

# SUBLIMAZE<sup>®</sup> Injection

*Fentanyl*

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## Consumer Medicine Information

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### What is in this leaflet

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This leaflet answers some common questions about SUBLIMAZE 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 SUBLIMAZE 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.

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### What SUBLIMAZE is used for

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SUBLIMAZE 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.

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

SUBLIMAZE may be addictive. Addiction is unlikely in patients who receive it under medical supervision.

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### Before you are given SUBLIMAZE

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#### When you must not be given SUBLIMAZE

SUBLIMAZE should not be used:

- if you have an allergy to SUBLIMAZE, 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 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.

SUBLIMAZE 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 SUBLIMAZE

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 SUBLIMAZE 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 and tranylcypromine (for depression) and selegiline (for Parkinson's disease). They should be stopped for 14 days before SUBLIMAZE is given.
- ritonavir (a protease inhibitor used to treat HIV).

These medicines may be affected by SUBLIMAZE or may affect how well SUBLIMAZE 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**

SUBLIMAZE 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**

SUBLIMAZE can increase the effect of alcohol.

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## **Using SUBLIMAZE**

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### **How it is given**

SUBLIMAZE is given by your doctor as an injection into a muscle or a vein. Your doctor will decide how much SUBLIMAZE you need. This will depend on your age, body weight, medical conditions and history.

### **Adults**

The usual dose of SUBLIMAZE 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 SUBLIMAZE.

### **Children 2 to 12 years old**

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

**SUBLIMAZE 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 dialling:

- Australia: 13 11 26
- New Zealand: 0800 POISON or 0800 764 766.

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## **While you are given SUBLIMAZE**

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### **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 SUBLIMAZE 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.

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## **Side Effects**

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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
- postoperative 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.

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## **After you have been given SUBLIMAZE**

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Keep SUBLIMAZE injection in the pack until use. Protect from light.

Keep SUBLIMAZE 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 SUBLIMAZE, 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.

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## **Product Description**

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### **What it looks like**

SUBLIMAZE injection is a clear, colourless solution. It is available in 2 mL, 10 mL, and 20 mL glass ampoules. The 20 mL glass ampoule is not currently marketed. The 2 mL ampoule is available in boxes of 10, and the 10 mL and 20 mL ampoules are available in boxes of 5, for hospital use only.

### **Registration numbers**

100 micrograms/2 mL ampoule: AUST R 48263

500 micrograms/10 mL ampoule: AUST R 48264

1000 micrograms/20 mL ampoule (not currently marketed): AUST R 48265

### **Ingredients**

SUBLIMAZE contains 50 micrograms of fentanyl per mL (as fentanyl citrate). The 2 mL ampoule contains 100 micrograms of fentanyl, the 10 mL ampoule contains 500 micrograms of fentanyl, and the 20 mL ampoule (not currently marketed) contains 1000 micrograms (1 milligram) of fentanyl.

SUBLIMAZE also contains sodium chloride and water.

### **Sponsor**

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This leaflet was prepared in May 2011.

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