

Fentanyl B. Braun Injection

FOR INTRAVENOUS OR INTRAMUSCULAR USE ONLY

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about B. BRAUN FENTANYL injection. 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 receiving B. BRAUN FENTANYL against the benefits this medicine is expected to have for you.

If you have any concerns about receiving SUBLIMAZE, ask your doctor or pharmacist.

Keep this leaflet with your medicine. You may need to read it again.

What B. BRAUN FENTANYL is used for

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.

B. BRAUN FENTANYL injection contains a medicine called fentanyl. It 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.

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.

Before you are given B. BRAUN FENTANYL

When you must not be given B. BRAUN FENTANYL

B. BRAUN FENTANYL should not be used:

- 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.
- in children less than two years old.

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.

Before you are given B. BRAUN FENTANYL

You must tell your doctor if:

- you are pregnant or planning to become pregnant
- you are breast feeding or wish to breastfeed. Fentanyl is excreted in human milk
- you have a lung disease or breathing problems
- you have a brain disorder
- you know you have a slow or irregular heart beat
- you have or have ever had kidney or liver diseases
- you are an alcoholic
- you have an underactive thyroid gland.

If you have not told your doctor or pharmacist about any of the above, tell them before you are given SUBLIMAZE.

Your doctor will decide whether or not to treat you with B. BRAUN FENTANYL or whether to adjust the dose or alter your treatment.

Taking other medicines

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

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, such as, sleeping tablets, tranquillisers or strong pain-killers.
- medicines for mental disorders or a group of medicine called 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).

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.

Effect on driving and operating machinery

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.

Effect of alcohol

B. BRAUN FENTANYL can increase the effect of alcohol.

Using B. BRAUN FENTANYL

How it is given

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

muscle or a vein. Your doctor will decide how much B. BRAUN FENTANYL you need. This will depend on your age, body weight, medical conditions and history.

Adults

The usual dose of B. BRAUN FENTANYL ranges from 25 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.

Children 2 to 12 years old

The usual dose ranges from 20 micrograms to 30 micrograms per 10 kg of body weight.

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

If you are given too much (overdose)

Immediate medical care is required. The main symptom is markedly weakened breathing.

If you think you or anybody else has taken too much SUBLIMAZE, contact your doctor, pharmacist or the Poisons Information Centre who will advise you what to do.

You can contact the Poisons Information Centre by dialing:

- Australia: 13 11 26

While you are given B. BRAUN FENTANYL

Things you must 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.

Things you must 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.

If you do not understand the instructions provided with this medicine, ask your doctor or pharmacist for help.

Side Effects

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some side effects. Do not be alarmed by this list of possible side effects. You may not experience any of them.

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

Tell your doctor immediately if you notice any of the following as you may need urgent medical care:

- 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 heart beat or cardiac arrest
- a feeling of choking which is caused by the spasm of the muscles around the voice box
- allergic reactions such as skin rash, redness and swelling of the face, neck or throat.
- severe drowsiness
- convulsions
- loss of consciousness

Tell your doctor if you experience any of the following:

- 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

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

After you have been given B. BRAUN FENTANYL

Keep B. BRAUN FENTANYL injection in the pack until use. Protect from light.

Keep B. BRAUN FENTANYL injection in a cool dry place where the temperature stays below 30°C.

Keep your medicines where children cannot reach them. A locked cupboard at least one-and-a-half metres (1.5 m) above the ground is a good place to store medicines.

Do not store B. Braun Fentanyl, or any other medicine, in the bathroom or near a sink. Do not leave medicines in the car or on window sills.

Heat and dampness can destroy some medicines.

Product Description

What it looks like

B. BRAUN FENTANYL injection is a clear, colourless solution. It is available in 2 mL, 5 mL and 10 mL glass ampoules.

Registration numbers

100 micrograms/2 mL ampoule:
AUST R XXXXX

250 micrograms/5 mL ampoule:
AUST R XXXXX

500 micrograms/10 mL ampoule:
AUST R XXXXX

Ingredients

B. BRAUN FENTANYL contains 50 micrograms of fentanyl per mL (as fentanyl citrate). The 2 mL ampoule contains 100 micrograms of fentanyl, the 5 mL ampoule contains 250 micrograms of fentanyl, and the 10 mL ampoule contains 500 micrograms of fentanyl.

B. BRAUN FENTANYL also contains sodium chloride and water.

Sponsor

B. Braun Australia Pty Ltd
17 Lexington Drive
Bella Vista NSW 2153
Australia

This leaflet was prepared in August 2014.