Important risk minimisation information for patients and Carers

Abstral® (fentanyl) Sublingual tablets

Patient and Carer Guide
Abstral® (fentanyl)

This guide has been approved by Saud i Food and Drug Authority (SFDA) on November 22nd 2020

How Abstral® can help you manage breakthrough cancer pain

Provided as a service to patients by
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Many people who are suffering from cancer will experience regular pain. This ongoing and continuous pain is sometimes called “background pain” and is usually managed by taking prescribed painkillers on a regular basis. 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(minutes)
- Is severe and intense, “breaking through” your background pain relief medication
- Rarely lasts 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 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.

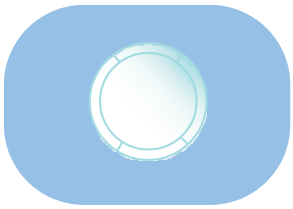
The experience of pain is different for everyone. It is therefore very important that you receive the right type and dose of pain medication to control the particular type of pain you are experiencing.

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

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

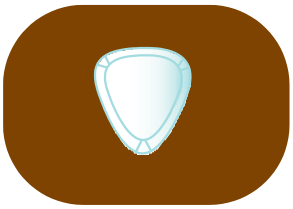
Abstral® is available in six strengths. You may need to try different strengths of Abstral® over a number of episodes of breakthrough pain to find the most appropriate dose. Your doctor will instruct you what to do. A dose may involve taking more than one Abstral® tablet at a time.

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



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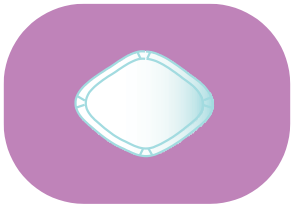

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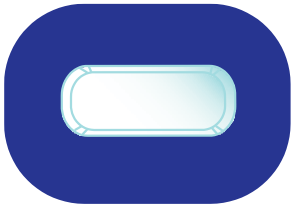


800 microgram

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 and your doctor have found a dose of Abstral® that controls your breakthrough cancer 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 doses of Abstral®.

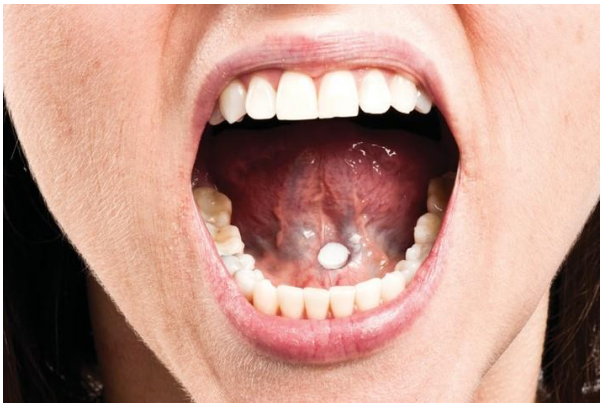
Abstral® is different to other medicines you may have used to treat your breakthrough pain. You must always use the dose of Abstral® prescribed by your doctor – this may be different from that which you have used with other medicines for breakthrough pain.

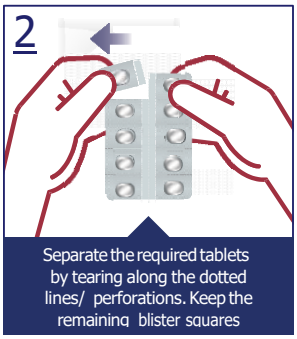
If you are not getting enough pain relief for your breakthrough cancer pain episode, this might indicate that your Abstral® dose needs adjusting. **Do not attempt** to change the dose of your medication yourself. If you experience any problems, you should consult your healthcare provider immediately.

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® 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
- 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.





IMPORTANT!

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

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, 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

- 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
- 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.

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. 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®. 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®.

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.

Reporting of side-effects

If you suspect you are developing any side-effects, talk to your doctor, pharmacist or nurse. This includes any possible side-effects not listed in the package leaflet.

The National Pharmacovigilance Centre (NPC)

Saudi Food and Drug Authority (SFDA)

SFDA call center: 19999

Toll free phone: 8002490000

Fax: +966-11-2057662

E-mail: npc.drug@sfda.gov.sa

Website: http://ade.sfda.gov.sa/

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

For extra copies please contact:

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