ABSTRAL® Sublingual Tablets
Fentanyl (as citrate)

Consumer Medicine Information

What is this leaflet about ABSTRAL. It does not contain all the available information. It is therefore important that you do not suck, chew or swallow the tablet.

What is ABSTRAL used for?
The medicine is used to treat breakthrough cancer pain in adult patients with cancer who are already receiving and are tolerant to (maintenance) opioid therapy for chronic cancer pain. Breakthrough pain is a transient episode of otherwise controlled chronic background pain.

ABSTRAL belongs to a group of medicines called analgesics. It is an opioid analgesic and it acts by blocking pain and your emotional response to pain.

Before you take ABSTRAL

When you must not take it

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking ABSTRAL, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- chronic obstructive pulmonary disease
- difficulty breathing, wheezing, chronic cough, asthma or other chronic breathing condition
- myasthenia gravis
- hypercapnia (too much carbon dioxide in the blood) or other evidence of increased intracranial pressure, reduced consciousness, coma or brain tumours
- bradycardia (slow heart beat) or bradyarrhythmias
- liver or kidney problems
- low blood pressure
- mouth wounds or mucositis (inflammation and ulceration of the mouth or gut lining)

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you start taking ABSTRAL.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines may be affected by ABSTRAL, or may affect how well ABSTRAL works. These include:

- some antibiotics (e.g. erythromycin)
- some antifungal medicines (e.g. ketoconazole, itraconazole)
- some antiviral medicines (e.g. ritonavir)
- other analgesics used to treat pain
- antitussives (cough suppressants)
- general anaesthetics
- muscle relaxants
- some antihistamines
- medicines used to help you relax, sleep or relieve anxiety, such as barbiturates, benzodiazepines and other sedatives
- antipsychotic agents, medicines used to treat mental disorders
- other medicines such as clonidine, buprenorphine, nalbuphine or pentazocine
- some antidepressants e.g. phenelzine, selegiline. Taking ABSTRAL with these medicines may increase the risk of a potentially life threatening condition called serotonin syndrome.

You may need different amounts of your medicine, or you may need to take a different medicine.

Your pharmacist or doctor will have more information on medicines to be careful with or avoid while using this medicine.

How to take ABSTRAL

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

If your mouth is dry, take a sip of water to moisten it. Spit out or swallow the water.

STEP 1: Remove the tablet(s) from the blister pack immediately before use as follows:

- Separate one of the blister squares from the pack by tearing along the dotted lines/perforations (keep the remaining blister squares together)
- Peel back the edge of the foil as indicated by the arrow on the coloured strip, and gently remove the tablet.

Do not try to push ABSTRAL sublingual tablets through the foil top, as this will damage the tablet.

Useful tips

- Avoid using with alcohol or other medicines that may make you sleepy
- Do not use your tablet if you are taking another fentanyl product
- If you are being treated with another opioid drug, your dose may have to be adjusted
- Taking ABSTRAL may make you feel drowsy. If you think it necessary to drive a car or operate machinery, do so with caution.
- Avoid sudden changes in the position of your body
- You should not stop taking ABSTRAL until you have been told to do so.
- You should take the tablets on an empty stomach.
- You should avoid using oral hygiene products containing alcohol or menthol
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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.

How to store this medicine

ABSTRAL is a sublingual tablet. Each tablet contains fentanyl (as citrate) 1000 micrograms (0.001 milligrams). ABSTRAL tablets are supplied in blisters with the foil pack kept intact until immediately before use.

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Do not substitute ABSTRAL for any other pain reliever. Use of ABSTRAL without dose titration and by individuals not already taking regular opioid medication may result in fatal overdose.

If you do not understand the instructions for use, ask your doctor or pharmacist for help.

How much to take

The recommended dosage will depend on the level of pain you are experiencing.

When starting ABSTRAL

You must start with the lowest dose tablet (100 µg). If adequate pain relief is not achieved within 30 minutes, your doctor may recommend a supplemental (second) 100 µg tablet.

If your pain is still uncontrolled after the second dose you cannot take another ABSTRAL tablet for this episode of pain.

If adequate pain relief was not achieved for an earlier episode of breakthrough cancer pain, your doctor may suggest you take additional tablets or higher strength tablets for your next episode(s) of breakthrough cancer pain. This is because everyone's pain is different and finding the right dose for you is important.

Do not take more than two doses of ABSTRAL for each episode of breakthrough cancer pain.

You should wait at least 2 hours before taking ABSTRAL to treat another episode of breakthrough cancer pain.

You must tell your doctor immediately if you are using ABSTRAL more than four times per day, as the doctor may wish to change your medicine for your chronic cancer pain.

Once your chronic pain has been controlled, your doctor may need to change your dose of ABSTRAL further.

For best results, let your doctor know about your pain and how ABSTRAL is working for you so that the dose can be changed if needed.

Do not change doses of ABSTRAL or your other pain medicines on your own.

Contact your doctor if your recommended dose of ABSTRAL does not relieve your breakthrough cancer pain. Your doctor will decide if your dose needs to be changed.
After using ABSTRAL

Storage

Keep your medicine in the original pack until it is time to take it.

Keep your medicine in a cool dry place where the temperature stays below 25°C.

Do not store ABSTRAL or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop using this medicine or the expiry date has passed, please return all unused medicine to your pharmacist as soon as possible.

Product description

What it looks like

- ABSTRAL 100 µg tablets are white, round and flat with bevelled edges.
- ABSTRAL 200 µg tablets are white, oval-shaped and flat with bevelled edges.
- ABSTRAL 300 µg tablets are white, arc triangle-shaped and flat with bevelled edges.
- ABSTRAL 400 µg tablets are white, diamond-shaped and flat with bevelled edges.
- ABSTRAL 600 µg tablets are white, "D"-shaped and flat with bevelled edges.
- ABSTRAL 800 µg tablets are white, caplet-shaped and flat with bevelled edges.

ABSTRAL is available in foil blister pack sizes of 10 or 30 tablets.

Ingredients

ABSTRAL contains either 100 µg, 200 µg, 300 µg, 400 µg, 600 µg or 800 µg of fentanyl (as citrate) as the active ingredient.

ABSTRAL also contains the following inactive ingredients:

- mannitol
- microcrystalline cellulose
- colloidal anhydrous silica
- croscarmellose sodium
- magnesium stearate

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Sponsor

ABSTRAL is supplied in Australia by:

A.Menarini Australia Pty Ltd
Level 8, 67 Albert Avenue
Chatswood, NSW 2067
1800 644 542

Australian Registration Number

- 100 µg strength AUST R 193332
- 200 µg strength AUST R 193335
- 300 µg strength AUST R 228199
- 400 µg strength AUST R 193336
- 600 µg strength AUST R 228208
- 800 µg strength AUST R 228209.

This leaflet was prepared in June 2015.

For the most up to date version of this leaflet please go to www.menarini.com.au/cmi.