



## PACKAGE LEAFLET: INFORMATION FOR THE USER

**ACTIQ® 200 micrograms compressed lozenge with integral oromucosal applicator**  
**ACTIQ® 400 micrograms compressed lozenge with integral oromucosal applicator**  
**ACTIQ® 600 micrograms compressed lozenge with integral oromucosal applicator**  
**ACTIQ® 800 micrograms compressed lozenge with integral oromucosal applicator**  
**ACTIQ® 1200 micrograms compressed lozenge with integral oromucosal applicator**  
**ACTIQ® 1600 micrograms compressed lozenge with integral oromucosal applicator**

### Fentanyl

**Read all of this leaflet carefully before you start using this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What ACTIQ is and what it is used for
2. Before you use ACTIQ
3. How to use ACTIQ
4. Possible side effects
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6. Further information

### 1. WHAT ACTIQ IS AND WHAT IT IS USED FOR

ACTIQ contains the active ingredient fentanyl which is a strong pain-relieving medicine known as an opioid. It is used to treat breakthrough pain in adult patients with cancer who are already taking other opioid pain medicines for their constant (around-the-clock) cancer pain.

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

### 2. BEFORE YOU USE ACTIQ

**Do not use ACTIQ if**

- You have not been using a prescribed opioid pain medicine every day on a regular schedule, for at least a week, to control your persistent pain. If you have not been using these medicines you must not use ACTIQ because it may increase the risk that breathing could become dangerously slow and/or shallow, or even stop.
- You are allergic (hypersensitive) to fentanyl or any of the other ingredients of ACTIQ.
- You are currently taking monamine-oxidase (MAO) inhibitors (used for severe depression) or have done so in the past 2 weeks.
- You suffer from severe breathing problems or severe obstructive lung conditions.

**Take special care with ACTIQ**

If you have any of the following talk to your doctor or pharmacist before starting ACTIQ:

- You are suffering from any condition that has an effect on your breathing (such as asthma, wheezing, or shortness of breath).
- You have a head injury or have suffered any loss of consciousness.
- You have an exceptionally slow heart rate.
- You have liver or kidney problems, as these organs have an effect on the way in which your system breaks down the medicine.
- You have low blood pressure due to a low amount of fluid in the circulation.
- You are diabetic.
- You are over 65 years old as you may need a lower dose and any dose increase will be reviewed very carefully by your doctor.

**Taking/using other medicines**

Please tell your doctor or pharmacist before starting ACTIQ if you are taking or have recently taken any of the following medicines:

- Any medicines which might normally have a sedative effect (make you sleep), such as sleeping pills, medicines to treat anxiety, certain medicines for allergic reaction (antihistamines), or tranquillisers.
- Some muscle relaxants (e.g. baclofen, diazepam).
- Any medicines that might have an effect on the way in which your body breaks down ACTIQ such as ritonavir or other medicines that help control HIV infection, or other so-called CYP3A4 inhibitors such as ketoconazole, itraconazole, or fluconazole (used for treatment of fungal infections) and troleandomycin, clarithromycin, or erythromycin (medicines for treatment of bacterial infections).
- Any medicine which may reduce or reverse the effect of ACTIQ (e.g. naloxone, pentazocine, buprenorphine) as these may lead to withdrawal symptoms.
- If you are due to have surgery requiring a general anaesthetic.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

**Using 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.
- You should not drink grapefruit juice while taking ACTIQ because it may affect the way your body breaks down ACTIQ.
- Do not drink alcohol while using ACTIQ. It can increase the risk of experiencing dangerous side effects.

**Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine.

**Pregnancy:** ACTIQ should not be used during pregnancy unless you have discussed this with your doctor. You should not use ACTIQ during childbirth because fentanyl may cause breathing difficulties in the new-born child. There is also a risk that the new-born child experiences withdrawal symptoms of the drug if ACTIQ is used for a long time during pregnancy.

**Breast-feeding:** Fentanyl can get into breast milk and may cause side effects in the breast-fed infant. Do not use ACTIQ if you are breast-feeding unless you have discussed this with your doctor. Breast-feeding should not be restarted until at least 24 hours after the last use of ACTIQ.

**Driving and using machines**

This medicinal product may affect the ability to drive and operate machinery.

You should discuss with your doctor whether it is safe for you to drive, or operate machinery in the few hours after taking ACTIQ. Do not drive or operate machinery if you: are feeling sleepy or dizzy; have blurred or double vision; have difficulty in concentrating. It is important you know how you react to ACTIQ before driving or operating machinery.

**Important information about some of the ingredients of ACTIQ**

ACTIQ contains glucose and sucrose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking ACTIQ. Each lozenge contains approximately 2 grams of glucose. This should be taken into account if you have diabetes mellitus. The glucose content of the lozenge may be harmful to the teeth. You should always make sure you clean your teeth regularly.

### 3. HOW TO USE ACTIQ

When you first start using ACTIQ, your doctor will work with you to find the dose that will relieve your breakthrough pain. It is very important that you use ACTIQ exactly as the doctor tells you. If you are not sure about the right dose or if you have questions about taking this medicine, you should contact your doctor.

When you place the lozenge in your mouth, it dissolves and the active ingredient is released and is absorbed through the lining of your mouth, into the blood system. Taking the medicine in this way allows it to be absorbed quickly and to relieve your breakthrough pain quickly.

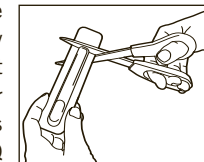
You should start to feel some relief quickly while you are taking ACTIQ. Until the dose that effectively controls your breakthrough pain has been determined, if you do not get enough pain relief from just one ACTIQ unit, your doctor may allow you to use a second ACTIQ unit of the same strength to treat an episode of breakthrough pain. Do not use a second unit unless you are allowed to do so and do not use more than two units to treat a single episode of breakthrough pain. You must let your doctor know immediately if you are using ACTIQ more than four times per day, as he may wish to change your medicine for your persistent pain. Following on from this, when your persistent pain has been controlled, your doctor may need to change your dose of ACTIQ further. For the most effective relief, let your doctor know about your pain and how ACTIQ is working for you so that the dose can be changed if needed.

Do not change doses of ACTIQ or your other pain medicines on your own. Change in dosage must be prescribed and monitored by your doctor.

**Taking the medicine**

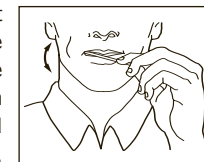
- Each ACTIQ unit is sealed in its own blister package. Open the package only when you are ready to use it.

- 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 ACTIQ unit and cut the long tab end completely off (as shown).

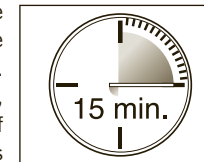


- Separate the printed backing from the blister package and pull the printed backing completely off the blister package.

- Remove the ACTIQ unit from the blister package and immediately place the lozenge in the mouth between your cheek and gum. Using the handle, actively move the lozenge round in your mouth especially along your cheeks. Twirl the handle often.



- To get the most effective relief, finish the lozenge completely in 15 minutes. If you finish too quickly, you will swallow more of the medicine and get less relief from your breakthrough pain.



- Do not bite, suck or chew the lozenge as this will result in lower blood levels and less pain relief than when taken as directed.

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

### **How often should you use ACTIQ?**

Once a dose has been reached that effectively controls your pain, you should not use more than four ACTIQ lozenges per day. If you think you might need to use more than four ACTIQ lozenges per day, you should notify your doctor immediately.

### **How many ACTIQ lozenges should you use?**

Do not use more than two units to treat any single episode of breakthrough pain.

### **If you use more ACTIQ than you should**

- The most common side effects are feeling sleepy, sick or dizzy. If you begin to feel dizzy, sick, or very sleepy before the lozenge is completely dissolved, 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 and/or shallow breathing. This can occur if your dose of ACTIQ is too high or if you take too much ACTIQ. If this occurs, please seek immediate medical assistance.

### **What to do if a child or adult accidentally takes ACTIQ**

If you think someone has accidentally taken ACTIQ please seek immediate medical assistance. Try to keep the person awake (by calling their name and shaking their arm or shoulder) until emergency help arrives.

### **If you forget to use ACTIQ**

If the breakthrough pain is still ongoing, you may take ACTIQ as prescribed by your physician. If the breakthrough pain has stopped, do not take ACTIQ until the next breakthrough pain episode.

### **If you stop using ACTIQ**

You should only stop using ACTIQ on the advice of your doctor. There are usually no noticeable effects if you stop taking ACTIQ. You should continue to take your usual opioid medicine to treat your persistent pain as instructed by your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## **4. POSSIBLE SIDE EFFECTS**

Like all medicines, ACTIQ can cause side effects, although not everybody gets them. If you notice any of these, contact your doctor.

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 below.

**The most serious side effects are shallow breathing, low blood pressure and shock. If you become very sleepy or have slow and/or shallow breathing, you or your carer should contact your doctor immediately and call for emergency help.**

- Note to Carers:

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

- Using the handle, remove the ACTIQ unit from the person's mouth and keep it out of the reach of children or pets until it is disposed of.
- CALL FOR EMERGENCY HELP.
- While waiting for emergency help, if the person seems to be breathing slowly, prompt them to breathe every 5-10 seconds.

**Very common side effects** (affecting more than 1 person in 10)

- Nausea/feeling sick, constipation
- Sleepiness, dizziness

**Common side effects** (affecting between 1 to 10 people in 100)

- Confusion, anxiety, hallucinations, abnormal thinking
- Asthenia (weakness)
- Headaches, muscle jerks
- Dry mouth, mouth ulcers/inflammation, tongue problems (for example, burning sensation or ulcers), taste alteration
- Vomiting, abdominal pain, indigestion
- Sweating, itchy skin
- Accidental injury (for example, falls)

**Uncommon side effects** (affecting between 1 to 10 people in 1000)

- Feeling unwell, decreased appetite, wind, abdominal bloating
- Tingling or numbness, difficulty coordinating movements
- Abnormal dreams, feeling detached, depression, mood swings, excessive feeling of well being
- Shortness of breath
- Blurred or double vision
- Skin rash, increased or altered sensitivity to touch
- Difficulty passing urine

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

Whilst using the ACTIQ lozenge you may experience irritation at the application site and gum bleeding.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

## **5. HOW TO STORE ACTIQ**

**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 the reach and sight of children.**

- Do not use ACTIQ after the expiry date shown on the package label and the carton.
- Do not store above 30°C.
- Always keep ACTIQ in its blister package until you are ready to use it. Do not use if the blister package has been damaged or opened before you are ready to use it.
- If you are no longer using ACTIQ, or if you have unused ACTIQ units in your home, return all unused packs to your doctor or pharmacist.

### **How to dispose of ACTIQ after use**

Partially used ACTIQ lozenge may contain enough medicine to be harmful or life-threatening to a child. Even if there is a little or no medicine left on the handle, the handle itself must be properly disposed of as follows:

- If the medicine is totally gone, throw the handle away in a waste container that is out of reach of children and pets.
- If any medicine remains on the handle, place the lozenge under hot running water to dissolve the remainder and then throw the handle away in a waste container that is out of the reach of children and pets.
- If you do not finish the entire lozenge and you cannot immediately dissolve the remaining medicine, put the lozenge out of the reach of children and pets until such a time as you can dispose of the partially used lozenge as instructed above.
- Do not flush partially used lozenge, handles, or the blister packaging down the toilet.

## **6. FURTHER INFORMATION**

### **What ACTIQ contains:**

The active substance is fentanyl. Each individual lozenge contains either:

- 200 micrograms fentanyl (as citrate),
- 400 micrograms fentanyl (as citrate),
- 600 micrograms fentanyl (as citrate),
- 800 micrograms fentanyl (as citrate),
- 1200 micrograms fentanyl (as citrate),
- 1600 micrograms fentanyl (as citrate).

The other ingredients are:

#### *Lozenge:*

Dextrates hydrated (equivalent to approximately 2 grams of glucose).

Citric acid, disodium phosphate, artificial berry flavour (maltodextrin, propylene glycol, artificial flavours, and triethylcitrate), magnesium stearate.

*Edible glue used to attach the lozenge to the handle*  
Modified maize based food starch E1450, confectioner's sugar (as sucrose and maize starch), water.

#### *Imprinting ink*

Water, de-waxed white shellac, propylene glycol, blue synthetic coal tar dye E133

### **What ACTIQ looks like and contents of the pack**

ACTIQ consists of a white to off-white solid lozenge attached to a handle for oromucosal application. The lozenge may appear slightly mottled on storage. This is due to slight changes in the flavouring agent of the product and does not affect how the product works in any way.

ACTIQ exists in 6 different strengths: 200, 400, 600, 800, 1200 and 1600 micrograms. The dosage strength is marked on the white lozenge, on the handle, on the blister package and on the carton to ensure that you are taking the right medicine. Each strength is associated with a specific colour.

ACTIQ lozenges are supplied in individual blister packages.

Blister packages are supplied in cartons of 3, 6, 15 or 30 individual ACTIQ units.

Not all pack size may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

#### *Marketing Authorisation Holder*

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UK

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