



Important risk minimisation information for patients and their carers

Abstral[®] (sublingual fentanyl citrate tablet)

Patient and Carer Guide

How Abstral[®] can help you manage breakthrough cancer pain

Provided as a service to patients by Kyowa Kirin Ltd

KYOWA KIRIN

Abstral® Patient and Carer Guide

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What is breakthrough cancer pain?

Many people who are suffering from cancer will experience regular pain. This ongoing and continuous pain is sometimes called “background pain”. However, people that experience background pain may also experience periods of particularly severe and intense pain that “breaks through” the regular or background pain. This is known as breakthrough cancer pain (BTcP).

Breakthrough cancer pain usually:

- Comes on very quickly
- Is severe and intense, “breaking through” your background pain relief medication
- Rarely lasts more than 30 minutes
- Is not controlled by normal background pain medication
- Can be predictable or unpredictable (and it can be brought on by activities such as walking, coughing or sneezing)

Because breakthrough cancer pain comes on so quickly and is very intense, it needs a specially designed medicine to tackle the pain, which is different to your background cancer pain medicine. The medicines for breakthrough pain are fast-acting and provide pain relief which lasts for about the same amount of time as an episode of breakthrough pain.

The experience of pain is different for everyone. It is therefore very important that you talk to the doctors and nurses looking after you, so that they can find the right type and dose of painkillers to control the type of pain you are experiencing.

You shouldn't feel worried about saying that your pain is not properly controlled. Your doctors and nurses are there to help you.

What is Abstral®?

- Abstral® contains a drug called fentanyl. This is a treatment for adults who must already be taking strong pain-relieving medicine (opioids) for their persistent cancer pain, but require treatment for their breakthrough cancer pain
- Abstral® is only to be used for breakthrough cancer pain. Abstral® must not be used for other short-term pain. If you are not sure, talk to your doctor
- Abstral® comes in a tablet form that must be allowed to dissolve under your tongue to work. It will dissolve quickly, and has been proven to provide pain relief as early as 10 minutes after taking it. Abstral® has also been shown to provide pain relief over 60 minutes
- It is important that you remain on the medicine (opioids) that you are already taking to control your regular cancer pain
- Your doctor will tell you whether Abstral® is suitable for you
- Abstral® should only be used by you, according to your doctor's instructions. It should not be used by anyone else as it could present a serious risk to their health, especially to children
- You should read the patient information leaflet before you start taking Abstral® to make sure it is right for you. Please see the section on page 9 of this booklet called **How to take Abstral®** for a detailed description of how to take your medicine



Starting Abstral® and finding the right dose for you

Before taking Abstral® for the first time your doctor will explain how Abstral® should be taken to effectively treat your breakthrough pain.

Abstral® is available in a range of strengths. You may need to try different strengths of Abstral® over a number of episodes of breakthrough pain to find the most appropriate dose. Your doctor will instruct you what to do. A dose may involve taking more than one Abstral® tablet at a time.

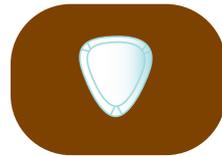
The different strength tablets are different shapes and come in colour coded boxes to avoid confusion. Your doctor or pharmacist can advise you about these.



100 microgram



200 microgram



300 microgram



400 microgram



600 microgram



800 microgram

Your doctor or other healthcare professional will monitor you closely whilst finding the best dose for you, in order to minimise the risk of adverse reactions.

Once you've found the right dose

Once you and your doctor have found a dose of Abstral[®] that controls your breakthrough cancer pain you should take this dose no more than four times a day. You must leave at least 2 hours between doses of Abstral[®].

Abstral[®] is different to other medicines you may have used to treat your breakthrough pain. You must always use the dose of Abstral[®] prescribed by your doctor – this may be different from that which you have used with other medicines for breakthrough pain.

If you are not getting enough pain relief for your breakthrough cancer pain episode, this might indicate that your Abstral[®] dose needs adjusting. Do not attempt to change the dose of your medication yourself. If you experience any problems you should consult your healthcare provider immediately.

How to take Abstral®

- Abstral® is a very strong painkiller and must never be taken by anyone but the person it is prescribed for
- If your mouth is dry, sip some water before taking Abstral®
- Place the Abstral® tablet under your tongue, as far back as you can, and let it dissolve completely
- Do not bite, chew, suck, or swallow the tablet or it will not work properly
- Do not eat or drink anything until the tablet has completely dissolved

NB. For more information on how to take Abstral®, please read the “Patient Information Leaflet” which can be found in your Abstral® pack.



Requirements for storing Abstral®

Abstral® contains an active substance in an amount that can be fatal to a child, therefore it is important to keep all tablets out of the reach and sight of children.

- Abstral® should be kept in a locked storage place away from other people
- Do not store Abstral® above 25°C
- Abstral® should be kept in the blister packet and not in a pill box
- Do not use Abstral® beyond the expiry date printed on the packaging
- Any unused or expired Abstral® tablets should be returned to your pharmacist. Do not dispose of this medication through household waste



Adverse effects which might be experienced

- As with other similar pain medicines, Abstral® can cause some side-effects and does carry a risk of accidental overdosing and a risk of abuse. Your healthcare provider should inform you how to minimise these risks
- Abstral® has similar side-effects to those associated with your strong pain-relieving medicine (opioids) for cancer pain. More information on these is detailed in the package leaflet. Your healthcare provider can inform you how to minimise the risks of experiencing side-effects
- Please tell your doctor or pharmacist of any medicines you are currently or have recently been taking
- If you have not been regularly taking or using a prescribed opioid medicine to control your persistent pain, Abstral® could cause severe breathing difficulties. If you have not been using these medicines you must not use Abstral® because it may increase the risk that breathing could become dangerously slow and/or shallow or even stop
- Abstral® should only be used by you, according to your doctor's instructions. It should not be used by anyone else as it could present a serious risk to their health, especially to children

Once you know the dose that gives you the best pain relief (your personal optimal dose) you should take your dose of Abstral® no more than 4 times daily. You must wait at least 2 hours from taking your last dose before treating your next episode of breakthrough pain with Abstral®. If your doses are taken too often, or too close together, there is greater risk of side-effects.

If you follow the instructions on how to take Abstral®, and follow the advice of your healthcare provider on how many Abstral® tablets to take, it is extremely unlikely that you will take too much.

However, in the unlikely event of an overdose you may feel very drowsy or may feel short of breath with only slow or shallow breathing. In the event of an overdose take the following steps:

- Immediately remove any remaining tablet(s) from your mouth
- Tell someone nearby (another person in your house or your nurse/carer) what has happened
- Immediately contact your designated healthcare provider or other emergency medical help
- Your nurse/carer should keep you awake by talking to you or shaking you gently now and again

If you think someone has taken Abstral® by accident seek emergency medical help immediately.

If you do experience any of the side-effects listed on the patient information leaflet, or experience any other side-effects which you think are related to taking Abstral®, inform your healthcare provider. They may be able to help reduce these while ensuring that you continue treatment.

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.

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

The risk of developing a condition called serotonin syndrome may increase if you are taking Abstral® together with certain other medications. These medicines including antidepressants and medicines that are used for some types of psychiatric disorders, anti-sickness medications and other pain killers.

Serotonin syndrome causes a range of symptoms including:

- agitation, hallucinations, coma
- high body temperature (above 38°C), increase in heart rate, sudden changes in blood pressure
- unusual muscle tightness, lack of coordination
- gastrointestinal symptoms such as nausea, vomiting, diarrhoea

Please remember to tell your doctor or pharmacist about any medicines you are taking, as they will be able to assess these risks and will decide whether Abstral® is suitable for you. Certain medicines, including some painkillers, may reduce the effects of Abstral®. Do not consume alcohol without consulting your doctor. Refer to the patient leaflet for further information. If you develop any of the symptoms above and are worried about serotonin syndrome you should contact your healthcare provider immediately.

Breathing difficulties

If you start to feel unusually drowsy, or your breathing becomes shallow and/or slow, you or your carer should contact your doctor or local hospital immediately.

Breastfeeding

Fentanyl can get into breast milk and may cause side-effects in the breastfed infant. Do not use Abstral® if you are breastfeeding.

You should not start breastfeeding within 5 days after the last dose of Abstral®.

Learning more – frequently asked questions

Q. When should I take Abstral®?

A. Take Abstral® as soon as an episode of breakthrough cancer pain begins

Q. How quickly does Abstral® work?

A. Abstral® has been shown to provide pain relief as early as 10 minutes

Q. What should I do if I experience any side-effects when taking Abstral®?

A. If you experience any side-effects when taking Abstral®, you should speak to your doctor or nurse who may be able to resolve them while still controlling your breakthrough cancer pain

Additionally, if you start to feel unusually sleepy, or if your breathing becomes slow or shallow, you or your carer should immediately contact your doctor or local hospital for emergency help

Q. What is the maximum number of breakthrough cancer pain episodes I can treat with Abstral® in a single day?

A. Once you and your doctor have found a dose of Abstral® that controls your breakthrough pain you should take this dose no more than four times in any 24 hour period.

Q. How long should I leave between treating episodes of breakthrough pain?

A. It is important to leave at least 2 hours before treating another episode of breakthrough pain

Q. What should I do if I take an overdose?

A. If you think you have taken an overdose of Abstral®, immediately contact your local hospital for emergency help

Q. What should I do if I accidentally swallow Abstral®?

A. If you swallow your Abstral® tablet instead of allowing it to dissolve under your tongue, do not take another tablet to replace it during that breakthrough cancer pain episode. You should consult your doctor or nurse for advice

Q. What should I do if I am still experiencing breakthrough cancer pain?

A. You should consult your doctor or nurse for advice

Q. Are other medicines available to help control my breakthrough cancer pain?

A. There are a range of medicines available for controlling breakthrough cancer pain. Your doctor or nurse will be able to advise you about the most effective medicine for your needs.

Useful contact details

If you have any questions about Abstral® or your pain management, please contact your health professional.

Doctor:

Address:

Telephone:

Nurse:

Address:

Telephone:

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Please consult the Patient Information Leaflet (PIL) in the Abstral® product package. The PIL is also available for electronic download at www.mhra.gov.uk.