Pharmacist's Guide for dispensing ACTIQ® (fentanyl) Lozenges

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, www.hpra.ie.

Adverse events may also be reported to Teva Pharmaceuticals Ireland *via* email to medinfo@tevauk.com or *via* phone on +44 (0) 207 540 7117.

INTRODUCTION

This guide is designed to help you understand the proper dispensing of ACTIQ® (fentanyl lozenges) for patients experiencing breakthrough cancer pain.

Please read this guide carefully before dispensing ACTIQ® and keep it for future reference. The pharmacist dispensing checklist should be reviewed before dispensing the product. Encourage patients to communicate all medication-related issues to their prescriber.

Note: ACTIQ® lozenges should only be initiated/supervised by physicians who are experienced, knowledgeable and qualified in the management of cancer pain using opioid therapy. Special care should be taken when patients transition from the hospital to home-based care. Pharmacists play an important role in supervising the provision and use of ACTIQ®.

The following materials are also available:

- A Patient/Carer Guide to the safe use of ACTIQ® Lozenges
- A Prescriber's Guide for Prescribing ACTIQ®

Please ensure that you familiarise yourself with the Patient/Carer Guide before providing it to patients. You must complete the Pharmacist Checklist for dispensing Actiq® for each patient (See page 10)

This Pharmacist's Guide (and the other materials listed above) can be viewed or downloaded from the Health Products Regulatory Authority 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).

*For a full list of medicines that have Educational Materials use the advanced search option and click on 'Only Medicines with Educational Materials'

WHAT IS ACTIQ®?

ACTIQ® for the treatment of breakthrough pain

ACTIQ® is an opioid analgesic. ACTIQ® is indicated for the management of breakthrough pain in patients who are already receiving maintenance opioid therapy for chronic cancer pain.[1]

ACTIQ® is suitable for patients with breakthrough pain who have been receiving maintenance opioid therapy for a week or longer, consisting of:

- At least 60 mg of oral morphine daily, **or**
- At least 25 micrograms of transdermal fentanyl per hour, **or**
- At least 30 mg of oxycodone daily, **or**
- At least 8 mg of oral hydromorphone daily, **or**
- An equianalgesic dose of another opioid.[1]

Breakthrough Pain

Breakthrough pain is a transitory exacerbation of pain that occurs on a background of otherwise controlled persistent pain.

HOW IS ACTIQ® USED?

As a pharmacist, you should talk to patients before dispensing ACTIQ® to ensure they understand how to use ACTIQ® correctly, according to the Summary of Product Characteristics (SmPC) and Package Leaflet (PL):

1 Lozenge

One ACTIQ® lozenge per breakthrough pain episode, with the possibility of taking a second lozenge of the same strength after at least 30 minutes (15 minutes after the patient completes consumption of a single ACTIQ® lozenge) if the breakthrough pain episode is not relieved.

No more than two ACTIQ® lozenges should be used to treat any individual breakthrough pain episode.

No more than 4 lozenges

Patients should limit consumption to a maximum of four ACTIQ® lozenges per day.[1]

- ➔ The number of ACTIQ strengths available to the patient at any time should be minimised to prevent confusion and potential overdose
- ➔ The initial dose of ACTIQ used should be 200 micrograms, titrating upwards as necessary through the range of available dosage strengths (200, 400, 600, 800, 1200 and 1600 micrograms)

Method of administration

ACTIQ is intended for oromucosal administration, and therefore should be placed in the mouth against the cheek and should be moved around the mouth using the applicator, with the aim of maximising the amount of mucosal exposure to the product. The ACTIQ unit should be sucked, not chewed, as absorption of fentanyl via the buccal mucosa is rapid in comparison with systemic absorption via the gastrointestinal tract. Water may be used to moisten the buccal mucosa in patients with a dry mouth.

The ACTIQ unit should be consumed over a 15 minute period. If signs of excessive opioid effects appear before the ACTIQ unit is fully consumed it should be immediately removed, and consideration given to decreasing future dosages.

Please note that ACTIQ® lozenges are not interchangeable with other Fentanyl products.

RISKS ASSOCIATED WITH OFF-LABEL USE OF ACTIQ®

Importance of preventing off-label use

- ➔ The use of ACTIQ® in any way other than that described in the approved SmPC is considered off-label use. If you are concerned that off-label use may be taking place, please contact the prescriber to discuss your concerns.
- ➔ Off-label use can take many forms, including prescribing:
  - For an indication other than breakthrough pain in cancer patients, including any other type of pain, acute or chronic.
  - If the patient is not receiving maintenance opioid therapy for their background pain.
  - More frequent dosing than licensed.
  - To someone who is under 16-years old.
- ➔ Each of these off-label uses poses a **risk** to the patient. At worst, it can lead to **addiction, overdose, and death.** Side effects are generally increased with off-label use.

Medication errors are particularly important to avoid when prescribing an opioid.

Medication errors include:

- ➔ Unintentional drug prescribing error.
- ➔ Drug administration error.
- ➔ Drug dispensing error.
- ➔ Incorrect dosage administered.
- ➔ Use of an incorrect route of administration.

In order to minimize the risk of medication errors, all ACTIQ® labels are color-coded differently for each of the strengths of action.

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

OVERDOSE

Repeated use of ACTIQ® may lead to Opioid Use Disorder (OUD). Abuse or intentional misuse of ACTIQ® may result in overdose and/or death. Off-label use (e.g. use in children or in patients without maintenance opioid therapy) and medication error (e.g. accidental exposure to ACTIQ®) may also result in overdose.

The symptoms of fentanyl overdose/toxicity are:

- Altered mental status
- Loss of consciousness
- Coma
- Cardiorespiratory arrest
- Respiratory depression, respiratory distress, and respiratory failure, which have resulted in death
- Cases of Cheyne-Stokes respiration have been observed in case of fentanyl overdose, particularly in patients with history of heart failure.

Any of these symptoms require immediate medical attention, as these can lead to death without proper medical treatment. Patients or their carers should therefore immediately call the **emergency number (112 or 999)** in the event of an overdose or the appearance of the symptoms mentioned.

- Please ensure that patients and carers are made aware of the signs of fentanyl overdose/toxicity described above, understand the potential seriousness and have been adequately instructed on what to do in an emergency.
- Watch for signs that the patient may not be using the product as prescribed, and be aware of the serious risk of misuse, abuse, medication error, overdose, and addiction.
- Ensure that the patient is aware of the potential for misuse, abuse, overdose, and addiction associated with ACTIQ®.

SAFETY, STORAGE AND DISPOSAL

Safety, Storage and disposal

Remind the patient of the following important storage instructions:

- ACTIQ® should only be handled by patients or their carers. Please advise the patient to never let anyone else handle or use the product.
- The particular danger to children if exposed to ACTIQ®.
- Please ensure patients understand that in order to prevent theft, diversion (misuse for illegal purposes), and other misuse of the drug, they should store ACTIQ® in a suitably secure place. Fentanyl, the active constituent of ACTIQ®, is a target for people who abuse narcotic medicines or other street drugs and therefore the storage instructions must be closely followed.[1]

Please counsel patients on these additional safety and disposal instructions:

- Instructions for opening the blister pack for the lozenges (Package Leaflet)
- Appropriate disposal of ACTIQ® lozenges - any used or unused but no longer required product or waste material should be disposed of in accordance with local requirements.[1]

Dental Decay

Normal oral hygiene is recommended to reduce any potential harm to the teeth. Because ACTIQ contains approximately 2 grams of sugar, frequent consumption increases the risk of dental decay. The occurrence of dry mouth associated with the use of opioid medicinal products may add to this risk. During treatment with ACTIQ, regular dental visits are advised.

RISKS ASSOCIATED WITH "OPIOID USE DISORDER" (OUD)

- Repeated use of Actiq may lead to opioid use disorder (OUD). Abuse or intentional misuse of Actiq may result in overdose and/or death.
- The risk of developing OUD is increased in patients with a personal or a family history (parents or siblings) of substance use disorders (including alcohol use disorder), in current tobacco users or in patients with a personal history of other mental health disorders (e.g. major depression, anxiety and personality disorders).
- Patients will require monitoring for signs of drug-seeking behaviour (e.g. too early requests for prescriptions). Monitoring should also include a review of prescription frequency for concomitant opioids and pyschoactive drugs (such as benzodiazepines).

It is important to pay careful attention to the signs of OUD, as detection will ultimately help the patient. For example, tolerance (the need for more drugs to achieve the same effect) and withdrawal are criteria associated with OUD. A patient with withdrawal symptoms may complain of nausea and vomiting, anxiety, insomnia, hot and cold flushes, sweating, muscle cramps, watery discharge from the eyes and nose, and/or diarrhoea.[2]

Patients/carers should be informed of the risks of abuse and dependence and informed of the need for periodic review by their doctor. If you believe that a patient might have an issue with their treatment or if OUD is recognised, discuss your concerns immediately with the patient's prescribing doctor.

Report any known off-label use, diversion, misuse, abuse, addiction, and overdose via HPRA Pharmacovigilance, www.hpra.ie.

Adverse events may also be reported to Teva Pharmaceuticals Ireland
via email to medinfo@tevauk.com or via phone on +44 (0) 207 540 7117.

CHECKLIST FOR DISPENSING ACTIQ®

- [ ] Ensure that all the criteria of the approved indication are fulfilled. ACTIQ® should only be prescribed for breakthrough pain in patients already receiving maintenance opioid therapy for chronic cancer pain. If you are unsure about a difference between the label and a prescriber's request, please contact the prescriber for clarification
- [ ] Give the patient and/or carer instructions on how to use the lozenges
- [ ] Make sure the patient/carer reads the Package Leaflet inside the ACTIQ® package
- [ ] Supply the patient/carer with the ACTIQ® Patient/Carer guide and explain the use of the dose monitoring card
- [ ] Explain the risks of using more than the recommended amount of ACTIQ®
- [ ] Advise the patient/carer of signs of fentanyl overdose and the need for immediate medical assistance
- [ ] Explain secure storage and the need to keep ACTIQ® out of the reach and sight of children

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References

1. ACTIQ® Lozenges — Summary of Product Characteristics (SmPC). Teva Pharma B.V.
2. Clinical guidelines for withdrawal management and treatment of drug dependence in closed settings. Geneva: World Health Organization (WHO); 2009. 4, Withdrawal management. https://www.ncbi.nlm.nih.gov/books/NBK310652/. (Accessed on 18 October 2022)