

Patient Leaflet

 Cephalo **Actiq**[®] 
(oral transmucosal fentanyl citrate)

 **WARNING: Keep out of the reach of children**

Read this information carefully before using *Actiq*. If you have any questions after reading this patient leaflet, talk to your doctor.

Actiq contains medicine that could be harmful or fatal to a child. You **MUST** keep *Actiq* out of the reach of children. Explain to children that *Actiq* is a medicine for your use only. *Actiq* can cause injury or death in people who are not already taking prescription opioid (narcotic) pain medicines on a regular schedule to relieve chronic cancer pain. If you have not been taking these types of medicines, do not use *Actiq* because it may cause your breathing to slow down to a dangerous level or even to stop. Some examples of opioid pain medicines are Duragesic[®], Dilaudid[®], mehadone, morphine, MS Contin[®], and OxyContin[®].

Actiq must only be used for breakthrough cancer pain. Do not use *Actiq* if you have pain that will go away in a few days, such as pain from surgery, from doctor or dentist visits, or any other short-lasting pain.

Do not let anyone else use *Actiq*. It is for your use only.

If someone accidentally takes *Actiq*:

If the person is not awake and alert, call 911 or call for emergency help immediately.

If the person is awake and alert, call Poison Control at 1-800-690-3924.

WARNING: MAY BE HABIT FORMING

 **WARNING: Keep out of the reach of children**

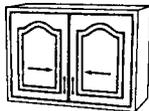
Important Information For People Who Have Children In The Home: You **MUST** keep *Actiq* out of the reach of children. *Actiq* contains medicine that could be harmful or fatal to a child. Please pay close attention to the child warnings in this patient leaflet.

How to use the *Actiq* Welcome Kit

You have been prescribed an *Actiq* Welcome 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* Welcome Kit to protect the children in your home.

Child-resistant lock

After you have chosen a storage space for *Actiq* and your other medicines, secure this space with the child-resistant lock included in the Welcome Kit.



Portable locking pouch

You may keep a small supply of *Actiq* in the portable locking pouch so that it is 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.



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* 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 to dispose of *Actiq* after use).



If you did not receive an *Actiq* Welcome Kit, please call 1-800-896-5855.

How to store *Actiq* in your home

- *Actiq* and your other medicines must be stored in a locked storage space. Be sure to use the child-resistant lock that you received in the Welcome Kit.
- Always keep *Actiq* in its foil package until you are ready to use it. Do not use *Actiq* if the foil package has been damaged or opened before you are ready to use it.
- Store *Actiq* at room temperature. Do not refrigerate or freeze. Do not store *Actiq* above 86°F (30°C). Remember, the inside of your car can get hot in the summer.

What is *Actiq*?

Actiq contains a prescription opioid (narcotic) pain-relieving medicine called fentanyl. When you place *Actiq* in your mouth, it slowly dissolves and the medicine is absorbed through the lining of your mouth. From your mouth, it goes into your bloodstream, where it works to relieve your breakthrough cancer pain.

When to use *Actiq*

Actiq is used to relieve the flares called breakthrough cancer pain, that your regularly prescribed pain medicine does not control. *Actiq* should be taken along with your regularly prescribed cancer pain medicine. Do not stop taking your regularly prescribed pain medicine.

When not to use *Actiq*

- You should not use *Actiq* if you are having short-term pain, including pain from injuries and surgery.
- You should not use *Actiq* unless you have breakthrough cancer pain and have been taking a prescription opioid (narcotic) pain medicine every day on a regular schedule.

How to use *Actiq*

When you first start using *Actiq*, your doctor will help you find the dose of *Actiq* that will relieve your pain. Use *Actiq* exactly as your doctor or nurse told you to use it. Your doctor will tell you how often you can take *Actiq* safely.



Step 1. Each *Actiq* unit is sealed in its own foil package. Do not open the 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.



Step 2. 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* 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.



If for some reason you are not finishing the entire unit each time you have an episode of breakthrough cancer pain, you should call your doctor or nurse.

Do not bite or chew Actiq. You will get less relief of your breakthrough cancer pain.

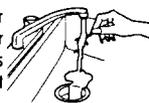
If you begin to feel dizzy or sick to your stomach before you have finished the medicine, remove Actiq from your mouth. Either dispose of Actiq immediately or put it in the temporary storage bottle for later disposal.

You may drink some water before using Actiq, but you should not drink or eat anything while using Actiq.

How to 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 immediately and properly dispose of the Actiq handle 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 immediately dissolve the medicine under hot running water, put the Actiq in the temporary storage bottle that you received in the Actiq Welcome 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 partly 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 foil pouches down the toilet.

What to expect from Actiq

You should begin to feel some relief while you are taking Actiq. You may not get full relief for up to 45 minutes after you have finished taking Actiq. If you do not get enough pain relief from just one Actiq, your doctor may allow you to use another one. Do not use a second Actiq unless your doctor or nurse tells you that you may do so.

Some people will have side effects with Actiq. The most common side effects are feeling sleepy, sick to your stomach, or dizzy. If you begin to feel very sleepy, remove the Actiq from your mouth or call another person in your household to help you.

For best results, let your doctor or nurse know about your pain and how Actiq is working for you so the dose can be changed, if needed.

Important safety information for patients and caregivers

You and the other people in your home should be aware of some important information about Actiq. Always feel free to contact your doctor or nurse with any questions or concerns you may have about Actiq and any side effects.

- A serious side effect of Actiq is slow, shallow breathing. This can occur if your dose of Actiq is too high or if you take too much Actiq. You and your caregivers should discuss this side effect with your doctor. **Attention Caregivers:** If you see that the person taking Actiq has slow breathing or if you have a hard time waking the person up, remove the Actiq from their mouth and call for emergency help. (See What to do if a child or an adult accidentally takes Actiq.)
- Actiq may change the effect of other medicines (prescription and over-the-counter). Actiq will also add to the effects of alcohol and medicines that make you sleepy (like sleeping pills, anxiety medicines, antihistamines, or tranquilizers). Make sure that you talk to your doctor before drinking alcohol or taking any medicines (other than your regularly scheduled opioid [narcotic] pain medicines) while using Actiq.

- Actiq may cause some people to become sleepy, dizzy, or less alert. Discuss this with your doctor to get advice on whether it is safe for you to drive or operate machinery. Until you have experienced how this medicine affects you, do not drive a car or operate potentially dangerous machinery. You should discuss this further with your doctor.
- Frequent use of products that contain sugar may increase the risk of dental cavities (each Actiq unit contains about 1/2 teaspoon of sugar). The occurrence of dry mouth associated with the use of opioid medications may add to this risk (Actiq contains the opioid medication fentanyl). You should consult your dentist to ensure appropriate dental care while using Actiq.
- Diabetic patients should inform their physician that they are taking Actiq, which contains 2 grams of sugar per unit (approximately 1/2 teaspoon).
- Do not use Actiq if you are pregnant or nursing unless told that you may do so by your doctor.

What to do if a child or an adult accidentally takes Actiq

Actiq contains medicine that could be harmful or fatal to a child or an adult who has not been prescribed Actiq. In these people, Actiq can cause their breathing to slow down or even stop. If you think someone has accidentally taken Actiq, follow these steps immediately:

1. Remove the Actiq unit from the person's mouth.
2. If the person is asleep, keep them awake by calling their name and shaking their arm or shoulder.
3. If the person is **not** awake and alert, call 911 or call for emergency help. If the person is awake and alert, call Poison Control at 1-800-690-3924.

While waiting for emergency help:

4. If the person seems to be breathing slowly, every 5 to 10 seconds tell them to breathe.
5. If the person has stopped breathing, give mouth-to-mouth resuscitation until emergency help arrives.

How to know if someone has accidentally taken Actiq

If someone has accidentally taken Actiq, they may have these symptoms:

- Very sleepy
- Itching, especially around the nose and eyes
- Dizzy
- Sick to their stomach or vomiting
- Not breathing or breathing very slowly

When to call your doctor or nurse

- If you have side effects that bother you and do not go away.
- If you want to take any over-the-counter medicines.
- If another doctor has prescribed with new medicines for you.
- If you do not get enough breakthrough cancer pain relief.
- If you are using Actiq more than four times a day.
- If you are not finishing the entire Actiq unit.

When Actiq is 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:

Step 1. Remove all Actiq from the locked storage space.

Step 2. Remove one Actiq unit from its pouch using scissors, and hold the Actiq by its handle over the toilet bowl.

Step 3. Using wire-cutting pliers, cut the medicine end off so that it falls into the toilet.

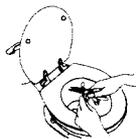
Step 4. Throw the handle away in a place that is out of the reach of children.

Step 5. Repeat steps 2, 3, and 4 for each Actiq.

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 foil pouches down the toilet.

If you need help with disposal of Actiq, call 1-800-896-5855. If you still need help, call your local Drug Enforcement Administration (DEA) office.



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Manufactured for:
Cephalon, Inc., West Chester, PA 19380
U.S. Patent No. 4,671,953

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