

B. BRAUN FENTANYL Injection

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 using B. BRAUN FENTANYL Injection?

B. BRAUN FENTANYL Injection contains the active ingredient fentanyl citrate. B. BRAUN FENTANYL Injection is used to provide short-term pain relief and to help anaesthesia when you have an operation. It is a strong painkiller for use in hospitals.

For more information, see Section [1. Why am I using B. BRAUN FENTANYL Injection?](#) in the full CMI.

2. What should I know before I use B. BRAUN FENTANYL Injection?

Do not use 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 use B. BRAUN FENTANYL Injection?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with B. BRAUN FENTANYL Injection 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 use B. BRAUN FENTANYL Injection?

- B. BRAUN FENTANYL is given by your doctor as an injection into a muscle or a vein.
- Your doctor will decide how much you need. It depends on your age, body weight, medical conditions and history.

More instructions can be found in Section [4. How do I use B. BRAUN FENTANYL Injection?](#) in the full CMI.

5. What should I know while using B. BRAUN FENTANYL Injection?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if you become pregnant.• Tell your doctor or pharmacist if you are about to start taking a new medicine.• Tell your doctor or nurse if you do not feel well after being given B. BRAUN FENTANYL.
Things you should not do	<ul style="list-style-type: none">• Do not use B. BRAUN FENTANYL to treat any other complaint unless your doctor says so.• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
Driving or using machines	<ul style="list-style-type: none">• B. BRAUN FENTANYL can have a negative effect on your alertness and ability to drive and operate machinery. Do not drive or operate machinery until your doctor says it is safe.
Drinking alcohol	<ul style="list-style-type: none">• Do not drink alcohol while using B. BRAUN FENTANYL.• B. BRAUN FENTANYL can increase the effect of alcohol.
Looking after your medicine	<ul style="list-style-type: none">• B. BRAUN FENTANYL should be kept in the pack until use, protected from light, in a cool dry place where the temperature stays below 30°C.• B. BRAUN FENTANYL will be kept in a locked cupboard in the hospital pharmacy or operating theatre.

For more information, see Section [5. What should I know while using B. BRAUN FENTANYL Injection?](#) in the full CMI.

6. Are there any side effects?

Common side effects include: dizziness, low or high or variable blood pressure, hiccups, blurred vision, nausea, vomiting, excessive sweating, itching, sedation, headaches, post-operative confusion or agitation, vein pain or inflammation, chills or lower body temperature, visual disturbance. Serious side effects include: difficulty breathing, muscle stiffness or involuntary movements, irregular heartbeat or cardiac arrest, allergic reactions, severe drowsiness, convulsions, loss of consciousness.

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**

B. BRAUN FENTANYL should only be used 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

B. BRAUN FENTANYL 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

B. BRAUN FENTANYL can cause life-threatening or fatal breathing problems (slow, shallow, unusual or no breathing), even when used as recommended. These problems can occur at any time during use, but the risk is higher when first starting B. BRAUN FENTANYL 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 while using B. BRAUN FENTANYL

Using B. BRAUN FENTANYL 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 minimize the dose and duration of use; monitor you for signs and symptoms of breathing difficulties and sedation. You must not drink alcohol while using B. BRAUN FENTANYL.

B. BRAUN FENTANYL Injection

Active ingredient(s): fentanyl citrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using B. BRAUN FENTANYL Injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using B. BRAUN FENTANYL Injection.**

Where to find information in this leaflet:

- [1. Why am I using B. BRAUN FENTANYL Injection?](#)
- [2. What should I know before I use B. BRAUN FENTANYL Injection?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use B. BRAUN FENTANYL Injection?](#)
- [5. What should I know while using B. BRAUN FENTANYL Injection?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using B. BRAUN FENTANYL Injection?

B. BRAUN FENTANYL Injection contains the active ingredient fentanyl citrate. B. BRAUN FENTANYL Injection belongs to a group of medicines known as narcotic analgesics or opioids. Fentanyl relieves pain by blocking the nerves in the brain that recognise pain messages from the body.

B. BRAUN FENTANYL Injection is used to provide short-term pain relief and to help anaesthesia when you have an operation. It is a strong painkiller for use in hospitals.

Your doctor may have prescribed B. BRAUN FENTANYL for another reason. Ask your doctor if you have any questions about why this medicine has been prescribed for you.

B. BRAUN FENTANYL may be addictive. Addiction is unlikely in patients who receive it under medical supervision.

You may be at more risk of addiction if:

- you or someone in your family have a strong history of drug and alcohol abuse or mental illness
- you require repeated injections of B. BRAUN FENTANYL
- you need increasingly larger doses of B. BRAUN FENTANYL to control your pain.

2. What should I know before I use B. BRAUN FENTANYL Injection?

Warnings

Do not use B. BRAUN FENTANYL Injection if:

- if you have an allergy to B. BRAUN FENTANYL, other strong pain killers or any of the ingredients. See Product Description at the end of this leaflet for a list of ingredients.
- if you suffer from asthma or if you are particularly prone to breathing difficulties (for example, in the case of head injury, coma or brain tumour).
- if you have taken a type of medicine known as monoamine oxidase inhibitors (MAOIs) within the last 14 days. These include phenelzine, moclobemide and tranylcypromine (for

depression) and selegiline (for Parkinson's disease).

- if you suffer from a condition known as myasthenia gravis which causes constant weakness of muscles as fentanyl may cause rigidity of thoracic muscles.
- in children less than two years old.
- if you are being treated long term for non-cancer pain.

Check with your doctor if you:

- have any other medical conditions including:
 - have a lung disease or breathing problems such as severe asthma, severe bronchitis or emphysema
 - have a brain disorder
 - know you have a slow or irregular heartbeat or heart problems
 - have or ever had kidney or liver problems
 - have an underactive thyroid gland
 - take any medicines that slows down your reactions (CNS depressants), especially benzodiazepines or related drugs
 - or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs ("addiction")
 - are a smoker
 - have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses
- take any medicines for any other condition

Fentanyl can cause sleep-related breathing disorders such as sleep apnoea and sleep related hypoxemia (low oxygen in the blood). The symptoms can include breathing pauses during sleep, night awakening due to shortness of breath, difficulties to maintain sleep or excessive drowsiness during the day.

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Fentanyl is excreted in human milk.

Children

- B. BRAUN FENTANYL is not recommended for use in children under 2 years.

B. BRAUN FENTANYL should not be used if the packaging is torn or shows signs of tampering. It should not be used

beyond the expiry date (month and year) printed on the pack.

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 B. BRAUN FENTANYL Injection and affect how it works. In particular, tell your doctor or pharmacist if you are taking any of the following:

- medicines which make you feel drowsy or slow to react (CNS depressants), such as benzodiazepines or related drugs, sleeping tablets, tranquillisers, alcohol, strong pain-killers or some illegal drugs. This also includes a group of medicines called neuroleptics, for example, droperidol.
- The dose of B. BRAUN FENTANYL may have to be decreased. Also, if you receive a strong painkiller or other CNS depressant after receiving B. BRAUN FENTANYL during surgery, the dose of the painkiller or other CNS depressants may need to be lowered to reduce the risk of potentially serious side effects such as breathing difficulties, with slow or shallow breathing, severe drowsiness and decreased awareness, coma and death.
- medicines known as monoamine oxidase inhibitors (MAOIs). These include phenelzine, moclobemide and tranylcypromine (for depression) and selegiline (for Parkinson's disease). They should be stopped for 14 days before B. BRAUN FENTANYL is given.
- medicines for depression known as selective serotonin re-uptake inhibitors (SSRIs) or serotonin norepinephrine re-uptake inhibitors (SNRIs). These include fluoxetine, paroxetine, sertraline and venlafaxine.
- ritonavir (a protease inhibitor used to treat HIV).
- medicines for infections such as voriconazole or fluconazole.
- Some painkillers for nerve pain (gabapentin and pregabalin).

These medicines may be affected by B. BRAUN FENTANYL or may affect how well B. BRAUN FENTANYL works. Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect B. BRAUN FENTANYL Injection.

4. How do I use B. BRAUN FENTANYL Injection?

How much to take / use

- Your doctor will decide how much B. BRAUN FENTANYL you need. This will depend on your age, body weight, medical conditions and history.
- In adults, the usual dose of B. BRAUN FENTANYL ranges from 50 micrograms to 100 micrograms depending on what it is being used for. Repeat doses may be given in some cases. If you are elderly, you may be given a lower dose of B. BRAUN FENTANYL.
- In children 2 to 12 years old, the usual dose ranges from 20 micrograms to 30 micrograms per 10 kg body weight. **B. BRAUN FENTANYL is not recommended for use in children under 2 years.**

How B. BRAUN FENTANYL Injection is given

B. BRAUN FENTANYL is given by your doctor as an injection into a muscle or a vein.

For how long B. BRAUN FENTANYL injection is given

- The doctor will decide for how long the medicine will be given.

If you are given too much B. BRAUN FENTANYL Injection

The doctor or the anaesthetist giving you B. BRAUN FENTANYL will be experienced in its use, so it is unlikely that you will be given too much.

In the unlikely event that overdose occurs, your doctor or the anaesthetist will take the necessary actions. The symptoms of overdose could include:

- Slow, unusual or difficult breathing
- Drowsiness, dizziness or unconsciousness
- Slow or weak heartbeat
- Nausea or vomiting
- Convulsions or fits
- Muscles stiffness
- Lowering of blood pressure
- Lowering of heart rate
- A brain disorder (known as toxic leukoencephalopathy)

If these symptoms occur, you may be administered another medicine (e.g. naloxone) to help reverse the effects.

If you think that you have been given too much B. BRAUN FENTANYL Injection, you may experience markedly weakened breathing and need urgent medical attention.

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.

5. What should I know while using B. BRAUN FENTANYL Injection?

Things you should do

- Always follow your doctor's instructions carefully.
- Tell your doctor if you become pregnant.
- Tell your doctor or pharmacist if you are about to start taking a new medicine.
- Contact your doctor if you experience severe upper abdominal pain possibly radiating to the back, nausea, vomiting or fever as this could be symptoms associated with inflammation of the pancreas (pancreatitis) and the biliary tract system.
- Tell your doctor or nurse if you do not feel well after being given B. BRAUN FENTANYL (see 6. Are there any side effects?).

You may have difficulty swallowing, regurgitation, chest pain that is not related to your heart, especially if you have been using this medicine for a long time.

Things you should not do

- Do not use B. BRAUN FENTANYL to treat any other complaint unless your doctor says so.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not drive or operate machinery until your doctor says it is safe to do so.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how B. BRAUN FENTANYL Injection affects you.

B. BRAUN FENTANYL can have a negative effect on your alertness and ability to drive and operate machinery. Do not drive or operate machinery until your doctor says it is safe.

Drinking alcohol

Tell your doctor if you drink alcohol.

B. BRAUN FENTANYL can increase the effect of alcohol. Do not drink alcohol while being given B. BRAUN FENTANYL.

Addiction

You can become addicted to B. BRAUN FENTANYL even if you take it exactly as prescribed. B. BRAUN FENTANYL may become habit forming causing mental and physical dependence. If abused, it may become less able to reduce pain.

Dependence

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

Tolerance

Tolerance to B. BRAUN FENTANYL may develop, which means that the effect of the medicine may decrease. If this happens, more may be needed to maintain the same effect.

Withdrawal

Continue taking your medicine for as long as your doctor tells you. If you stop having this medicine suddenly, your pain may worsen and you may experience some or all of the following withdrawal symptoms:

- Nervousness, restlessness, agitation, trouble sleeping or anxiety
- Body aches, weakness or stomach cramps
- Loss of appetite, nausea, vomiting or diarrhoea
- Increased heart rate, breathing or pupil size
- Watery eyes, runny nose, chills or yawning
- Increased sweating.

B. BRAUN FENTANYL given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn. Also, if women received this medicine during pregnancy, there is a risk that their newborn infants will experience neonatal withdrawal syndrome.

Looking after your medicine

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

B. BRAUN FENTANYL should be kept in the pack until use, protected from light, in a cool dry place where the temperature stays below 30°C.

B. BRAUN FENTANYL will be kept in a locked cupboard in the hospital pharmacy or operating theatre.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

The hospital staff looking after you will dispose of any remaining B. BRAUN FENTANYL appropriately.

B. BRAUN FENTANYL should not be used after the date (month and year) printed after "EXP". The anaesthetist will inspect B. BRAUN FENTANYL before use to determine that it is still within its use by date.

6. Are there any side effects?

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.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none">• dizziness• low or high or variable blood pressure which may cause headache, weakness or dizziness• hiccups• blurred vision• nausea, vomiting• excessive sweating• itching• an unusual sense of well being• sedation• headaches• post-operative confusion or agitation• neurological or airway complications of anaesthesia• vein pain or inflammation• chills or lowered body temperature• visual disturbance• sleep-related breathing disorders (central sleep apnoea syndrome)• pancreatitis – symptoms including severe upper abdominal pain, back pain or fever• spasm of sphincter of Oddi – symptoms including upper abdominal pain or bloating• adrenal insufficiency symptoms such as weakness, fatigue, lack of appetite, nausea, vomiting or lower blood pressure• androgen deficiency symptoms such as loss of libido, impotence (erectile dysfunction) or your menstrual cycle stops	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

If you become dependent on B. BRAUN FENTANYL and your injections are suddenly stopped or greatly reduced, you may experience withdrawal symptoms such as nausea, vomiting, diarrhoea, anxiety and shivering.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> difficulty in breathing (abnormally slow and/or weak breathing or increased breathing rate or a temporary cessation of breathing) muscle stiffness or involuntary muscle movements, including slow, stiff or jerking movements slow, fast or irregular heartbeat or cardiac arrest a feeling of choking which is caused by the spasm of the muscles around the voicebox allergic reactions such as skin rash, redness and swelling of the face, neck or throat severe drowsiness convulsions loss of consciousness 	<p>Tell your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

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 B. BRAUN FENTANYL Injection contains

Active ingredient (main ingredient)	fentanyl citrate
Other ingredients (inactive ingredients)	sodium chloride and water for injections
Potential allergens	None

Do not take this medicine if you are allergic to any of these ingredients.

What B. BRAUN FENTANYL Injection looks like

B. BRAUN FENTANYL injection is a clear, colourless solution. B. BRAUN FENTANYL contains 50 micrograms of fentanyl per mL (as fentanyl citrate). It is available in 2 mL and 10 mL glass ampoules. The 2 mL ampoule is available in boxes of 10 and the 10 mL ampoule is available in boxes of 5 and 10, for hospital use only.

100 micrograms/2 mL ampoule: AUST R 227122

500 micrograms/10 mL ampoule: AUST R 227124

Who distributes B. BRAUN FENTANYL Injection

B. Braun Australia Pty Ltd
Level 2, 4 Burbank Place
Norwest NSW 2153
Australia

Toll free number: 1800 251 705

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