

Actiq® Fentanyl Citrate

(lozenge with integral applicator)

Consumer Medicine Information

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This leaflet answers some common questions about *Actiq*. It does not contain all of the available information. Reading this leaflet does not take the

place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of your taking *Actiq* against the benefits they expect it will have for you.

If you have any concerns about taking *Actiq*, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may want to read it again.

What is Actiq used for?

Actiq contains a medicine called fentanyl citrate. Fentanyl is a strong pain-relieving medicine and belongs to a group of medicine known as opioids.

Actiq lozenge with integral applicator is a system for delivering fentanyl directly through the lining of the mouth. When you place *Actiq* in your mouth, it dissolves and the medicine is absorbed through the lining of your mouth, into the blood system. Taking the medicine in this way allows it to be absorbed very quickly to relieve your **breakthrough pain**.

Breakthrough pain is additional sudden pain that occurs in spite of your having taken your usual opioid pain-relieving medicines.

Keep using the opioid pain medicine you take for your persistent (around-the-clock) cancer pain during your *Actiq* treatment.

Opioid medicines are those that contain active ingredients such as morphine, fentanyl citrate, codeine, methadone, oxycodone, pethidine or buprenorphine.

The use of *Actiq* by people who are not taking prescription opioid medicines on a regular basis could result in life-threatening side effects.

Your doctor may have prescribed *Actiq* for another use. Ask your doctor if you have any questions about why *Actiq* lozenges has been prescribed for you.

Medicines like *Actiq* can lead to addiction. This is unlikely when *Actiq* is used correctly.

Actiq is only available on a doctor's prescription.

Before you take Actiq

Actiq is not suitable for everyone.

When you must not take it

Do not take *Actiq* if:

- You have short term pain, including pain from injuries, from doctors or dentists visits, surgery or headaches/migraines.
- You have **not** been using a prescribed opioid pain medicine every day on a regular schedule, for at least one week, to control your persistent pain. This may increase the risk that your breathing could slow down to a dangerous level, or even stop.
- You are allergic to fentanyl, or any of the other ingredients in the formulation (*see list at the end of this leaflet*).
- You are pregnant or breastfeeding, unless your doctor tells you it is safe.

Do not use *Actiq* after the expiry date shown on the blister package label and

the carton. The unit is normally white, however a slightly mottled appearance may occur on storage. This is due to slight changes in the flavouring of the product and does not affect how the product works in any way.

Do not take *Actiq* if the packaging seems to have been opened.

If you become pregnant whilst taking *Actiq*, you should stop taking it and see your doctor immediately. Young women taking *Actiq* and who are at risk of becoming pregnant should make sure that they are using adequate contraception.

Before you start to take it

Tell your doctor if you:

- Have any allergies.
- Are pregnant or intend to become pregnant.
- Are breastfeeding or planning to breast-feed.
- Your other opioid pain medicine you take for your persistent (around-the-clock) cancer pain is not stabilised yet.
- Have or have had any of the following medical conditions:
 - Chronic diseases of the lung, or other condition which has an effect on your breathing
 - Head injury
 - Diabetes
 - Exceptionally slow heart rate
 - Liver or kidney diseaseThese organs have an effect on the way in which your system breaks down the medicine.

Taking/using other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your

pharmacy, supermarket or health food store.

Take special care with *Actiq* if:

- You are taking any medicines which might normally have a **sedative effect** (make you sleep), such as:
 - o sleeping pills
 - o medicines to treat anxiety
 - o antihistamines, or
 - o tranquillisers.
- You are taking any medicines or other substances that might have an effect on the way in which your body breaks down *Actiq*, such as:
 - o drugs used to treat fungal infections
 - o certain antibiotics, or
 - o grapefruit juice.
- You intend to drink alcohol, drive, or operate machinery in the few hours after taking *Actiq*.
Your doctor will be able to advise you on this.

How to take Actiq

Do not take *Actiq* to treat any condition other than that directed by your doctor.

How many to take

1. **Your doctor will advise you on the appropriate starting dose of *Actiq* for the relief of your breakthrough pain.**

It is very important that you use *Actiq* in the manner as directed by your doctor. If you are not sure about the right dose or if you have questions about taking *Actiq*, you should contact your doctor.

You should start to feel some pain relief quickly while you are taking *Actiq*.

2. **Until the dose that effectively controls your breakthrough pain has been determined, if you do not get enough pain relief from just one *Actiq*, your doctor may allow you to use a second dose to treat an episode of breakthrough pain.**

Do not use a second *Actiq* unit unless your doctor tells you to do so and never use more than two *Actiq* units to treat a single episode of breakthrough pain.

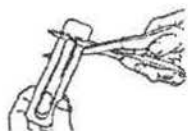
3. It is recommended that you wait at least 4 hours before treating another episode of breakthrough pain with *Actiq*.
4. **You must tell your doctor immediately if you are using *Actiq* more than four times per day, as the doctor may wish to change your medicine for your persistent pain.**
Once your persistent pain has been controlled, your doctor may need to change your dose of *Actiq* further.
5. **For best results, let your doctor know about your pain and how *Actiq* is working for you so that the dose can be changed if needed.**
6. **Do not change doses of *Actiq* or your other pain medicines on your own. Contact your doctor if your right dose of *Actiq* does not relieve your breakthrough pain. Your doctor will decide if your dose needs to be changed.**

Change in dosage must be directed and monitored by your doctor.

DO NOT TAKE MORE THAN THE DOSE YOUR DOCTOR HAS RECOMMENDED.

How to take it

1. Each *Actiq* unit is sealed in its own blister package. Do not open the package until you are ready to use *Actiq*. Hold the blister package with the printed side away from you. Grasp the short tab end of the blister package. Place scissors close to the end of the *Actiq* unit and cut the long tab end completely off (as shown). Separate the printed backing from the blister package and pull the printed backing **completely** off of the blister package. Remove the *Actiq* unit from the blister package.



2. Place *Actiq* in your mouth between your cheeks and gums. Using the handle, move *Actiq* round in your mouth especially along your cheeks. Twirl the handle often. You may drink some water before using *Actiq*, to help with taking the product but you **should not drink or eat anything while using *Actiq*.**



3. To get the most effective relief, finish the *Actiq* completely in 15 minutes. If you finish *Actiq* too quickly, you will swallow more of the medicine and get less relief of your breakthrough pain. It is also most important that you **do not**

bite or chew *Actiq* for the same reason.



4. If you begin to feel dizzy or sick before you have finished the medicine, remove the *Actiq* unit from your mouth and dispose of it immediately, as instructed in this leaflet. If for some reason you are not finishing the entire *Actiq* unit each time you have an episode of breakthrough pain, you should call your doctor.
5. Once a dose has been arrived at which effectively controls your pain, you **should not use more than four units of *Actiq* per day.** If you think you might need to use more than four *Actiq* units per day, you should notify your doctor immediately.
6. **Do not use more than two *Actiq* units to treat a single episode of breakthrough pain.**

Taking *Actiq* with food or drink

Actiq may be used **before or after** but not during meals. You may drink some water before using *Actiq* to help moisten your mouth, but you should not drink or eat anything while taking the medicine.

When to take it

Actiq must only be used for **breakthrough pain.** Breakthrough pain is additional sudden pain that occurs in spite of your having taken your usual opioid pain-relieving medicines.

How long to take it

You should not normally stop taking *Actiq* for breakthrough pain unless your doctor tells you to.

If you feel unwell during your course of treatment, tell your doctor.

On the advice of your doctor, you may stop taking *Actiq* if you are no longer experiencing breakthrough pain. There are usually no noticeable effects if you stop taking *Actiq*. You should continue to take your usual opioid medicine to treat your persistent (around-the-clock) pain as instructed by your doctor.

How to dispose of *Actiq* after use

- Partially used *Actiq* units may contain enough medicine to be harmful or life-threatening to a child.
- Even if there is little or no medicine left on the handle, the handle itself must be properly disposed of, as follows:
 - o If the medicine is totally gone, throw the handle away in a waste container that is out of reach of children and pets.
 - o If any medicine remains on the handle, place the unit under hot running water to dissolve the remainder and then throw the handle away in a waste container that is out of reach of children and pets.
 - o If you do not finish the entire *Actiq* unit and you cannot immediately dissolve the remaining medicine, put the *Actiq* unit out of reach of children and

pets until such a time as you can dispose of the partially used *Actiq* unit as instructed above.

- o Do not flush partially used *Actiq* units, *Actiq* handles, or the blister packaging down the toilet.

If you have taken too many *Actiq* units

Telephone your doctor or go to casualty at your nearest hospital immediately if you think that you or anyone else may have taken too many *Actiq* units even if there are no signs of discomfort or poisoning.

The most common side effects are feeling sleepy, sick or dizzy. If you begin to feel very sleepy, remove the *Actiq* unit from your mouth and call another person in your house to help you.

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 carer should discuss this side effect with your doctor.

Note to carers

If you see that the patient taking *Actiq* has slow breathing or if you have a hard time waking the person up, take the following steps IMMEDIATELY:

1. Using the handle, remove the *Actiq* unit from the person's mouth and keep it out of reach of children or pets until the *Actiq* unit is disposed of.
2. CALL FOR EMERGENCY HELP
3. See instructions below for what to do if a child or adult accidentally takes *Actiq*.

***What to do if a child or adult
ACCIDENTALLY takes Actiq***

If you think someone has accidentally taken *Actiq* follow these steps:

1. If the person is asleep, keep them awake by calling their name and shaking their arm or shoulder.
2. CALL FOR EMERGENCY HELP.
3. While waiting for emergency help:
 - If the person seems to be breathing slowly, prompt them to breathe every 5-10 seconds.
 - If the person has stopped breathing give mouth to mouth resuscitation until help arrives.

If someone has accidentally taken *Actiq*, they may have the following symptoms:

- Very sleepy
- Itching, especially around the nose and eyes
- Dizzy
- Feeling sick or vomiting
- Not breathing, or breathing very slowly

While you are taking Actiq***Things you must do***

Make sure that all of your doctors and pharmacists know about your use of *Actiq*. Remind them if any new medicines are about to be started, including any medicines that you may purchase without a prescription.

Things that you must not do

Do not use *Actiq* to treat any complaint other than that directed by your doctor. It may not be safe to use *Actiq* for another complaint.

Actiq should only be used by the person for whom it was prescribed. Do not give *Actiq* to someone else even if their symptoms are the same. It may not be safe for another person to use *Actiq*.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking *Actiq*. Like all medicines, *Actiq* can cause side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- Headache
- Nausea/vomiting
- Feeling unwell
- Weakness, dizziness
- Sleepiness, sedation
- Constipation
- Anxiety

If you feel excessively dizzy, sleepy or otherwise ill while taking *Actiq*, use the handle to remove the *Actiq* unit and dispose of it according to the instructions given in this leaflet. Then contact your doctor for further directions on using *Actiq*.

Do not drive or operate machinery if you are feeling sleepy, dizzy or have difficulty in concentrating.

Tell your doctor immediately, or get someone to take you to accident and emergency at your nearest hospital if you notice any of the following:

- Becoming very sleepy

- Having slow or shallow breathing.

Whilst using the Actiq lozenge you may experience irritation, pain and ulcer at the applications site and gum bleeding.

Other side effects not listed in this leaflet may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell. Do not be alarmed by this list of possible side effects. You may not experience any of them.

After using Actiq

Storage

- Keep Actiq in their individual blister package and carton box until it is time to take your dose. If you take Actiq out of its blister package, it may not keep well. Do not use Actiq if the blister package has been damaged or opened before you are ready to use it.
- Keep Actiq in a cool dry place where the temperature stays below 30°C.
- Do not store it or any other medicine in the bathroom or near a sink.
- Do not leave it in the car on hot or cold days. Heat, cold and dampness can destroy some medicines.
- Keep Actiq lozenges where children cannot reach it. A locked cupboard at least one- and-a-half metres above the ground is a good place to store medicines.

The pain-relieving medicine in Actiq is very strong and could be life-threatening if taken accidentally by a child. Actiq must be kept out of reach of children.

Disposal

If you are no longer using Actiq, or if you have unused Actiq units in your home:

RETURN ALL UNUSED UNITS TO THE PHARMACIST OR DOCTOR.

Product description

What Actiq looks like

The Actiq unit consists of a white solid medication attached to a handle (applicator). Each unit contains 200 micrograms, 400 micrograms, 600 micrograms, 800 micrograms, 1200 micrograms or 1600 micrograms of the active ingredient fentanyl.

The dosage strength is marked on the white medication, on the handle, and on the blister package, to ensure that you are taking the right medicine.

Each blister package contains one individual Actiq unit, supplied in cartons of 3 individual Actiq units.

Ingredients

The **active ingredient** is fentanyl, present in the product as fentanyl citrate.

Actiq also contains the following **inactive ingredients**:

Dextrates, anhydrous citric acid, anhydrous dibasic sodium phosphate, artificial berry flavour (maltodextrin, propylene glycol, artificial flavours, and triethyl citrate), magnesium stearate, confectioner's sugar (as sucrose and maize starch), purified water, and starch sodium octenyl

succinate (E1450). The imprinting ink used contains ethanol, purified water, de-waxed white shellac, propylene glycol, ammonium hydroxide and brilliant blue FCF CI42090.

Each unit of *Actiq* provides approximately 2 grams of glucose load from the dextrates.

Manufacturer/Supplier

Actiq lozenge units are made in the USA by Anesta Corp., a wholly owned subsidiary of Cephalon, Inc.,

and are supplied in Australia by:

Orphan Australia Pty. Ltd.
300 Frankston Dandenong Road
Dandenong Victoria 3175.
www.orphan.com.au

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Australian Registration Number:

Actiq 200 µg AUST R 91598
Actiq 400 µg AUST R 91600
Actiq 600 µg AUST R 91601
Actiq 800 µg AUST R 91602
Actiq 1200 µg AUST R 91603
Actiq 1600 µg AUST R 91604

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