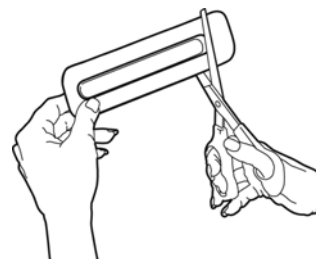
Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal and dietary supplements. Some medicines may cause serious or life-threatening medical problems when taken with *Actiq*. Sometimes, the doses of certain medicines and *Actiq*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

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

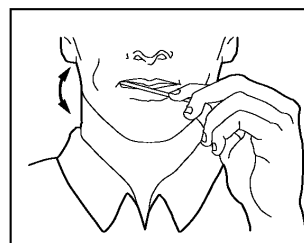
Know the medicines you take. Keep a list of them to show your doctor and pharmacist.

How should I use *Actiq*?

- **Use *Actiq* exactly as prescribed by your doctor.** Do not use *Actiq* more often than prescribed. **Talk to your doctor about your pain. Your doctor can decide if your dose of *Actiq* needs to be changed.**
- Each unit of *Actiq* is sealed in its own blister package.
- **Do not open the blister package until you are ready to use *Actiq*.**



- When you are ready to use *Actiq*, cut open the package using scissors and remove the *Actiq* unit. The end of the unit marked with "ACTIQ" and the strength of the unit ("200", "400", "600", "800", "1200", or "1600") is the end that is to be placed in your mouth as described below.

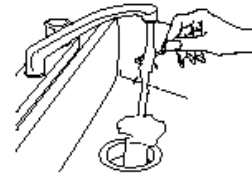


- Place *Actiq* in your mouth between your cheeks and gums and actively suck on the medicine.
- Move *Actiq* around in your mouth, especially along your cheeks.
- Twirl the handle often.
- Finish the *Actiq* unit completely in 15 minutes to get the most relief. If you finish *Actiq* too quickly, you will swallow more of the medicine and get less relief.
- **Do not bite or chew *Actiq*. You will get less relief for your breakthrough pain.**
- You may drink some water before using *Actiq* but you should not drink or eat anything while using *Actiq*.
- If you begin to feel dizzy, sick to your stomach, or very sleepy before *Actiq* is completely dissolved, remove *Actiq* from your mouth. Dispose of *Actiq* right away or put it in the temporary storage bottle in the Child Safety Kit for later disposal.
- **Use 1 unit of *Actiq* for an episode of breakthrough cancer pain. Consume 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 dose of *Actiq* at this time.**
- **Wait at least 4 more hours before using *Actiq* again for another episode of breakthrough cancer pain.**
- **Remember, you must continue taking your regularly-used around-the-clock opioid medicine while taking *Actiq*.**
- **Limit the use of *Actiq* to four or fewer units per day.**
- **Talk to your doctor if your dose of *Actiq* does not relieve your breakthrough cancer pain. Your doctor will decide if your dose of *Actiq* 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.
- **If you take too much *Actiq* or overdose, call 911 or your local emergency number for help.**

How should I dispose of *Actiq* 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.** Please follow these directions to dispose of the handle:

1. Once 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.
2. If any medicine remains on the handle after you have finished, place the handle under hot running water until the medicine is gone, and then throw the handle away out of the reach of children and pets.



3. If you did not finish the entire *Actiq* unit and you cannot dissolve the medicine under hot running water right away, put the *Actiq* in the temporary storage bottle that you received in the *Actiq* Child Safety Kit for safe keeping. Push the *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.**
4. Dispose of the handles in the temporary storage bottle as soon as you can by following the directions in steps 1 and 2. You must dispose of all handles in the temporary storage bottle at least once a day.

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

What should I avoid while taking *Actiq*?

- **Do not drive, operate heavy machinery, or do other dangerous activities** until you know how *Actiq* affects how alert you are. *Actiq* can make you sleepy. Ask your doctor 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.
- **Do not take any medicine while using *Actiq* until you have talked to your doctor. Your doctor will tell you if it is safe to take other medicines while you are using *Actiq*.** Be especially careful about 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 *Actiq*?

- ***Actiq* 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 *Actiq*?”
- **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) *Actiq* 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 *Actiq*.**

- ***Actiq* can cause your blood pressure to drop.** This can make you feel dizzy if you get up too fast from sitting or lying down.
- ***Actiq* can cause physical dependence.** Do not stop taking *Actiq* 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 dependency is not the same as drug addiction.
- **There is a chance of abuse or addiction with *Actiq*.** 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 *Actiq* are nausea, vomiting, dizziness and sleepiness. Other side effects include headache, low energy and constipation. 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 doctor 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 have occurred in patients taking *Actiq*. When taking *Actiq*, you should talk to your dentist about proper care of your teeth.

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 *Actiq*. For a complete list, ask your doctor.

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*?

- **Keep *Actiq* 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 *Actiq*, get emergency help right away.**
- ***Actiq* is supplied in single sealed child-resistant blister packages.** Store *Actiq* at room temperature, 59° to 86°F (15° to 30°C) until ready to use.
- **Always keep *Actiq* in a secure place to protect from theft.**

How should I dispose of unopened *Actiq* units when they are no longer needed?

- Dispose of any unopened *Actiq* units remaining from a prescription as soon as they are no longer needed.
- If you are no longer using *Actiq* or if you have unused *Actiq* in your home, please follow these steps to dispose of the *Actiq* as soon as possible.
 1. Remove all *Actiq* from the locked storage space.
 2. Remove one *Actiq* unit from its blister package using scissors, and 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 steps 2, 3, and 4 for each *Actiq*.
 6. Flush the toilet twice after 5 *Actiq* units have been cut. Do not flush more than 5 *Actiq* units at a time.
 - 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.

General Information About the Safe and Effective Use of *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 doctor. You can also ask your pharmacist or doctor for information about *Actiq* that is written for healthcare professionals. You can also call Cephalon, Inc., at 1-800-896-5855.

What are the ingredients of *Actiq*?

Active Ingredient: fentanyl citrate

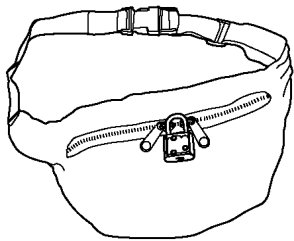
Inactive Ingredients: Sugar, citric acid, dibasic sodium phosphate, artificial berry flavor, magnesium stearate, modified food starch, and confectioner's sugar.

How do I use the *Actiq* Child Safety Kit?

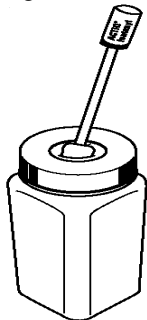
- You can use the *Actiq* Child Safety Kit to help you store *Actiq* and your other medicines out of the reach of children. It is very important that you use the items in the *Actiq* Child Safety Kit to protect the children in your home.

- If you were not offered a Child Safety Kit when you received your medicine, call Cephalon, Inc., at 1-800-896-5855 to request one.

The *Actiq* Child Safety Kit contains important information on the safe storage and handling of *Actiq*. The kit contents include:



- A **child-resistant lock** for you to secure the storage space where you keep *Actiq* and any other medicines at home.
- A **portable locking pouch** for you to keep a small supply of *Actiq* nearby for your immediate use. The rest of your *Actiq* must be kept in the locked storage space.
 - Keep this pouch secured with its lock and keep it out of the reach and sight of children.



- A **child-resistant temporary storage bottle**.
- If for some reason you cannot finish the entire *Actiq* unit and cannot immediately dissolve the medicine under hot tap water, immediately put the *Actiq* unit in the temporary storage bottle for safe keeping.
 - 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.
- See “How should I dispose of unopened *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.

Manufactured by:
Cephalon, Inc., Salt Lake City, UT 84116

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Printed in USA

Label Code: XXXXXX

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