

***Patient Guide***  
***For Actiq<sup>®</sup>***  
***(fentanyl citrate)***  
***Lozenges***

## ***You have been prescribed Actiq® (fentanyl citrate) lozenge for your Breakthrough Cancer Pain (BTcP)***

### **Important**

- Do not use Actiq® unless you have been regularly using other opioid medicines for your persistent cancer pain for at least a week
- Do not give Actiq® to anyone else
- Keep Actiq® in a safe and secure place away from other people, especially children. Accidental use by an adult or a child is a medical emergency and may be life threatening. If an adult or child accidentally takes Actiq®, call for emergency medical help immediately
- Actiq® should only be used for BTcP
- Do not use Actiq® if you are below 16 years of age

**Please read the Patient Information Leaflet that comes with Actiq®** before you start taking it, and each time you get a new prescription, as it may contain new information. Please share this important information with members of your household. If you have any concerns about Actiq®, any other treatment you are having, or your medical condition, you should discuss these with your doctor.

### **The most important information you should know about Actiq® is:**

1. Your doctor has prescribed a starting dose of Actiq®. Do not substitute Actiq® for other fentanyl medicines for BTcP without talking with your doctor
2. Actiq® can cause life-threatening effects, especially breathing problems:
  - If you are not regularly using other opioid medicines for your persistent cancer pain
  - If you do not use it **exactly** as prescribed by your doctor
3. Since each Actiq® lozenge contains about 2 grams of sugar, it is important to keep regular oral hygiene by brushing your teeth at least twice daily and flossing at least once a day, as well as visiting the dentist twice a year for regular cleaning of your teeth. Rinsing your mouth with water or brushing your teeth a few minutes after Actiq® application could also help you prevent dental decay
4. Do not hesitate to talk with your doctor if you have any questions about your treatment

### **Before starting your treatment with Actiq®, be aware:**

- **Use Actiq® only if taking a prescribed opioid pain medicine every day on a regular schedule, for at least a week, to control your persistent pain**

- You should never stop taking your opioid persistent pain treatment while taking Actiq® without first talking to your doctor
- Actiq® should **never** be used for **any pain other than your BTcP**
- When you first start taking Actiq®, your doctor will work with you to find the dose that will effectively relieve your BTcP with minimal undesirable effects - this dose is known as the maintenance dose. The process of finding the right maintenance dose is called the titration process

**For complete information about Actiq®, please read the Patient Information Leaflet that came with your medicine.**

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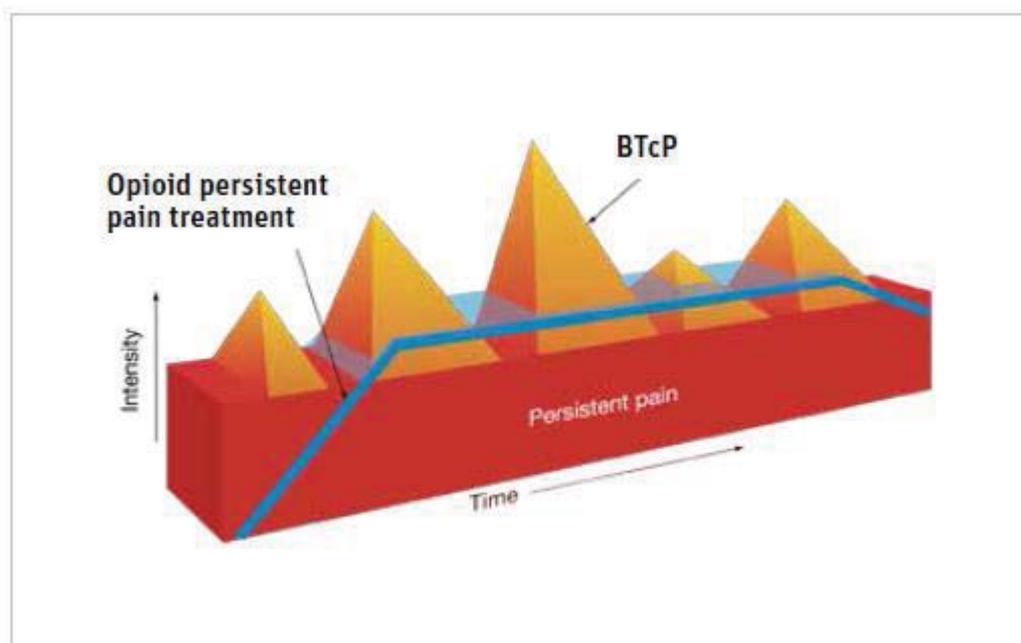
### **Additional information**

## ***Breakthrough Cancer Pain (BTcP)***

### **What is BTcP?**

**Persistent cancer pain** is pain related to your cancer that lasts throughout the day. Your doctor has given you an opioid medicine that should relieve this pain for the entire day.

Even if your opioid medicine controls your persistent cancer pain most of the time, you can still experience sudden flares or spikes of moderate to severe pain (as shown in diagram below). This is **BTcP** – pain that ‘breaks through’ the pain relief provided by your opioid medicine.



## ***Actiq®***

### **What is Actiq®?**

Actiq® is a pain-relieving medicine, belonging to a class of drugs called opioids, which is used to treat BTcP in adult patients with cancer who are already taking other pain treatment for their persistent cancer pain. Actiq® is a prescription only medicine that contains the active ingredient fentanyl citrate, in the form of a lozenge.

### **How does Actiq® work?**

Actiq® lozenge needs to be placed between the cheek and gum, where it dissolves and the active ingredient, fentanyl, is absorbed through the lining of your mouth into the blood system and throughout your body.

It travels to your central nervous system – the brain and spinal cord – where it works to relieve your pain.

### **How is Actiq® different from the medicine I already take for my persistent pain?**

The medicine you already take for your persistent pain is an opioid medicine that works all day long. Actiq® is a treatment specifically for your BTcP (an additional, sudden pain episode that rises above the persistent pain). You must continue to take your opioid treatment for persistent pain while you are using Actiq®.

### **When should I use Actiq®?**

Once your doctor has determined that Actiq® is an appropriate treatment for you, you should take Actiq® as soon as you start to feel an episode of BTcP. You should only use Actiq® if you are using other opioid pain medicine on a daily basis.

### **Does Actiq® have a taste?**

Yes, Actiq® contains artificial berry flavour.

### **Is there sugar in Actiq®?**

Yes, Actiq® contains about 2 grams of sugar. Therefore it is important to keep regular oral hygiene by brushing your teeth at least twice daily and flossing at least once a day, as well as visiting the dentist twice a year for regular cleaning of your teeth. Rinsing your mouth with water or brushing your teeth a few minutes after each Actiq® application could also help you prevent dental decay.

### **How is Actiq® packaged?**

Actiq® lozenges are supplied in individual blister packages.

## Remember

**You must continue to take your opioid medicine for persistent pain while you are using Actiq®**

- Only use Actiq® if you are using other opioid pain medicine on a daily basis
- Only use Actiq® if you have been experiencing BTcP episodes
- Never stop using your opioid treatment for persistent pain while you are taking Actiq® without talking to your doctor
- Never use Actiq® for the treatment of any pain other than BTcP
- Under no circumstance should you give Actiq® to anyone else
- Use Actiq® exactly as your doctor or pharmacist has told you

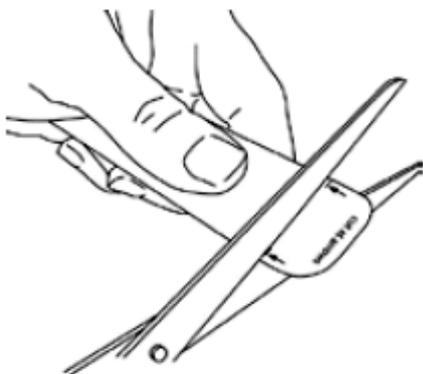
## Using Actiq®

### How do I take Actiq®?

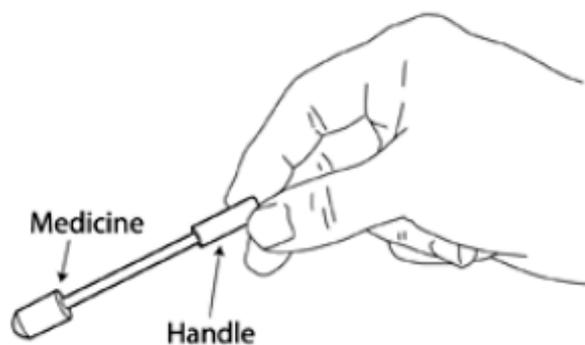
- You may drink some water before using Actiq® but you should not drink or eat anything while using Actiq®
- Each unit of Actiq® is sealed in its own blister package. **Do not open the blister package until you are ready to use Actiq®**

#### 1. Peel it

When you are ready to use Actiq®, cut open the package using scissors. Peel back the blister backing, and remove the Actiq® unit



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



**2. Place it**

Place the medicine end of the Actiq® unit in your mouth between your cheeks and gums

**3. Twirl the handle** often. Using the handle, keep moving the lozenge round in your mouth, especially along your cheeks

**Finish the Actiq® unit completely over 15 minutes** in order to get the most relief. If you finish Actiq® too quickly, you will swallow more of the medicine and get less relief



**4. Do not bite, suck or chew Actiq®** as this will result in less pain relief than when taken as directed

## **Remember**

### **Use Actiq® exactly as prescribed by your doctor**

- It is important that you understand the correct way to use Actiq®. Read the instructions in the Patient Information Leaflet and this brochure, and ask your doctor or pharmacist if there is anything further you want to know
- Keep lozenges in their blister packages until you are ready to take Actiq® in order to protect them from moisture. Do not store Actiq® in pill boxes. Once a blister is opened, the lozenge must be taken immediately

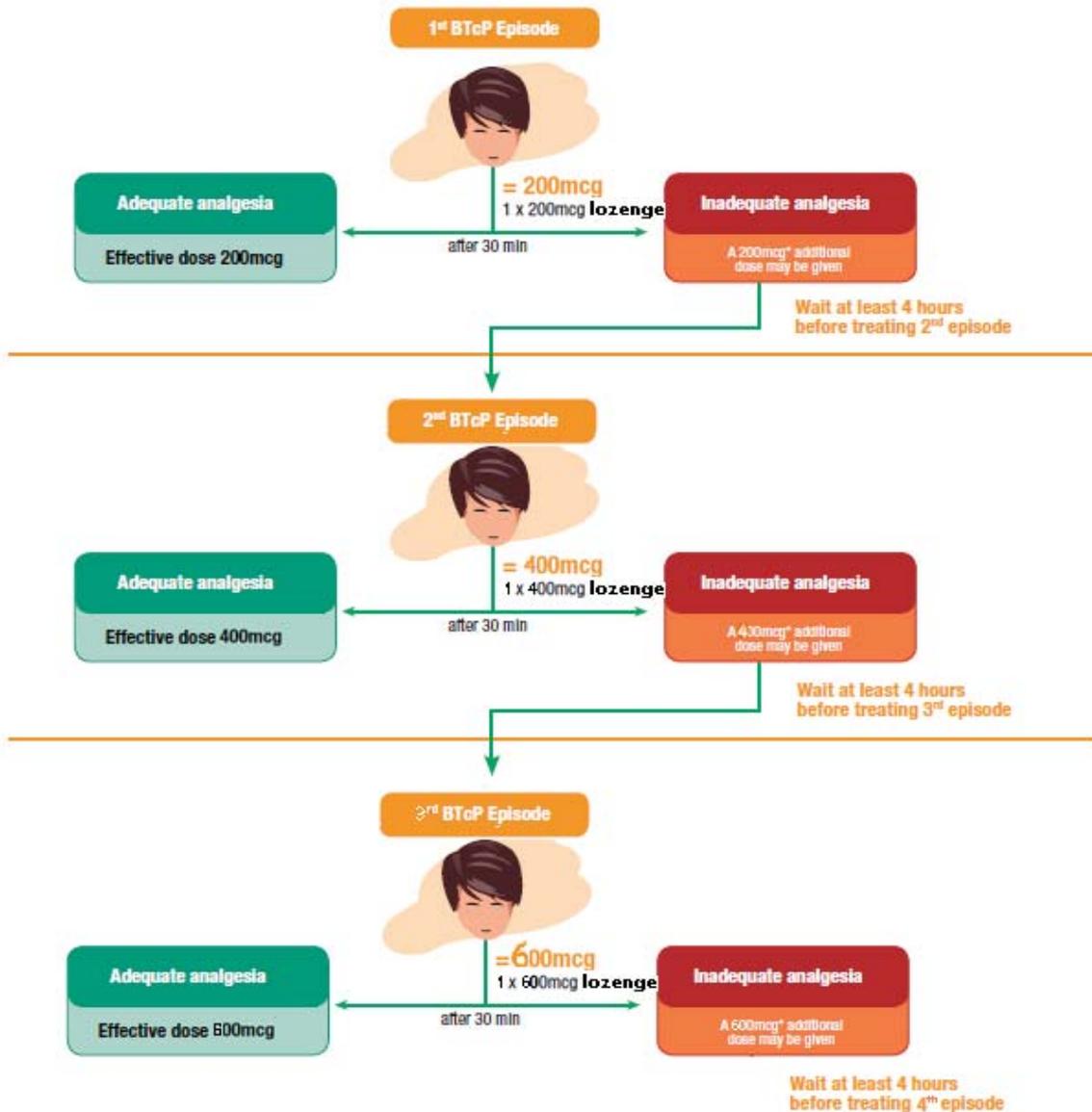
### **How does my doctor find the dose of Actiq® that is right for me?**

Actiq® comes in several dosage strengths.

Your doctor may gradually increase the dosage strength of Actiq® to find the right dose for you that will effectively relieve your BTcP with minimal undesirable effects, a process called titration.

## The Titration Process

1. Consume Actiq® unit over 15 minutes
2. Wait 15 minutes more
3. If inadequate pain relief, consume **ONLY ONE** additional unit over 15 minutes
4. Take no more than 2 units per breakthrough pain episode
5. Wait at least 4 hours before treating another episode of breakthrough pain with Actiq®



My Actiq® maintenance dose is: \_\_\_\_\_

Once your maintenance dose has been determined, you will take one lozenge of that strength per episode and limit consumption to a maximum of four Actiq units per day.

By following your doctor's instructions during this dose adjustment period and telling the doctor how you are feeling, you can help to determine the correct dose for you. A treatment diary can be useful to help you to remember your experiences, so that you discuss them with your doctor. Ask your doctor for details.

Once you are on a regular dose of Actiq®, your doctor will prescribe lozenges containing that dose. You should then use **only one** Actiq® lozenge *per* BTcP episode.

**What if I still have pain after a single dose of Actiq® once my correct dose has been determined?**

Contact your doctor if your correct dose of Actiq® does not relieve your BTcP. Your doctor will decide if your dose needs to be changed.

**When can I treat another BTcP episode with Actiq®?**

Follow the instructions that you received from your doctor or pharmacist about how often to take Actiq®. Wait at least 4 hours before treating another episode. If you regularly suffer more than 4 BTcP episodes *per* day, you should contact your doctor.

**Can I bite, chew or swallow Actiq®?**

No. Do not bite, chew or swallow a whole Actiq® lozenge.

**What happens if I swallow Actiq®?**

If you swallow Actiq® lozenge before it can cross the lining of your mouth, you may get less relief for your BTcP.

**Can I take Actiq® if I have a dry mouth?**

Yes. The lozenges may take longer to dissolve; therefore water can be used to moisten the oral cavity before using a lozenge.

**While taking Actiq®, should I continue taking my opioid treatment for persistent pain?**

You **must** take your opioid medicine for persistent cancer pain as long as you are taking Actiq®. Do not stop taking your opioid treatment for persistent pain without talking to your doctor.

**Remember**

- Use Actiq® exactly as prescribed by your doctor
- Wait at least 30 minutes before taking one more dose of Actiq® for an unrelieved BTcP episode during the dose adjustment phase
- Wait at least 4 hours before treating another BTcP episode
- If you regularly suffer from more than 4 BTcP episodes *per* day, you should contact your doctor

## ***Possible side effects of Actiq®***

### **What are the possible or likely side effects of Actiq®?**

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 care-giver should call immediately for emergency medical help.

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

- Vomiting, nausea/feeling sick, constipation, stomach (abdominal) pain
- Asthenia (weakness), sleepiness, dizziness, headaches
- Shortness of breath

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

- Confusion, anxiety, seeing or hearing things that are not there (hallucinations), depression, mood swings
- Feeling unwell
- Muscle jerks, feeling of dizziness or "spinning", loss of consciousness, sedation, tingling or numbness, difficulty coordinating movements, increased or altered sensitivity to touch, convulsions (fits)
- Dry mouth, mouth inflammation, tongue problems (for example, burning sensation or ulcers), taste alteration
- Wind, abdominal bloating, indigestion, decreased appetite, weight loss
- Blurred or double vision
- Sweating, skin rash, itchy skin
- Difficulty passing urine
- Accidental injury (for example, falls)

### **Uncommon side effects** (affecting 1 to 10 people in 1,000)

- Tooth decay, gum bleeding, mouth ulcers, paralysis of the gut
- Coma, slurred speech, abnormal dreams, feeling detached, abnormal thinking, excessive feeling of well being
- Widening of blood vessels
- Hives

**The following side effects have also been reported with the use of Actiq® lozenge but it is not known how often they may occur:**

Receding gums, inflammation of the gum, tooth loss, severe breathing problems, flushing, feeling very warm, diarrhoea, swelling of arms or legs, fatigue, insomnia, pyrexia, withdrawal syndrome (may manifest by the occurrence of the following side effects nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating)

For further information on Actiq® and possible side effects, see the Patient Information Leaflet that comes with your medicine. If you notice any side effects when taking Actiq®, contact your doctor.

### What should I do if I have any of the following symptoms?

Call your doctor and get emergency medical help right away if you:

- Have trouble breathing
- Have slow, shallow breathing (little chest movement while breathing)
- Have extreme drowsiness, with slowed breathing
- Swelling of the tongue, lip or throat which may be early signs of serious allergic reaction
- Feel faint, very dizzy, confused, or have unusual symptoms

These symptoms may indicate that you have taken too much Actiq® (an overdose), or that the dose you are taking is too high for you. If you feel very dizzy or very sleepy before the lozenge has completely dissolved, you should immediately rinse your mouth with water and spit the remaining pieces of the lozenge into a sink or toilet.

**These symptoms may lead to serious problems or death if not treated right away**

### Remember

#### Know when to call for emergency medical help

The most serious side effects of Actiq® are shallow breathing, low blood pressure and shock. If you have trouble breathing, have slow, shallow breathing, extreme drowsiness with slowed breathing, feel faint, very dizzy, confused or have unusual symptoms:

- Immediately spit out any remaining lozenge
- Do not take another dose of Actiq®
- Call your doctor and get emergency medical help right away

## ***Interactions with Actiq®***

### **Can I take or use other medicines while taking Actiq®?**

Before starting Actiq®, please tell your doctor or pharmacist if you are taking, or have recently taken, any of the following medicines:

- Any medicines which might make you sleepy - such as sleeping pills, medicines to treat anxiety, some medicines for allergic reaction (antihistamines), or tranquillisers
- Some muscle relaxants - such as baclofen, diazepam
- Any medicines that might affect how 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 fungal infections) and troleandomycin, clarithromycin, or erythromycin (medicines for bacterial infections) and so-called 'CYP3A4 inducers' such as rifampicin or rifabutin (medicines for bacterial infections), carbamazepine, phenobarbital or phenytoin (medicines used to treat convulsions/fits)
- Medicines called Monoamine-Oxidase (MAO) inhibitors (used for severe depression), or have done so in the past 2 weeks
- Certain types of strong pain killers, called partial agonist/antagonists e.g. buprenorphine, nalbuphine and pentazocine (medicines for treatment of pain). You could experience symptoms of withdrawal syndrome (nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating) while using these medicines.

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

### **Can I take 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 using Actiq® because it may affect the way your body breaks down Actiq®
- Do not drink alcohol while using Actiq® as this can increase the risk of experiencing dangerous side effects

## ***Safe use, storage and disposal of Actiq®***

### **What do I need to know before I start taking Actiq®?**

#### **You should not use Actiq® if:**

- You have not been using a prescribed opioid 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 of your breathing becoming dangerously slow and/or shallow, or even stopping
- You are allergic to fentanyl or any of the other ingredients of Actiq®
- You suffer from severe breathing problems or severe obstructive lung conditions (for example, chronic bronchitis)

#### **You should take special care with Actiq® if you have any of the following and should talk to your doctor or pharmacist before starting Actiq®:**

- Your other opioid medicine taken for your persistent cancer pain is not stabilised yet
- 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
- You have an exceptionally slow heart rate or other heart problems
- 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 amount of fluid in the circulation or low blood pressure
- You have diabetes

### **Can I drive or operate machinery after taking Actiq®?**

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

### **Can I use Actiq® if I am breastfeeding?**

Do not use Actiq® if you are breastfeeding. You can commence breastfeeding 5 days after stopping Actiq®.

### **What should I do if someone else accidentally takes Actiq®?**

If you think someone has accidentally taken Actiq®, please seek immediate medical assistance. Try to keep the person awake until emergency help arrives. If someone has accidentally taken Actiq®, they may have the same side effects as described in the question “What if I take more Actiq® than I should?”

### **What if I take more Actiq® than I should?**

The most known side effects of taking too much Actiq® are feeling sleepy, sick or dizzy. If you begin to feel very dizzy or very sleepy before the lozenge is completely dissolved, rinse your mouth with water and spit the remaining pieces of the lozenge right away.

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 if I forget to take Actiq®?**

If the BTcP is still ongoing, you may take Actiq® as prescribed by your doctor. If the BTcP has stopped, do not take Actiq® until the next BTcP episode.

### **How should I store Actiq®?**

Store Actiq® in the original package in order to protect from moisture. The pain-relieving medicine in Actiq® is very strong and could be life-threatening if taken accidentally by a child. Actiq® must be kept in a safe place out of the sight and reach of children. Do not use Actiq® after the expiry/use before date shown on the blister package label and the carton.

### **What if I no longer need to take Actiq®?**

You should discontinue Actiq® when it is no longer required. You should continue to take your usual opioid medicine to treat your persistent pain and you may contact your doctor to confirm its correct dose. If you have any further questions on the use of this product, ask your doctor or pharmacist.

### **How should I dispose of unopened Actiq® lozenges when they are no longer needed?**

Medicines should not be disposed of *via* wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

#### **Remember**

##### **Prevent theft and misuse of Actiq®**

- Keep Actiq® in a safe place, whilst in and outside your home, to protect it from being stolen. It can be a target for people who abuse medicines
- Never give Actiq® to anyone else, even if they have the same symptoms as you, as it may cause serious or life-threatening side-effects, including death
- If you think someone has accidentally taken Actiq®, get emergency medical help immediately and try to keep the person awake until help arrives
- Keep Actiq® out of the sight and reach of children
- Medicines should not be disposed of *via* wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

### ***Important considerations***

#### **Continue to use your persistent pain treatment every day while you are using Actiq®**

Actiq® must only be used if you are regularly using other opioid pain medicines and your body is used to these medicines.

#### **Use Actiq® exactly as prescribed by your doctor**

It is important to understand the correct way to use Actiq®. Wait at least 4 hours before treating another episode of BTcP and talk to your doctor if you regularly need to treat more than 4 episodes *per* day.

### Keep Actiq® out of the sight and reach of children

Keep Actiq® in a safe and secure place away from children and anyone for whom it has not been prescribed.

### Prevent theft and misuse of Actiq®

Keep Actiq® in a safe place to protect it from being stolen. It can be a target for people who abuse medicines.

### If someone accidentally takes Actiq®

#### Call for emergency help immediately

See the Patient Information Leaflet that comes in the Actiq® package for additional important information. If you have questions after reading it, speak with your doctor

### Avoid dental cavity or tooth loss

Keep regular oral hygiene, visit your dentist twice a year and rinse your mouth with water or brush your teeth a few minutes after Actiq® application.

### ***Additional information***

Doctor:

Doctor's daytime phone number:

Out of hour's office phone number:

Emergency medical care phone number:

#### **Other healthcare team members**

Name:

Phone:

Name:

Phone:

Name:

Phone:

## **Reporting of Side Effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly *via* the Yellow Card Scheme at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

By reporting side effects you can help provide more information on the safety of this medicine.

## **Further Information**

For further information regarding your treatment and prescription with Actiq®, please contact your doctor or pharmacist.

To obtain additional copies of this Guide or Actiq® Treatment Diary, please visit the Teva UK website at [www.tevauk.com](http://www.tevauk.com) where copies can be downloaded from the Actiq® patient product page or alternatively, please contact Teva UK Limited Customer Services Department on:

Telephone Number: 0800 590 502

Email: [tevaukdeptcustomers@tevapharm.com](mailto:tevaukdeptcustomers@tevapharm.com)