

SUBLIMAZE® Injection

Fentanyl

Consumer Medicine Information

WARNING

Limitations of use

SUBLIMAZE 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

SUBLIMAZE 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

SUBLIMAZE 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 SUBLIMAZE 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 SUBLIMAZE

Using SUBLIMAZE 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 using SUBLIMAZE.

What is in this leaflet

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.

What SUBLIMAZE is used for

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 opioid analgesics. 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.

You may be at more risk of addiction if:

- You or someone in your family have a history of drug and alcohol abuse or mental illness
- You require repeated injections of SUBLIMAZE

- You need increasingly larger doses of SUBLIMAZE to control your pain.

Before you are given SUBLIMAZE

When you must not be given SUBLIMAZE

SUBLIMAZE should not be used:

- if you have an allergy or known intolerance to fentanyl, other strong pain killers or any of the ingredients at the end of this leaflet - see Product Description 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.

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 such as severe asthma, severe bronchitis or emphysema
- you have a brain disorder
- you know you have a slow or irregular heart beat or heart problems
- you have or have ever had kidney or liver problems
- you or someone in your family have a history of drug and alcohol abuse or mental illness
- you have an underactive thyroid gland
- if you take any medicine that slows down your reactions (CNS depressants), especially benzodiazepines or related drugs.

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 (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 SUBLIMAZE may have to be decreased. Also, if you receive a strong painkiller or other CNS depressant after receiving SUBLIMAZE 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 SUBLIMAZE 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.

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.

Addiction

You can become addicted to SUBLIMAZE even if you take it exactly as prescribed.

SUBLIMAZE 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 SUBLIMAZE. Taking it may result in physical dependence. Physical dependence means that you may experience withdrawal symptoms if you stop taking SUBLIMAZE suddenly, so it is important to take it exactly as directed by your doctor.

Tolerance

Tolerance to SUBLIMAZE 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 rate or pupil size
- watery eyes, runny nose, chills or yawning
- increased sweating.

SUBLIMAZE given to the mother during labour can cause breathing problems and signs of withdrawal in the newborn.

Using SUBLIMAZE

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 or if you have a problem with your kidneys, 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)

The doctor or the anaesthetist giving you SUBLIMAZE will be experienced in its use, so it is

unlikely that you will be given too much.

In the unlikely event that an 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
- Muscle stiffness
- Lowering of blood pressure
- Lowering of heart rate

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

If you think you or anybody else has been given too much SUBLIMAZE, contact your doctor or nurse immediately 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

While you are given SUBLIMAZE

Things you must do

Tell your doctor or nurse if you do not feel well after being given SUBLIMAZE (see SIDE EFFECTS).

Things you must not do

Do not drive or operate machinery until your doctor says it is safe to do so.

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 nurse to answer any questions you may have.

Tell your doctor or nurse 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

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

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

Storage and disposal

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

SUBLIMAZE will be kept in a locked cupboard in the hospital pharmacy or operating theatre.

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

The hospital staff looking after you will dispose of any remaining SUBLIMAZE appropriately.

Product Description

What it looks like

SUBLIMAZE injection is a clear, colourless solution. 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 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

Ingredients

SUBLIMAZE contains 50 micrograms of fentanyl per mL (as fentanyl citrate). The 2 mL ampoule contains 100 micrograms of fentanyl, and the 10 mL ampoule contains 500 micrograms of fentanyl.

SUBLIMAZE also contains sodium chloride and water.

Sponsor

PIRAMAL CRITICAL CARE PTY

LIMITED

Level 20, Tower A, The Zenith

821 Pacific Highway

Chatswood

NSW 2067

Australia

Telephone: 1800413707

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