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

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

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

Table of contents

INTRODUCTION

Dear Patient,

Your doctor has prescribed ACTIQ® lozenges. This guide is intended to help you (or your carer) familiarise yourself with important information related to the treatment of your cancer breakthrough pain, as well as the correct application and risks of the ACTIQ® lozenges.

Please make sure you have read the guide carefully before using ACTIQ® and keep it for future reference.

ACTIQ® should only be used if you/your carer has received the proper information regarding the use of the drug and the safety precautions.

In case of any questions, always refer to your doctor or pharmacist.

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 HPRA Pharmacovigilance, Website: ***www.hpra.ie***.

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

WHAT IS ACTIQ®?

ACTIQ® contains fentanyl, which is a strong pain-relieving medicine known as an opioid. ACTIQ® is used for adults and adolescents aged 16 years and above with cancer suffering from breakthrough pain. Breakthrough pain is pain that feels worse than the background pain you may suffer from most of the time, even though you are already taking around-the-clock opioid pain-relieving medicines.

The ACTIQ® unit comes as a lozenge on a stick.

Only use ACTIQ® if you:

- ➔ are 16 years of age or older and have cancer, **AND**
- ➔ are already being treated with opioids every day on a regular schedule for background cancer pain for at least a week, **AND**
- ➔ are suffering with additional sudden cancer pain that feels worse than your background cancer pain in spite of having taken your usual opioid medicines, **AND**
- ➔ 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:

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

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.

CANCER AND PAIN

What is breakthrough cancer pain?

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 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 Breakthrough cancer pain?

Breakthrough cancer pain 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 Breakthrough cancer pain, 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 Breakthrough cancer pain?

People with Breakthrough cancer pain 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 Breakthrough cancer pain. It is only suitable for patients who are already taking opioids for the treatment of background cancer pain.[3]

HOW DO I USE IT?

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 Breakthrough cancer pain 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 4 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.

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 not the same as other fentanyl products you may have used. Do not swap or change between ACTIQ® and other fentanyl products. Use ACTIQ® only as directed by your doctor.

2. ACTIQ® is available in different dose strengths (200 mcg, 400 mcg and 600 mcg). Each strength has a different colour code

    - 200 mcg – Grey
    - 400 mcg – Blue
    - 600 mcg – Orange

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 store ACTIQ® above 30°C and do not use ACTIQ® after the expiry date.

➔ ACTIQ® must be kept out of the sight and reach of children.

➔ Do not use ACTIQ® if the blister package has been damaged or opened before you are ready to use it and return all unused ACTIQ® packs in your home 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:

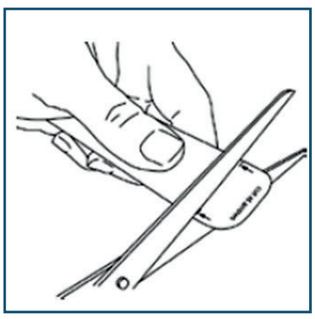
- ➔ If the medicine is totally gone, throw the handle away in a waste container that is out of reach of children and pets.
- ➔ If any medicine remains on the handle, place the lozenge under hot running water to dissolve the remainder and then throw the handle away in a waste container that is out of 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)*.

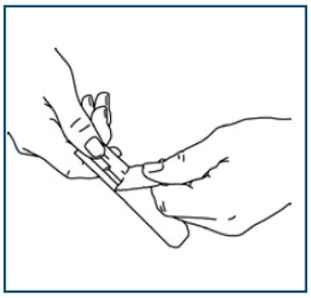
Figure 1



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

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

Figure 2



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 Figure 3 and 4)*.

Figure 3

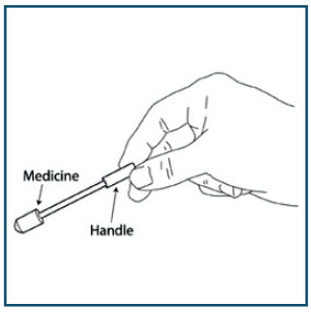


Figure 4

➔ 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 ABUSE, MISUSE, ADDICTION, OVERDOSE AND DEATH

Your doctor may need to check you more closely if:

- You or anyone in your family have ever abused or been dependent on (addicted to) alcohol, other medicines or illegal drugs.
- You are a smoker.
- You have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

Other points to note:

- Repeated use of ACTIQ may lead to dependence (addiction) and abuse which may result in life-threatening overdose. If you have concern that you may become addicted ACTIQ, it is important that you consult your doctor.
- Do not drink alcohol while using ACTIQ. It can increase the chances of getting serious side effects including death.
- Do not use more than two units to treat any single episode of breakthrough pain. Once a dose is found that effectively controls your pain, do not use more than four ACTIQ units each day. 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.

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.

A serious side effect of ACTIQ is slow and/or shallow breathing. This can occur if your ACTIQ dose is too high or is you take too much (overdose).

If you feel very dizzy, very sleepy or have slow or shallow breathing, remove the ACTIQ unit from your mouth and seek immediate medical assistance.

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 Health Products Regulatory Authority (HPRA) Website at: https://www.hpra.ie (enter 'Actiq' in 'Find a Medicines Search Area' click 'EdM' under the 'Documents' column for the relevant Actiq product).

KEEP TRACK OF HOW MANY DOSES YOU ARE TAKING

This 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.

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

References

1. Caraceni A, Shkodra M. Cancer pain assessment and classification. Cancers. 2019;11:510. doi:10.3390/cancers11040510 https://www.mdpi.com/2072-6694/11/4/510/pdf?version=1554900943 (Accessed on 21 Oct 2022)
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 21 Oct 2022).
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/opioids/providers/training/assessing-addressing-oud.html (Accessed on 21 Oct 2022)

DOSE MONITORING CARD

	Date	Time	Strength of ACTIQ® Lozenge	Comments/Notes
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				

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

DOSE MONITORING CARD

	Date	Time	Strength of ACTIQ® Lozenge	Comments/Notes
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				

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