PACKAGE LEAFLET: INFORMATION FOR THE USER

Abstral® 100, 200, 300, 400, 600, 800 Microgram Sublingual tablets

Fentanyl

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Abstral is and what it is used for
2. Before you take Abstral
3. How to take Abstral
4. Possible side effects
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1. What Abstral is and what it is used for

Abstral is a treatment for people **who must already regularly be taking strong pain-relieving medicine (opioids)** for their persistent cancer pain, but require treatment for their breakthrough pain. If you are not sure, talk to your doctor.

Breakthrough pain is pain which occurs suddenly, even though you have taken or used your usual opioid pain-relieving medicine.

The active substance in Abstral sublingual tablets is fentanyl. Fentanyl belongs to a group of strong pain-relieving medicines called opioids.

2. Before you take Abstral

Do not take Abstral

- if you are allergic (hypersensitive) to fentanyl or any of the other ingredients of Abstral
- if you have severe breathing problems

Before you start treatment with Abstral, **you must have been regularly taking or using a prescribed strong pain-relieving medicine, called an opioid, to control your persistent pain.** If you have not, this medicine could cause severe breathing difficulties (see section 4. Possible side effects). If you are not sure, talk to your doctor.

Take special care with Abstral

Tell your doctor before treatment if you have or have recently had any of the following, as your doctor will need to take account of these when prescribing your dose:

- a head injury, because Abstral may cover up the extent of the injury
- breathing problems or suffer from myasthenia gravis (a condition characterised by muscle weakness)
- a slow heart rate or low blood pressure
- liver or kidney disease, as this may require your doctor to more carefully adjust your dose
- a brain tumour and/or raised intracranial pressure (an increase of pressure in the brain which causes severe headache, a feeling of sickness and blurred vision)
- mouth wounds or mucositis (swelling and redness of the inside of the mouth)

When taking Abstral, if you are to have any surgery, inform your doctor or dentist that you are taking this medicine.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines (other than your regular opioid pain-relieving medicine), including medicines obtained without a prescription.

The following medicines may increase the effects of Abstral:

- Certain types of antifungal medicines containing e.g. ketoconazole or itraconazole (used to treat fungal infections).
- Certain types of antibiotic medicines used to treat infections (called macrolides, containing e.g. erythromycin).
- Certain types of antiviral medicines used to treat infections caused by viruses (called protease inhibitors, containing e.g. ritonavir).
- Medicines containing alcohol
- Medicines called monoamine-oxidase (MAO) inhibitors, which are used for severe depression and Parkinson's disease. Tell your doctor if you have taken this type of medicine within the last two weeks.

The following medicines may reduce the effects of Abstral:

- Certain types of strong pain killers containing e.g. buprenorphine or pentazocine

Abstral may add to the effect of medicines that make you feel sleepy, including:

- other **strong pain-relieving medicines** (opioid-type medicines e.g. for pain and cough)
- general anaesthetics (used to make you sleep during operations)
- muscle relaxants
- sleeping tablets
- medicines used to treat
  - depression
  - allergies
  - anxiety and psychosis
- medicines containing clonidine (used to treat high blood pressure).

Taking Abstral with food and drink

Abstral can make some people feel drowsy. Do not consume alcohol without consulting your doctor as it might make you feel more drowsy than usual.

Do not drink grapefruit juice while you are prescribed Abstral treatment as it may increase the side effects of Abstral.

Pregnancy and breast-feeding

You must not use Abstral during pregnancy unless you have been specifically told to by your doctor.

Fentanyl is passed on into breast milk and may cause extreme drowsiness and shallow breathing in the breastfed child. Consult your doctor and do not use Abstral during breast-feeding unless your doctor considers that the benefits for you are greater than the risks to the child.

Ask your doctor or pharmacist for advice before taking any medicine when pregnant or breast-feeding.

Driving and using machines

Abstral may impair your mental and/or physical ability to perform potentially hazardous tasks such as driving or operating machinery.

If you feel dizzy, sleepy or have blurred vision when you take Abstral, do not drive or use machinery.

3. How to take Abstral

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

Always take Abstral exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

This product 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 in children.

Initial Phase – Finding the most appropriate dose

For Abstral to work successfully, your doctor will need to identify the most appropriate dose for treating a single episode of breakthrough pain. Abstral sublingual tablets are available in a range of strengths. You may need to try different strengths of Abstral sublingual tablets over a number of episodes of breakthrough pain to find the most appropriate dose. Your doctor will help you do this and will work with you to find the best strength of tablet to use.

If you do not get adequate pain relief from one tablet your doctor may ask you to take two tablets to treat an episode of breakthrough pain. Do not take a second tablet unless your doctor tells you to as this may result in overdose. Your doctor will advise you which strength of tablet to use.

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

Maintenance Phase - Once you have found the most appropriate dose

Once you and your doctor have found a dose of Abstral tablets that controls your breakthrough pain you should take this dose no more than four times a day. **A dose of Abstral may consist of more than one tablet.**

If you think that the dose of Abstral that you are using is not controlling your breakthrough pain satisfactorily tell your doctor, as he may need to adjust your dose.

Taking the medicine

Abstral should be used sublingually. This means that the tablet should be placed under the tongue where it dissolves rapidly in order to allow fentanyl to be absorbed across the lining of the mouth. Once absorbed, fentanyl starts to work to relieve pain.

When you get an episode of breakthrough pain, take the dose advised by your doctor as follows:

- If your mouth is dry, take a sip of water to moisten it. Spit out or swallow the water.
- Remove the tablet(s) from the blister pack immediately before use.
- Peel back the tab of the foil top of one blister and gently remove the tablet. Do not try to push Abstral sublingual tablets through the foil top, like a normal tablet
- Place the tablet under your tongue as far back as you can and let it dissolve completely.
- Abstral will dissolve rapidly under the tongue and be absorbed in order to provide pain relief. It is therefore important that you do not suck, chew or swallow the tablet.
- You should not drink or eat anything until the tablet has completely dissolved under your tongue.

If you take more Abstral than you should

- remove any remaining tablets from your mouth
- tell your carer or another person in your house what has happened
- you or your carer should immediately contact your doctor, pharmacist or local hospital and discuss what action to take
- while waiting for the doctor, keep the person awake by talking to or shaking her/him now and then

Symptoms of overdose include:

- extreme drowsiness
- slow, shallow breathing

If these occur, seek emergency medical help immediately.

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

If you stop taking Abstral

You should only stop taking Abstral sublingual tablets on the advice of your doctor. You must continue to take/use your regular opioid pain relieving medicine for persistent pain as advised by your doctor.

There should be no noticeable effects if you stop taking Abstral, but possible symptoms of withdrawal are anxiety, tremor, sweating, paleness, nausea and vomiting.

However, if you are concerned about your pain relief, you should talk to your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Abstral can cause side-effects, although not everybody gets them.

If you start to feel unusually or extremely sleepy or your breathing becomes slow or shallow, you or your carer should immediately contact your doctor or local hospital for emergency help (see also section 3 "If you take more Abstral than you should").

Very common side effects (affects more than 1 user in 10) include:

- nausea, headache, sleepiness/tiredness, dizziness.

Common side effects (affects 1 to 10 users in 100) include:

- vomiting, diarrhoea, constipation, stomach ache, bloated feeling, indigestion, loss of appetite
- depression, difficulty in concentrating, excessive feeling of well being
- increased sensitivity to sound and noise, blurred or double vision
- low blood pressure, flushing/feeling hot, slow shallow breathing, feeling weak, feeling faint, reduced sensitivity to touch, numbness or tingling
- runny or blocked nose, dry mouth, sore throat, itching of the skin, skin rash, irritation under the tongue

Other known side effects associated with fentanyl products include:

- Very common side effects (affects more than 1 user in 10 people):
  excessive sweating
- Common side effects (affects 1 to 10 users in 100):
  feeling confused, feeling anxious or nervous, hallucinations, abnormal thinking, muscle twitching, difficulty sleeping, strange dreams, tongue or taste problems, flushing, mouth ulcers/blisters, blockage of the gut, difficulty swallowing, being accident-prone
- Uncommon side effects (affects 1 to 10 users in 1,000):
  feeling restless, feeling detached, moodswings, trembling, difficulty speaking, being forgetful, loss of coordination, vertigo, slow or fast heartbeat, high blood pressure, difficulty breathing, slow or shallow breathing, asthma, bloating, wind, thirst, difficulty going to the toilet, change in frequency of going to the toilet, feeling unwell
- Rare side effects (affects 1 to 10 users in 10,000):
  hiccups
- Very rare side effects (affects less than 1 user in 10,000):
  irregular heartbeat, stopping breathing, blood in the saliva, decrease in amount of urine, painful contraction of the bladder

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Abstral

The pain-relieving medicine in Abstral is very strong and could be life-threatening if taken accidentally by a child. Abstral must be kept out of the reach and sight of children.

Do not use Abstral after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

Store in the original blister in order to protect from moisture.

It is recommended to keep Abstral in a locked storage space.

Any unused product should be taken, if possible, to your pharmacist to be disposed of safely. Medicines should not be disposed of via wastewater or household waste. These measures will help to protect the environment.

6. Further information

What Abstral contains

The active substance is fentanyl. One sublingual tablet contains either:

100 micrograms fentanyl (as citrate)
200 micrograms fentanyl (as citrate)
300 micrograms fentanyl (as citrate)
400 micrograms fentanyl (as citrate)
600 micrograms fentanyl (as citrate)
800 micrograms fentanyl (as citrate)

The other ingredients are mannitol (E421), silicified microcrystalline cellulose, croscarmellose sodium and magnesium stearate.

What Abstral looks like and contents of the pack

Abstral is a small white sublingual tablet to be inserted under the tongue. It comes in a range of different strengths and shapes. Your doctor will prescribe the strength (shape) and number of tablets suitable for you.

The 100 microgram tablet is a white round tablet
The 200 microgram tablet is a white oval-shaped tablet
The 300 microgram tablet is a white triangle-shaped tablet
The 400 microgram tablet is a white diamond-shaped tablet
The 600 microgram tablet is a white "D"-shaped tablet
The 800 microgram tablet is a white capsule-shaped tablet

Abstral tablets are contained in blisters, available in cartons of 10 or 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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