Patient/Carer's Guide to the safe use of ACTIQ® (fentanyl) Lozenges

Please also refer to the Package Leaflet for ACTIQ® (fentanyl citrate) Lozenges

If you get any side effects, talk to your doctor or pharmacist. 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 https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

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INTRODUCTION

Dear Patient

Your doctor has prescribed ACTIQ® lozenges. This guide is intended to help you familiarise yourself with important information related to the treatment of your cancer breakthrough pain, as well as the correct application of the ACTIQ® lozenges. Please make sure you have read the guide carefully before using ACTIQ® and keep it for future reference.

Reporting side effects

If you get any side effects, talk to your doctor or pharmacist. 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 https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App Store.

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

CANCER AND PAIN

What is special about cancer pain?

For people with cancer, pain can affect their quality of life.[1]
Pain may be caused by the cancer itself, or it may be caused by cancer treatments or other cancer-related problems.[1] Some pain may have nothing to do with the cancer.

What is breakthrough cancer pain (BTcP)?

Some people with cancer have constant pain, which is called background pain. Your doctor will prescribe medication to keep this pain at about the same level over time.[1]
Breakthrough cancer pain (BTcP) is a pain that feels worse than the background pain you may feel most of the time. You may not know when to expect this pain and this can keep you from doing what you need or want to do.

How do I know if I have BTcP?

BTcP is usually:[2]

- ➔ Moderate to severe
- ➔ Comes on quickly (it can take just a few minutes for the pain to reach its peak)
- ➔ Relatively short-lived (it may last only around 30 minutes)

If you have pain that is not controlled by your current medications, tell your doctor. You may be experiencing BTcP, or your doctor may need to check if the medication you are taking for background pain is still right for you.

What happens if I have BTcP?

People with BTcP often need medicines called short-acting opioids, also known as fast-acting or rapid-onset opioids. They act quickly to provide relief and are used in addition to the medicines taken to treat background pain.[2]

ACTIQ® is an example of a rapid-onset opioid used to treat BTcP. It is only suitable for patients who are already taking opioids for the treatment of background cancer pain.[3]

WHAT IS ACTIQ®? HOW DO I USE IT?

ACTIQ® is a strong pain-relieving medicine known as an opioid for adults and adolescents aged 16 years and above suffering from BTcP.[3] BTcP is a pain that feels worse than the background pain you may suffer from most of the time, even though you are taking around-the-clock opioid pain-relieving medicines.

Only use ACTIQ® if you:

1. are 16 years of age or older and have cancer, **AND**
2. are already being treated with opioids for background cancer pain, **AND**
3. are suffering with another type of cancer pain that is temporary and feels worse than your background cancer pain, **AND**
4. your doctor or pharmacist have taught you how to use ACTIQ®

If even one of these points **does not** apply to you, talk to your doctor. Ask your doctor or pharmacist if you have any questions or concerns about ACTIQ®.

Important:

Do not use ACTIQ® to treat any type of pain that you do not think is related to your cancer, such as short-lasting headaches, muscle pains or toothaches.

What do I need to know about the use of ACTIQ®?

It is important that you follow your doctor's advice on how to use ACTIQ®.

1 Lozenge

Use one ACTIQ® lozenge *per* BTcP episode. While you and the doctor are finding out the dose of ACTIQ® that controls your breakthrough pain, you may not get enough pain relief 30 minutes after starting to use one ACTIQ® lozenge (15 minutes from when you finish using the ACTIQ® lozenge). If this happens, your doctor may allow you to use a second ACTIQ® lozenge of the same strength for that same episode of breakthrough pain.

No more than 4 lozenges

Limit the use to a maximum of four ACTIQ® lozenges *per* day. You must let your doctor know immediately if you are using ACTIQ® more than four times *per* day.

If you feel that you need to use ACTIQ® more often, consult your doctor for advice. They may need to change your other pain medicines.

You must let your doctor know immediately if you are using ACTIQ® more than four times *per* day, as a change may be required to your treatment regimen. Your doctor may change the treatment for your background cancer pain; when your background cancer pain is controlled, your doctor may need to change the dose of ACTIQ®. If your doctor suspects ACTIQ®-related increased sensitivity to pain (hyperalgesia), a reduction of your ACTIQ® dose may be considered. 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 dose must be prescribed and checked by your doctor.

If you are not sure about the right dose, or if you have questions about using ACTIQ®, talk to your doctor.

Important:

1. ACTIQ® is <u>not</u> the same as other fentanyl products you may have used. Use ACTIQ® only as directed by your doctor.

2. ACTIQ® is available in different dose strengths (200 mcg, 400 mcg and 600 mcg, 800 mcg, 1200 mcg and 1600 mcg). Each strength has a different colour code as follows:
   - 200 mcg – Grey
   - 400 mcg – Dark Blue
   - 600 mcg – Orange
   - 800 mcg – Purple
   - 1200 mcg – Green
   - 1600 mcg – Dark Red

3. You and your doctor may have tried different doses of ACTIQ® to determine the effective dose for you. It is important that you use only the dose strength that your doctor has prescribed.

How should I store ACTIQ®?

➔ Do not use ACTIQ® after the expiry date shown on the package label and the carton. The expiry date refers to the last day of that month

➔ Do not store ACTIQ® lozenges above 30°C

➔ ACTIQ® is a very strong pain-relieving medicine and could be life-threatening if taken accidentally by a child. ACTIQ® must be kept out of the sight and reach of children

➔ Always keep ACTIQ® in its blister package until you are ready to use it. Do not use ACTIQ® 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® lozenges in your home, return all unused packs to your doctor or pharmacist

Important: ***Some people abuse opioids such as ACTIQ®. Make sure that only you or your responsible carers handle or have access to your ACTIQ® lozenges.***

How do I dispose of ACTIQ®?

Partially used ACTIQ® lozenges 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:

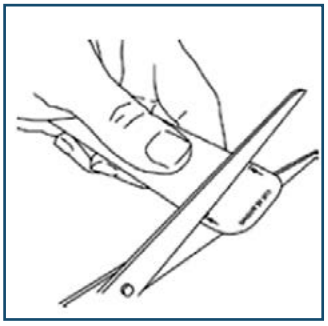
- ➔ If the medicine is totally gone, throw the handle away in a waste container that is out of reach of children and pets
- ➔ If any medicine remains on the handle, place the lozenge under hot running water to dissolve the remainder and then throw the handle away in a waste container that is out of the 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 lozenges, handles, or the blister packaging down the toilet

How to use ACTIQ® lozenges:

Opening the pack – each ACTIQ® unit is sealed in its own blister pack

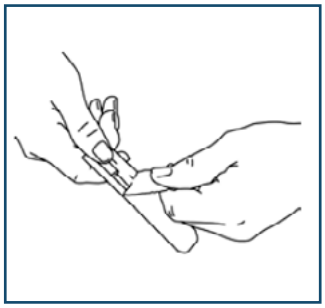
- ➔ Open the pack when you are ready to use it. Do not open ACTIQ® lozenge in advance
- ➔ Hold the blister pack with the printed side away from you
- ➔ Hold the short tab end of the blister pack
- ➔ Put scissors close to the end of ACTIQ® lozenge and cut the long tab end completely off (as shown in Figure 1)

Figure 1



- ➔ Separate the printed backing from the blister pack and pull the printed backing completely off the blister pack (as shown in Figure 2)

Figure 2



- ➔ Remove the ACTIQ® lozenge from the blister pack and put the lozenge in your mouth straight away

Using the ACTIQ® lozenge

➔ Put the lozenge between your cheek and gum

➔ Using the handle, keep moving the lozenge round in your mouth, especially along your cheeks. Twirl the handle often (as shown in Figures 3 and 4)

Figure 3

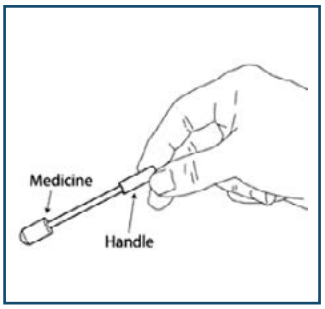


Figure 4

➔ To get the most effective relief, finish the lozenge completely within 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 or chew the ACTIQ lozenge. This would mean lower blood levels and less pain relief than when used as directed

ACTIQ®: RISKS OF USE

The warnings below appear on the outside of the ACTIQ® packs:

This product must only be used by patients already receiving maintenance opioid therapy for chronic cancer pain

Accidental use can cause serious harm and be fatal.

Can cause addiction
Contains opioid

Talk to your doctor or pharmacist if you have any questions about the use of ACTIQ® lozenges or possible side effects of ACTIQ®.

What are some of the possible side effects of ACTIQ®?

A full list of possible side effects is included in the Package Leaflet, which can be found within the ACTIQ® box. Some possible side effects include:

Very common side effects (may affect 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 (may affect up to 1 in 10 people)

- 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)

ACTIQ® contains approximately 2 grams of sugar; frequent use exposes you to an increased risk of dental decay that may be serious. It is important to take good care of your teeth during treatment with ACTIQ®. Visit your dentist regularly during treatment.

Overdose

Do not change doses of ACTIQ® or your other pain medicines on your own. Any change in dosage must be prescribed and checked by your doctor.
If you are not sure about the right dose, or if you have questions about using ACTIQ® lozenges, you should contact your doctor.

If you experience any of the following serious side effects – you may need urgent medical attention:

- ➔ Becoming very sleepy or having slow and/or shallow breathing
- ➔ Feel faint, very dizzy, confused, or have unusual symptoms

You or your carer should remove the ACTIQ® lozenge from your mouth, and immediately call for emergency help by calling 111 or 999 and then call your doctor.

Note to Carers: If you see that the patient using 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® lozenge 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

How do I know if I should worry about addiction?

You might be worried that you will become addicted to opioids. This is a common fear. Talk to your doctor or pharmacist about your concerns.

Some signs that there may be problems with the use of opioids are:

- ➔ You take more of the opioid than your doctor prescribed
- ➔ You want to stop taking it but feel like you can't
- ➔ You crave the opioid
- ➔ The use of the opioid is affecting your work, home or social life[4]

If you notice any of these signs, talk to your doctor.

How to best reduce your risk of having a problem with abuse of ACTIQ®:

1. Use ACTIQ® exactly as prescribed.
2. Talk to your doctor immediately if your pain is not under control or if you have concerns about your symptoms or medications.

Tell your doctor or pharmacist if you have any concerns or questions about your use of opioids. If you have any urgent concerns, contact the emergency numbers provided to you and seek medical help.

A note for carers: To help minimise any potential side effects of treatment with ACTIQ®, talk to the doctor or medically trained support staff. Please also read the Package Leaflet that comes in the ACTIQ® packaging.

For an electronic version of this guide and other helpful materials, see the Electronic Medicines Compendium Risk Minimisation Materials Directory at: https://www.medicines.org.uk/emc/rmm-directory (enter 'ACTIQ'® in 'Risk Minimisation Materials Search Area' and click search icon).

KEEP TRACK OF HOW MANY DOSES YOU ARE TAKING

The Dose Monitoring Card provided is intended to help you keep track of your use of ACTIQ®.
If you have any questions about your treatment with ACTIQ®, please talk to your treating doctor.
Every time you use your ACTIQ® lozenges, make sure you or your carer fills out the card.
Remember to contact your doctor long before you need to get a new prescription.

References

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2. Fallon M, Giusti R, Aielli F, *et al.* On behalf of the ESMO Guidelines Committee. Management of cancer pain in adult patients: ESMO clinical practice guidelines. Ann Oncol. 2018: 29(Suppl 4): iv166–iv191. https://www.sciencedirect.com/science/article/pii/S0923753419316989/pdfft?md5=5f77ca3f2346237b6544aff1f865f16a&pid=1-s2.0-S0923753419316989-main.pdf [Accessed on 24 March 2023].
3. ACTIQ® Product Information. Teva Pharma B.V.
4. Centers for Disease Control and Prevention (CDC). Module 5: Assessing and addressing opioid use disorder (OUD https://www.cdc.gov/drugoverdose/training/oud/accessible/index.html [Accessed on 24 March 2023].

DOSE MONITORING CARD

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