

ABSTRAL[®]

fentanyl (as citrate)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet answers some common questions about ABSTRAL.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking ABSTRAL against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What ABSTRAL is 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 cancer 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is only available on a prescription from your doctor.

Before you take ABSTRAL

When you must not take it

Do not take ABSTRAL if you have an allergy to:

- any medicine containing fentanyl or citrate
- any other similar medicines (such as other opioid analgesics)
- any of the ingredients listed at the end of this leaflet
- if you suffer from short-term pain other than breakthrough pain.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take ABSTRAL for other types of acute pain (e.g. post-operative pain, headache, migraine).

Do not take ABSTRAL if you are not already receiving (and are tolerant to) opioid maintenance therapy for cancer-related pain.

Do not take ABSTRAL if you are suffering from severe respiratory depression or severe obstructive lung conditions.

Do not give this medicine to anyone younger than 18 years of age.

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
- hyperkapnia (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 breastfeeding.

Fentanyl can get into breast milk and may cause side effects in the breast-fed 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. 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)
- some medicines used to treat bacterial infections (e.g. rifampicin or rifabutin)
- some medicines used to treat convulsions/fits (e.g. carbamazepine, phenobarbital or phenytoin)
- 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
- some antidepressants e.g. phenelzine, selegiline. Taking ABSTRAL with these medicines may increase the risk of a potentially life-threatening condition called serotonin syndrome

- certain types of strong pain killers, called partial agonist/antagonists e.g. buprenorphine, nalbuphine and pentazocine (medicines for treatment of pain). You could experience symptoms of withdrawal syndrome (nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating) while using these medicines.

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.

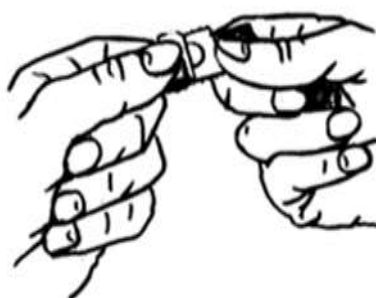
How to take ABSTRAL

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.

STEP 2: 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.

STEP 3: Dispose of the empty blister square.



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 microgram). If adequate pain relief is not achieved within 30 minutes, your doctor may recommend a supplemental (second) 100 mcg 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.

After you have found the right ABSTRAL dose

After you and your doctor have found the dose of ABSTRAL that provides adequate breakthrough cancer pain relief for you, this is the ongoing dose that you should take for each episode of breakthrough cancer pain.

DO NOT TAKE MORE THAN THE DOSE YOUR DOCTOR HAS RECOMMENDED FOR EACH 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.

How long to use it

You can use this medication whenever you have an episode of breakthrough pain.

You should discontinue ABSTRAL when you no longer have any breakthrough pain. You must however continue to take your usual opioid pain relieving medicine to treat your persistent cancer pain as advised by your doctor. You may experience withdrawal symptoms similar to the possible side effects of ABSTRAL when discontinuing ABSTRAL. If you experience withdrawal symptoms or if you are concerned about your pain relief you should contact your doctor. Your doctor will evaluate if you need medicine to reduce or eliminate the withdrawal symptoms.

Do not continue to use ABSTRAL if you no longer feel breakthrough cancer pain.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre on 13 11 26 (Australia) or 0800 764 766 (New Zealand) for advice, or go to Accident and Emergency at the nearest hospital if you think you or anyone else may have taken too much ABSTRAL. Do this even if there

are no signs of discomfort or poisoning.

While you are using ABSTRAL

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ABSTRAL.

Tell any other doctors, dentists and pharmacists who treat you that you are using this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are using this medicine.

It may affect other medicines used during surgery.

If you become pregnant while using this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Talk to your pharmacist or doctor if your breakthrough cancer pain does not improve.

Your pharmacist or doctor will assess your condition and decide if you should continue to take this medicine.

Things you must not do

Do not use ABSTRAL to treat any other complaints unless your pharmacist or doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not switch from ABSTRAL to other medicines that contain fentanyl without talking with your doctor.

ABSTRAL is NOT interchangeable with other fentanyl products.

Your doctor will prescribe starting and maintenance doses of ABSTRAL that may be different than other

fentanyl-containing medicines you may have been taking.

Do not take ABSTRAL for short-term pain that you would expect to go away in a few days, such as: pain from injuries, from doctors' or dentists' visits, surgery or headaches/migraines.

ABSTRAL can cause dizziness, drowsiness or blurred vision.

Do not drive or operate machinery while taking ABSTRAL as ABSTRAL can cause dizziness, drowsiness or blurred vision.

Do not consume alcohol while taking ABSTRAL, as dizziness and drowsiness may become worse.

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

Things to be careful of

Do not take high doses of ABSTRAL for long periods of time unless your doctor tells you to.

ABSTRAL may be habit forming.

Get emergency medical help right away if:

- **a child accidentally takes ABSTRAL. ABSTRAL can cause an overdose and death in any child who takes it**
- **an adult who has not been prescribed ABSTRAL takes it**

These are medical emergencies that can cause death.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ABSTRAL.

This medicine helps most people with breakthrough cancer pain, but it may have unwanted side effects in a few people. All medicines can have side effects, sometimes they are serious, most of the time they are not.

You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- headache
- drowsiness
- nausea
- vomiting
- constipation
- dry mouth
- sore mouth or mouth ulcers
- excessive sweating
- tiredness

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor or pharmacist immediately if you notice any of the following:

- shortness of breath
- fast or slow heart beat
- dizziness or light-headedness
- unusual or extreme mood swings
- blurred vision

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

If any of the following happen, tell your doctor or pharmacist immediately or go to Accident and Emergency at your nearest hospital:

- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rashes

The above list includes very serious side effects. You may need medical

attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

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 microgram tablets are white, round and flat with bevelled edges.

ABSTRAL 200 microgram tablets are white, oval-shaped and flat with bevelled edges.

ABSTRAL 300 microgram tablets are white, arc triangle-shaped and flat with bevelled edges.

ABSTRAL 400 microgram tablets are white, diamond-shaped and flat with bevelled edges.

ABSTRAL 600 microgram tablets are white, "D"-shaped and flat with bevelled edges.

ABSTRAL 800 microgram tablets are white, caplet-shaped and flat with bevelled edges.

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

800 micrograms: AUST R 228209

This leaflet was revised in March 2018.

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

[vA06-0]

Ingredients

ABSTRAL contains 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 by:

Australia:

A. Menarini Australia Pty Ltd

Level 8, 67 Albert Ave

Chatswood NSW 2067

Medical Information: 1800 644 542

New Zealand:

A. Menarini New Zealand Pty Ltd

4 Whetu Place

Rosedale 0632

Auckland

Medical Information: 0800 102 349

Australian Registration Number(s):

100 micrograms: AUST R 193332

200 micrograms: AUST R 193335

300 micrograms: AUST R 228199

400 micrograms: AUST R 193336

600 micrograms: AUST R 228208