ABSTRAL®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I taking ABSTRAL?

ABSTRAL contains the active ingredient fentanyl (as citrate). ABSTRAL is a strong pain medicine used to treat breakthrough cancer pain in adults who are already receiving an effective maintenance dose of opioid therapy for their underlying cancer pain. For more information, see Section 1. Why am I taking ABSTRAL? in the full CMI.

2. What should I know before I take ABSTRAL?

Do not take if you have ever had an allergic reaction to fentanyl or any of the ingredients listed at the end of the CMI. Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I take ABSTRAL? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ABSTRAL and affect how it works. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take ABSTRAL?

- ABSTRAL sublingual tablet is placed under your tongue until dissolved. Do not suck, chew or swallow the tablet
- Do not eat or drink anything until the tablet is completely dissolved. If needed, you can moisten your mouth by rinsing it with water before placing the tablet under your tongue.

More instructions can be found in Section 4. How do I take ABSTRAL? in the full CMI.

5. What should I know while taking ABSTRAL?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking ABSTRAL • Carefully follow your doctor's instructions on how much ABSTRAL to take for each breakthrough pain episode, especially when you first start taking ABSTRAL or change the dose • Talk to your doctor or pharmacist if your pain does not improve.
Things you should not do	• Do not take ABSTRAL for other types of pain (e.g. post-operative pain, headache, migraine) • Do not take ABSTRAL unless you have already been receiving opioid maintenance therapy for cancer-related pain for at least one week, because it may increase the risk of experiencing severe breathing difficulties • Do not take ABSTRAL if you have any lung conditions or breathing difficulties unless your doctor tells you to.
Driving or using machines	• Do not drive or operate machinery while taking ABSTRAL as it can cause dizziness, drowsiness or blurred vision.
Drinking alcohol	• Do not consume alcohol while taking ABSTRAL, as dizziness and drowsiness may become worse.
Looking after your medicine	• Keep your medicine in a cool dry place below 25°C • Keep your medicine where children cannot reach it.

For more information, see Section 5. What should I know while taking ABSTRAL? in the full CMI.

6. Are there any side effects?

The most common side effects of ABSTRAL are nausea, drowsiness and vomiting. Tell your doctor or pharmacist immediately or go to Emergency Department at your nearest hospital if you experience shortness of breath, wheezing or difficulty breathing, fast or slow heartbeat, dizziness or light-headedness, unusual or extreme mood swings, blurred vision, swelling of the face, lips, tongue or other parts of the body, or skin rashes.
For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING:

Limitations of use

ABSTRAL should only be taken when your doctor decides that other treatment options are not able to effectively manage your pain or you cannot tolerate them.

Hazardous and harmful use

ABSTRAL poses risks of abuse, misuse and addiction which can lead to overdose and death. Your doctor will monitor you regularly during treatment.

Life threatening respiratory depression

ABSTRAL can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing) even when taken as recommended. These problems can occur at any time during use, but the risk is higher when first starting ABSTRAL and after a dose increase, if you are older, or have an existing problem with your lungs. Your doctor will monitor you and change the dose as appropriate.

Use of other medicines or alcohol while taking ABSTRAL

Taking ABSTRAL with other medicines that can make you feel drowsy such as sleeping tablets (e.g. benzodiazepines), other pain relievers, antihistamines, antidepressants, antipsychotics, gabapentinoids (e.g. gabapentin and pregabalin), cannabis and alcohol may result in severe drowsiness, decreased awareness, breathing problems, coma and death. Your doctor will minimise the dose and duration of use, and monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while taking ABSTRAL.

ABSTRAL®

Active ingredient: fentanyl (as citrate)

Consumer Medicine Information (CMI)

This leaflet provides important information about taking ABSTRAL.

You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking ABSTRAL.

Where to find information in this leaflet:

1. Why am I taking ABSTRAL?
2. What should I know before I take ABSTRAL?
3. What if I am taking other medicines?
4. How do I take ABSTRAL?
5. What should I know while taking ABSTRAL?
6. Are there any side effects?
7. Product details

1. Why am I taking ABSTRAL?

ABSTRAL contains the active ingredient fentanyl (as citrate).

ABSTRAL belongs to a group of strong pain relieving medicines called opioid analgesics, and works by blocking the sensation of pain.

ABSTRAL is used to treat breakthrough pain in adults with cancer who are already receiving an effective maintenance dose of opioid therapy to control their persistent cancer pain. Breakthrough pain is a short episode of sudden intense pain despite well controlled persistent cancer pain.

2. What should I know before I take ABSTRAL?

Addiction

Opioids have a potential to cause addiction, even if taken exactly as prescribed. It is possible that ABSTRAL may become habit forming causing mental and physical dependence. If abused it may become less able to reduce pain. You may have a greater risk of becoming addicted to ABSTRAL if:

- you or anyone in your family have a history of substance abuse (including alcohol, prescription medicines, or illicit drugs)
- you or anyone in your family have a history of mental illness

Tolerance

As with all other opioid containing products, tolerance to ABSTRAL may develop, which means that you may need higher doses to control your breakthrough pain.

Dependence and Withdrawal

As with all other opioid containing products, your body may become used to you taking ABSTRAL. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking opioids suddenly, so it is important to take these exactly as directed by your doctor.

Continue taking your medicine for as long as you need it or your doctor tells you. If you stop taking ABSTRAL, you must continue to take your usual opioid pain relieving medicine to treat your persistent cancer pain as advised by your doctor. When you stop taking ABSTRAL there should be no

noticeable effects but your pain may worsen and some people may experience some or all of the following withdrawal symptoms:

- loss of appetite, nausea, vomiting or diarrhoea
- nervousness, restlessness, agitation, trouble sleeping or anxiety
- body aches, weakness or stomach cramps
- increased heart rate, breathing rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

Do not take ABSTRAL:

1. If you are allergic to fentanyl or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine
2. If you are allergic to any other similar medicines (such as other opioid analgesics)
3. For other types of short-term or acute pain (e.g. post-operative pain, headache, migraine)
4. If you are not already receiving (and are not tolerant to) opioid maintenance therapy for cancer-related pain
5. If you have any lung conditions or breathing difficulties.

Check with your doctor if you have or have had:

- Difficulty breathing, wheezing, chronic cough, asthma or other breathing conditions such as chronic obstructive pulmonary disease (COPD),
- Myasthenia gravis (immune disease that causes muscle weakness)
- A brain tumour, increased pressure in your skull, reduced alertness, coma, or head injury
- Heart problems
- Liver or kidney problems
- Low blood pressure
- Mouth wounds or mucositis (inflammation and ulceration of the mouth or gut lining)

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Prolonged treatment with fentanyl during pregnancy or use during labour can cause breathing problems, signs of withdrawal, severe harm or life-threatening damage in the newborn.

Newborns may experience symptoms such as shaking, agitation, stiff muscles, uncontrolled movements, breathing issues, slow heart rate and sleep issues

Talk to your doctor if you are breastfeeding or intend to breastfeed. Fentanyl can get into breast milk and may cause side effects in the breast-fed infant. You should not start breastfeeding until at least 5 days after the last dose of ABSTRAL.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ABSTRAL and affect how it works. These include:

- some antibiotics used to treat infections such as erythromycin, rifampicin or rifabutin
- some medicines used to treat fungal infections such as ketoconazole and itraconazole
- some medicines used to treat HIV infections such as ritonavir
- some medicines used to treat convulsions/fits such as gabapentin, pregabalin, carbamazepine, phenobarbital or phenytoin
- other medicines used to treat pain
- cough suppressants
- medicines used for surgery (anaesthetics) and muscle relaxants
- sedative antihistamines
- medicines used to help you relax, sleep, relieve anxiety, depression and mental disorders, such as barbiturates, benzodiazepines, cannabis
- some antidepressants such as phenelzine and selegiline, as these may increase the risk of a potentially life-threatening condition called serotonin syndrome. Symptoms of serotonin syndrome include confusion, fast heartbeat, hallucinations, restlessness, shaking, shivering, sudden jerking of muscles, sweating)
- alcohol
- certain types of strong pain killers such as buprenorphine, nalbuphine and pentazocine. You could experience symptoms of withdrawal syndrome (nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating) while using these medicines
- anticholinergics or medicines with anticholinergic activity, such as medicines to treat depression (e.g., tricyclic antidepressants), allergies (e.g., antihistamines), travel sickness or nausea (e.g. antiemetics), psychiatric disorders (e.g. antipsychotics or neuroleptics), muscle relaxants and medicines to treat Parkinson's disease, as these may result in increased adverse effects for those medicines.

Check with your doctor or pharmacist if you are not sure whether the medicines, vitamins or supplements you are taking will affect ABSTRAL

4. How do I take ABSTRAL?

- Follow all directions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet.
- If you do not understand the instructions for use, ask your doctor or pharmacist for help.

How much to take

You must follow your doctor's instructions on how much ABSTRAL to take. Your dose is the dose that eases your breakthrough pain. This dose is determined by slowly increasing the ABSTRAL dose as explained below.

When starting ABSTRAL

Your persistent cancer pain must be well controlled on regular opioid pain medicines before you start ABSTRAL for the breakthrough pain. Do not stop your regular pain medicines.

- You must start with 100 micrograms of ABSTRAL. If adequate pain relief is not achieved within 30 minutes, your doctor may recommend a supplemental (second) 100 microgram tablet.

Do not use more than two (2) doses of ABSTRAL for each episode of breakthrough cancer pain. Wait at least 2 hours before treating another episode of breakthrough pain with ABSTRAL.

- If your pain is not relieved after the second supplemental dose, you cannot take another ABSTRAL tablet for at least 2 hours. Your doctor may recommend other pain medicines to relieve this episode of breakthrough pain
- If adequate pain relief was not achieved for an earlier episode of breakthrough cancer pain, your doctor may slowly increase the dose for your next episode(s) of breakthrough cancer pain until you find a dose that gives you adequate relief and without severe side effects. This is because everyone's pain is different and finding the right dose for you is important.

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 your doctor may need to change your regular medicines for the persistent cancer pain**
- Your doctor may adjust your ABSTRAL dose whenever changes to your regular pain medications are made.
- Once your persistent pain has been controlled, your doctor may need to change your dose of ABSTRAL further
- **Let your doctor know if your ABSTRAL dose is no longer providing pain relief. Your doctor will decide if your dose needs to be changed.**
- **Do not change doses of ABSTRAL or your other pain medicines on your own.**

When to take ABSTRAL

You can take ABSTRAL whenever you have an episode of breakthrough cancer pain; up to four (4) doses per day.

You must wait for at least two (2) hours before treating another episode of breakthrough pain with ABSTRAL.

- You can discontinue ABSTRAL when you no longer have any breakthrough cancer pain, but you must tell your doctor before you do so. You must also 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 any withdrawal symptoms your doctor will evaluate if you need medicine to reduce or eliminate these.

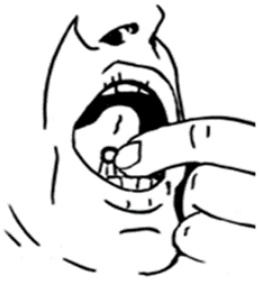
How to take ABSTRAL

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



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.

If you take too much ABSTRAL

If you or someone else receives too much ABSTRAL (overdose) or experiences one or more of the symptoms below, immediately call triple zero (000) for an ambulance. Keep the person awake by talking to them or gently shaking them every now and then. You should follow the above steps even if someone other than you accidentally takes ABSTRAL that was prescribed for you. If someone takes an overdose they may experience one or more of the following symptoms:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits.

If you think that you or someone else may have taken too much ABSTRAL, urgent medical attention may be needed. **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

When seeking medical attention, take this leaflet and remaining medicine with you to show the doctor. Also tell them about any other medicines or alcohol which have been taken.

5. What should I know while taking ABSTRAL?

Things you should do

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

Tell your doctor or pharmacist if you do not feel well while you are taking ABSTRAL

Call your doctor straight away if:

- You become pregnant while taking ABSTRAL
- Your breakthrough cancer pain does not improve.

Remind any doctor, dentist or pharmacist you visit that you are taking ABSTRAL. If you are going to have surgery, tell the surgeon or anaesthetist that you are taking ABSTRAL.

Things you should not do

- Do not take ABSTRAL to treat any other complaints unless your doctor or pharmacist tells you to
- Do not give your medicine to anyone else, even if they have the same condition as you
- Do not give ABSTRAL to anyone younger than 18 years of age
- Do not switch from ABSTRAL to other medicines that contain fentanyl without your doctor's advice as it can result in a fatal overdose. ABSTRAL is NOT interchangeable with other fentanyl products. Your doctor will prescribe starting and maintenance doses of the new fentanyl medicine if you are switched
- Do not substitute ABSTRAL for any other pain reliever. The use of ABSTRAL without dose titration or by individuals who have not already been taking regular opioid medication for at least one week may result in fatal overdose.
- 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.
- 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.

The below medical emergencies can cause death. 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

Driving or using machines

Do not drive or operate machinery while taking ABSTRAL as ABSTRAL may cause dizziness, drowsiness or blurred vision in some people.

Drinking alcohol

Tell your doctor if you drink alcohol.

Do not consume alcohol while taking ABSTRAL, as dizziness and drowsiness may become worse. There is an increased risk of decreased awareness, breathing difficulties, coma and death if taken at the same time as alcohol.

Looking after your medicine

- Keep your medicine where the temperature stays below 25°C
- Keep your medicine in the original pack until it is time to take it.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place, away from moisture, heat or sunlight; for example, do not store it:

- In the bathroom or near a sink, or
- In the car or on window sills.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

Keep this medicine in a safe and secure place where other people and young children cannot access it.

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

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or it is out of date, take all unused medicine to any pharmacy for safe disposal.

6. Are there any side effects?

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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects. Do not be alarmed by the following list of side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
General body-related: • headache, drowsiness, sleepiness, dizziness, tiredness • excessive sweating • dry mouth, sore mouth or mouth/gum/lip ulcers • blurred vision • low blood pressure • itchy skin rash, bruising • joint pain and stiffness • erectile dysfunction **Stomach and Bowel-related:** • nausea • vomiting • constipation • loss of appetite, stomach pain, indigestion • tongue disorder **Hormone-related:** • tiredness, weakness or low sex drive, nausea, infertility, anorexia	**Speak to your doctor if you have any of these less-serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
General body-related • unusual or extreme mood swings, anxiety, depression, change in mental status **Signs of taking too much ABSTRAL, or respiratory depression** • trouble breathing • pauses in breathing during sleep (sleep apnoea) • extreme drowsiness with slowed breathing • slow shallow breathing • feeling faint • dizziness • confusion or unconsciousness • inability to think, talk, or walk normally • hallucinations • tremors **Allergic reaction-related:** • sudden or rapidly developing rash, swelling, itchiness or hives on the skin • shortness of breath, wheezing or difficulty breathing or swallowing • swelling of face, lips, tongue, throat or other parts of the body **Heart-related:** • fast or slow heart beat **Stomach and Abdomen-related:** • difficulty swallowing, heart burn or pain in the chest not related to your heart • severe upper abdomen pain (gall bladder spasms or pancreatitis)	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ABSTRAL contains

Active ingredient (main ingredient)	fentanyl (as citrate)
Other ingredients (inactive ingredients)	• mannitol • microcrystalline cellulose • colloidal anhydrous silica • croscarmellose sodium • magnesium stearate

Do not take ABSTRAL if you are allergic to any of these ingredients. This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What ABSTRAL looks like

ABSTRAL 100 microgram tablets are white, round and flat with bevelled edges (AUST R 193332)

ABSTRAL 200 microgram tablets are white, oval-shaped and flat with bevelled edges (AUST R 193335)

ABSTRAL 300 microgram tablets are white, arc triangle-shaped and flat with bevelled edges (AUST R 228199)

ABSTRAL 400 microgram tablets are white, diamond-shaped and flat with bevelled edges (AUST R 193336)

ABSTRAL 600 microgram tablets are white, "D"-shaped and flat with bevelled edges (AUST R 228208)

ABSTRAL 800 microgram tablets are white, caplet-shaped and flat with bevelled edges (AUST R 228209)

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

Who distributes ABSTRAL

A. Menarini Australia Pty Ltd

Sydney, Australia

Medical Information: 1800 644 542

® = Registered Trademark

This leaflet was prepared in September 2025.

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

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