Abstral® (fentanyl) Sublingual Tablets

A Guide for Patients and Carers

This guide provides important information on how to minimise risks when using Abstral®

Provided as a service to patients by Kyowa Kirin Ltd

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What is breakthrough cancer pain? 1

It is common for people with cancer to experience pain, if this pain is continuous it is often known as “background pain”. This background pain is usually managed by taking prescribed painkillers on a regular basis. People who experience background pain might in addition suffer periods of particularly severe and intense pain that “breaks through” the background pain relief medication. This is known as breakthrough pain.

Breakthrough pain has some common characteristics:

- Usually comes on very quickly (minutes)
- Is severe and intense
- Rarely lasts for more than 30 minutes
- Is not controlled by background pain relief medication
- Can be predictable (caused by walking, coughing or sneezing) or unpredictable

Because breakthrough pain comes on so quickly and is very intense, effectively managing it needs a specially designed medicine that is different to your background pain relief medication. The medicines used to treat breakthrough pain are fast-acting and provide pain relief which lasts for about the same length of time as a breakthrough pain episode.

Pain is different for everyone. It is important that you receive the right type and dose of pain medication to control the particular type of pain you experience. By discussing your needs with the healthcare professionals looking after you, they can make sure this is achieved.

An introduction to Abstral®

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- Abstral® contains a drug called fentanyl. This is a treatment that is only suitable for adults who are already taking strong pain-relieving medicine (opioids) for their background cancer pain, but require additional treatment to control their breakthrough 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 background pain
  - If you have not been regularly taking or using a prescribed opioid medicine to control your persistent pain, this medicine 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
- 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

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

Abstral® comes in six strengths. The different strength tablets come in different shapes and are presented in colour-coded packaging to help avoid confusion.

100 microgram | 200 microgram | 300 microgram | 400 microgram | 600 microgram | 800 microgram

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

Your doctor will monitor you closely whilst finding the best dose for you; this will make sure that the risk of side-effects is minimised.

Once you've found the right dose 4

Once you and your doctor have found a dose of Abstral® that controls your breakthrough pain, you should take this dose to treat future episodes. You must not take Abstral® more than four times a day and take care to leave at least 2 hours between subsequent doses.

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 to the dose you have been prescribed for other medicines for breakthrough pain.

If you are not getting enough pain relief for your breakthrough 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.

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.

How to open the Abstral® pack

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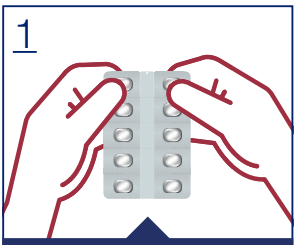
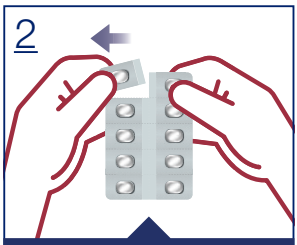
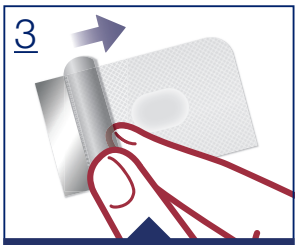


Remove the blister pack from the packaging.



Separate the required tablets by tearing along the dotted lines/ perforations. Keep the remaining blister squares together.



Peel off the foil top to release the tablet.

IMPORTANT!

Do not try to push Abstral® sublingual tablets through the foil top, as this will damage them.

How to take Abstral®

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- Abstral® is a very strong painkiller and must never be taken by anyone but the person it is prescribed for
- Take tablet at onset of breakthrough pain episode
- 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
- Allow the tablet to dissolve
- 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.

Storing Abstral®

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Abstral® contains an active substance (fentanyl) in an amount that can be fatal to a child. It is essential therefore 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, especially children
- 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

Side-effects which might be experienced

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- As with other similar pain relief medicines, Abstral® can cause some side-effects and carries risk of accidental overdosing and risk of abuse. Your healthcare provider should inform you how to minimise these risks
- The side-effects associated with Abstral® are similar to those of the pain-relieving medicine (opioids) you are taking to control background cancer pain. More information on these side-effects 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 taking a prescribed opioid medicine on a regular basis to control you background pain, Abstral® could cause severe breathing difficulties. These include breathing becoming increasingly shallow, or even stopping altogether. Abstral® must therefore only be used if you are taking regular opioid medicines.
- 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.

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
- Without delay **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.

The risk of certain side effects may increase if you are taking medicines such as certain antidepressants or anti-psychotics (medicines that are used for some types of mental distress or disorder).

As with other similar pain medicines, Abstral® may interact with these medicines and you may experience a number and range of side effects, details of which are described in the patient information leaflet.

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 tell you whether Abstral® is suitable for you. If you develop any side effects, you should contact your healthcare provider immediately.

Abstral® may add to the effect of alcohol and to medicines that make you feel sleepy. Refer to the patient leaflet for further information.

If monoamine-oxidase MAO inhibitors (used for severe depression and Parkinson's disease) have been taken within the last two weeks, they can increase the effects of Abstral®.

Certain types of strong pain killers may cause you to experience symptoms such as nausea, vomiting, diarrhoea, anxiety, chills, tremor and sweating while using the medicines.

Serotonin syndrome

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. 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.

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 are also encouraged to report any side-effects to the Health Products Regulatory Authority (HPRA). Reporting forms and information can be found at www.hpra.ie. Side-effects may also be reported to the HPRA by calling (01) 6764971. By reporting side-effects you can help provide more information on the safety of this medicine.

Breastfeeding

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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 until at least 5 days after the last dose of Abstral®.

Frequently asked questions 10

Q. When should I take Abstral®?

A. Take Abstral® as soon as an episode of breakthrough 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. Speak to your doctor or nurse who may be able to resolve them while still controlling your breakthrough pain.

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

Q. What is the maximum number of breakthrough 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 pain episode. You should consult your doctor or nurse for advice.

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

A. You should consult your doctor or nurse for advice.

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

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

Useful contact details

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

Doctor: .....

Address: .....

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Telephone: .....

Nurse: .....

Address: .....

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Telephone: .....

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

Marketing Authorisation Holder:
Kyowa Kirin Holdings B.V.
Bloemlaan 2
2132NP Hoofddorp
The Netherlands

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