

Important Risk Minimisation
Information for Patients and
Caregivers

Actiq(fentanyl)[®]
Patient Guide

For complete information about Actiq[®], please read the
Package Leaflet that came with your medicine.

You have been prescribed Actiq® (fentanyl lozenge) for Breakthrough Cancer Pain (BTcP)

For further information regarding your treatment and prescription with Actiq® please contact your physician.

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
- Actiq® should only be used for BTcP
- Do not use Actiq® if you are below 16 years of age
- 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 result in death. If an adult or child accidentally takes Actiq®, call for emergency medical help immediately

Please read the Package 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.

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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. This is BTcP – pain that ‘breaks through’ the pain relief provided by your opioid medicine.

Actiq®

What is Actiq®?

- Actiq® contains the active ingredient fentanyl, which is a strong pain-relieving medicine known as an opioid that 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 controlled substance because it is an opioid pain medicine that can be mis-used by people who abuse medicines.

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 flavor.

Is there sugar in Actiq®?

- Yes, Actiq® contains 2 grams of sugar. Therefore it is important to keep a 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.

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 has instructed

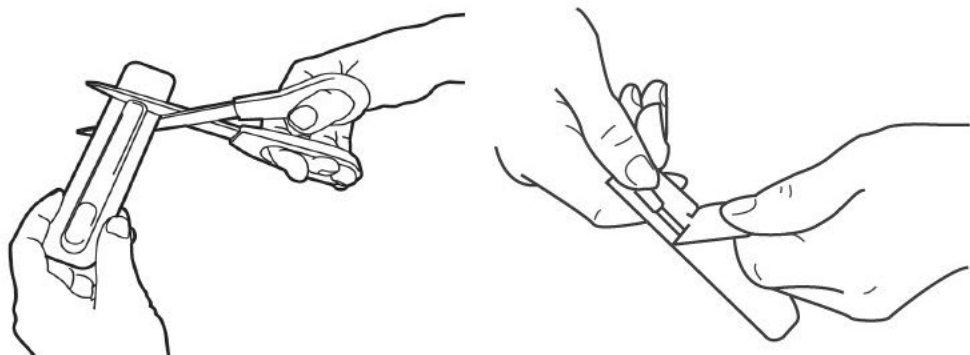
Using Actiq®

How do I take 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®.

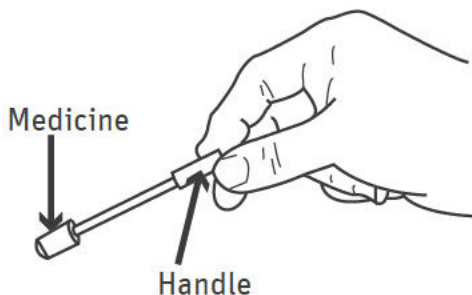
1. Opening the pack

- Hold the blister pack with the printed side away from you.
- Hold the short end of the blister pack.
- Put scissors close to the end of the Actiq® unit and cut the long tab end completely off.



2. Using the Actiq unit

- The end of the unit presented 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.



- Place the lozenge end of the Actiq® unit in your mouth between your cheeks and gum.
- Using the handle, keep moving the lozenge round in your mouth, especially along your cheeks. Twirl the handle often.
- Finish the Actiq® unit completely over 15 minutes.
- Do not bite, or chew the lozenge as this will result in less pain relief than when used 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 Package Leaflet and this brochure, and ask your doctor or pharmacist if there is anything further you want to know.

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.
- It is very important that you use Actiq® as the doctor tells you.

While the right dose is being found

- While you and the doctor are finding out the dose that controls your breakthrough pain, you may not get enough pain relief 30 minutes after starting to use one Actiq® unit (15 minutes from when you finish using the Actiq® unit).
- If this happens, your doctor may allow you to use a second Actiq® unit of the same strength for that same episode of breakthrough pain.
- Do not use a second unit unless your doctor tells you to.
- Never use more than two units to treat a single episode of breakthrough pain.

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 Pain Journal can be useful to help you to remember your experiences, so that you discuss them with your doctor. Ask your doctor for details.

How many units to use:

- Once the right dose has been found with your doctor, use one (1) unit for an episode of breakthrough pain.
- Contact your doctor if your right dose does not relieve your BTcP for several episodes of breakthrough pain in a row.

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®. Limit consumption to a maximum of four ACTIQ units per day. You must let your doctor know immediately if you are using Actiq more than four times a day, as a change may be required to your treatment regimen. If you regularly suffer more than 4 BTcP episodes per day, you should contact your doctor.

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 mouth 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

- Limit consumption to a maximum of four ACTIQ units per day.
- If you regularly suffer from more than 4 Breakthrough Cancer Pain 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.

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
- Convulsions (fits), muscle jerks, feeling of dizziness or “spinning”, loss of consciousness, sedation, tingling or numbness, difficulty coordinating movements, increased or altered sensitivity to touch
- 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)
- Malaise

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

- Tooth decay, paralysis of the gut, mouth ulcers, gum bleeding
- 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

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 HPRA Pharmacovigilance, www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Teva Pharmaceuticals Ireland by contacting Teva Medical Information on Tel No: +44 (0) 207 540 7117 or via email at: medinfo@tevausk.com.

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 seek 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 that might normally make you sleepy (have a sedative effect) such as sleeping pills, medicines to treat anxiety, antihistamines, or tranquilizers.
- Any medicines that might have an effect on the way in which your body breaks down Actiq®. This includes some medicines that help control HIV infection, some medicines used for the treatment of fungal infections, certain medicines for bacterial infections, and certain medicines used to treat convulsions.
- Some muscle relaxants.
- Certain medicines that may reduce or reverse the effect of Actiq® (e.g. naloxone, pentazocine, buprenorphine).
- Antipsychotics and certain anti-depressants.
- For more detailed information please refer to the Package Leaflet (PL).

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 (hypersensitive) to fentanyl or any of the other ingredients of Actiq® (listed in section 6 of the PL).
- You suffer from short-term pain other than breakthrough pain.
- You are currently taking monoamine-oxidase inhibitors (a drug for depression) or have taken them in the past two weeks.
- 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 or have had any loss of consciousness
- You have diabetes
- You are over 65 years old
- You take antipsychotics or certain antidepressants
- You have a 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 blood pressure due to a low amount of fluid in your circulation

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 the last dose of 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.

What if I take more Actiq® than I should?

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

- Do not store above 30 degrees.
- 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®?

- Do not stop taking Actiq® without talking to your doctor.
- Keep taking your usual opioid medicine to treat your persistent pain as instructed by your doctor.

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.

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 and always use Actiq® as prescribed by 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. 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 and your body is used to these medicines, 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
- Limit consumption to a maximum of four ACTIQ units per day. You must let your doctor know immediately if you are using Actiq more than four times a day, as a change may be required to your treatment regimen

Important considerations

Avoid dental cavity or tooth loss.

Since each Actiq® lozenge contains 2 grams of sugar, it is important to keep a 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.

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

If you have questions after reading the Package leaflet (PL) or this booklet, speak with your doctor.

Additional information

Doctor's name:

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:

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Teva by contacting Teva Medical Information on Tel No: +44 (0) 207 540 7117 or via email at: medinfo@tevauk.com.

For more detailed information please consult the Package Leaflet (PL) in the Actiq® product package. The PL is also available for electronic download at www.hpra.ie

Teva Pharmaceuticals Ireland,
Digital Office Centre Swords,
Suite 101-103, Balheary Demense,
Balheary Road, Swords,
Co. Dublin, K67E5AO.

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