

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S6

SUBLIMAZE® 2 mL solution for injection

SUBLIMAZE® 10 mL solution for injection

Each 1 mL contains 0,05 mg (50 µg) fentanyl as fentanyl citrate.

Sugar free.

SUBLIMAZE should only be used in facilities where immediate access to life support is available.

Read all of this leaflet carefully before you are given SUBLIMAZE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. What SUBLIMAZE is and what it is used for
2. What you need to know before you are given SUBLIMAZE
3. How SUBLIMAZE will be given to you
4. Possible side effects
5. How to store SUBLIMAZE
6. Contents of the pack and other information.

1. What SUBLIMAZE is and what it is used for

What is SUBLIMAZE?

The active ingredient in SUBLIMAZE is fentanyl. It belongs to a group of strong painkillers, which

SUBLIMAZE has been prescribed to you and should not be given to anyone else. It can cause addiction, and you may get withdrawal symptoms if you stop taking it suddenly. Your doctor or health care provider should have explained how long you will be receiving it and when it is appropriate to stop, and how to do it safely.

What is SUBLIMAZE used for?

SUBLIMAZE is a strong painkiller. SUBLIMAZE is used to prevent or relieve pain during different types of surgery. It can be used for short operations (where you go home on the same day) or longer operations (where you may stay in hospital for a number of days).

High doses of SUBLIMAZE are also used to lower your natural breathing rate when you are on a ventilator. During major operations, it is used together with a sedative known as a neuroleptic to put you to sleep.

2. What you need to know before you are given SUBLIMAZE

You should not be given SUBLIMAZE if:

- you are hypersensitive (allergic) to fentanyl or any of the other ingredients of SUBLIMAZE (listed in section 6)
- you have previously had an allergic reaction to SUBLIMAZE or a similar painkiller, called opioid analgesics
- you are suffering from uncontrolled bronchial asthma or are in heart failure secondary to chronic lung disease
- you are suffering from respiratory depression, especially in the presence of cyanosis (blue-coloured skin caused by too little oxygen in your blood) and excessive bronchial secretion (mucus)
- you are in a coma (unconscious) due to a head injury or brain tumour, and conditions in which increased pressure in your skull/brain occurs
- you had an operation on your biliary tract

- you are taking monoamine oxidase inhibitors (medicine used to treat depression, panic or anxiety disorders, or Parkinson's disease) or within 14 days of stopping such treatment (see Other medicines and SUBLIMAZE)
- you have a problem with or are dependent on the use of alcohol (alcoholism).

SUBLIMAZE should not be administered to children 2 years of age or younger.

Warnings and precautions

Take special care with SUBLIMAZE:

- SUBLIMAZE is a strong painkiller and should be given only by your doctor or health care provider.
- SUBLIMAZE may weaken breathing. This may also occur some time after the operation. Therefore, you will remain under supervision for a while after the operation. If you experience severe drowsiness or breathing problems, tell a doctor or health care provider immediately.
- If you have a lung disease or breathing problems, a brain disorder, impaired thyroid, liver or kidney function: always inform your doctor of this to ensure optimal care.
- If you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- If you feel you need to take more SUBLIMAZE to get the same level of pain relief. This may mean you are becoming tolerant to the effects of SUBLIMAZE or are becoming addicted to it. Consult your doctor who will discuss your treatment and may change your dose or prescribe an alternative pain reliever.

SUBLIMAZE should be kept in a safe and secure place, not accessible by others, due to the risks and fatal outcome associated with accidental ingestion, misuse and abuse of SUBLIMAZE.

Receiving SUBLIMAZE regularly, particularly for a long time, can lead to addiction. Your doctor should have explained how long you will be using it for and when it is appropriate to stop, how to

Increasing the dose of SUBLIMAZE can make you more sensitive to pain. If this happens, you need to speak to your doctor about your treatment.

Addiction can cause withdrawal symptoms when you stop receiving SUBLIMAZE. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your doctor will discuss with you how your dose will be gradually reduced before stopping SUBLIMAZE. It is important that you do not stop receiving SUBLIMAZE suddenly, as you will be more likely to experience withdrawal symptoms.

SUBLIMAZE should only be used by those they are prescribed for. Receiving higher doses or more frequent doses of an opioid may increase the risk of addiction.

Opioid-induced hyperalgesia (OIH) occurs when an opioid, such as SUBLIMAZE, used for pain relief, causes an increase in pain (called hyperalgesia) or an increased sensitivity to pain (called allodynia). OIH is a condition that can occur at any dosage of SUBLIMAZE, but it may occur more often with higher doses and longer-term use. Talk to your doctor or health care provider if your pain increases, if you feel more sensitive to pain, or if you have new pain after receiving SUBLIMAZE.

SUBLIMAZE may lead to increased pressure in your bile duct (the tubes that carry bile from your liver to your intestines), and spasms of the sphincter of Oddi (causing the small muscle not to open when it should) due to its anticholinergic effect.

Tell your doctor or health care provider before receiving SUBLIMAZE if you have or have ever had:

- an underactive thyroid gland
- muscle weakness called myasthenia gravis
- low blood volume (excessive blood loss)

- a recent head injury.

If you are an elderly person or weak due to ill health, your doctor will carefully monitor the amount of SUBLIMAZE they give you. If you are not sure if any of the above applies to you, talk to your doctor or health care provider before receiving SUBLIMAZE.

Tell your doctor before receiving SUBLIMAZE if:

- you or anyone in your family have ever abused or been dependent on alcohol, prescription medicines or illegal drugs (“addiction”)
- you are a smoker
- you have ever had problems with your mood (depression, anxiety or a personality disorder) or have been treated by a psychiatrist for other mental illnesses.

Repeated use of opioid painkillers, as in SUBLIMAZE, may result in the medicine being less effective (you become accustomed to it). It may also lead to dependence and abuse which may result in life-threatening overdose. If you are concerned that you may become dependent on SUBLIMAZE, it is important that you consult your doctor.

If your SUBLIMAZE treatment is stopped, withdrawal symptoms may occur. Please tell your doctor or health care provider if you think this is happening to you (see section 4. Possible side effects).

Children and adolescents

SUBLIMAZE should not be given to children younger than 2 years of age.

Other medicines and SUBLIMAZE

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Occasionally, it is necessary to adapt the dose in the case of combined use. Your doctor will decide what dose is appropriate for you.

Tell your doctor if you are taking:

- Certain medicines for depression called monoamine oxidase (MAO) inhibitors that should not be combined with SUBLIMAZE. These medicines should not be taken in the 2 weeks before SUBLIMAZE is given.
- Certain other medicines for depression, called selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs), such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine.
- Other strong painkillers, for example opioid analgesics, such as morphine and codeine, especially if it is for a long time. Your dose may have to be adapted.
- Painkillers for nerve pain (gabapentin and pregabalin).
- Antiretroviral medicines used to treat HIV infection (e.g. ritonavir) as you may need less SUBLIMAZE.
- Alcohol, illegal drugs or other medicines regularly or if you are taking a medicine that slows your reactions (for example, sleeping pills, tranquillisers, medicine for mental disorders).
- Certain medicines for infections caused by fungi (e.g. fluconazole, ketoconazole, itraconazole) and other medicines e.g. erythromycin, diltiazem and cimetidine. Your dose of SUBLIMAZE may need adjustment.

SUBLIMAZE with food, drink and alcohol

Talk to your doctor before receiving SUBLIMAZE if you are or have ever been addicted to alcohol.

It is unlikely that food and beverages will make SUBLIMAZE less effective if taken at the same time.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or health care provider for advice before being given this medicine.

Pregnancy

If you are pregnant, you should inform your doctor, who will decide whether you should be given SUBLIMAZE or not.

Breastfeeding

If you are breastfeeding or wish to do so, it is better to discuss this first with your doctor.

SUBLIMAZE is excreted in human milk. Talk to your doctor about when you may begin breastfeeding following administration of SUBLIMAZE.

Driving and using machines

SUBLIMAZE may have a negative effect on alertness or driving ability. Before driving a vehicle or operating a machine, you should wait 24 hours after SUBLIMAZE has been given. Always ask your doctor's advice first.

SUBLIMAZE contains sodium

SUBLIMAZE 2 mL: This medicine contains less than 1 mmol sodium (23 mg) per 2 mL ampoule, that is to say it is essentially sodium free.

SUBLIMAZE 10 mL: This medicine contains 35,4 mg sodium (main component of cooking/table salt) in each 10 mL ampoule. This is equivalent to 1,8 % of the recommended maximum daily dietary intake of sodium for an adult.

If you need to control your salt intake (controlled sodium diet) be aware that the contents of the ampoule may be diluted in a salt solution before being given to you. This salt solution also contains sodium.

3. How SUBLIMAZE will be given to you

You will not be expected to administer SUBLIMAZE to yourself. Your doctor or health care provider will administer SUBLIMAZE to you in the hospital for a specific condition. SUBLIMAZE is injected

The amount of SUBLIMAZE you will be given depends on your situation. Your doctor will determine how much SUBLIMAZE you need based on your body mass, age and medical condition.

If more SUBLIMAZE is administered to you than should be

Since a health care provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

The main symptom is markedly weakened breathing.

If you missed a dose of SUBLIMAZE

Since a health care provider will administer SUBLIMAZE, it is unlikely that the dose will be missed.

4. Possible side effects

SUBLIMAZE can have side effects. Undesired effects may occur during your operation and are managed by your doctor. However, some may also occur after the operation; therefore, you will remain under supervision for a while after the operation.

Not all side effects reported for SUBLIMAZE is included in this leaflet.

Should your general health worsen or if you experience any untoward effects please consult your doctor, pharmacist or health care provider for advice.

If any of the following happens, stop administration of SUBLIMAZE immediately:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to SUBLIMAZE. You may need urgent medical attention.

Tell your doctor immediately if you notice any of the following:

- abnormally slow and/or weak breathing
- increased breathing rate or a temporary stopping of your breathing; spasms of the breathing
- slow, fast or irregular heartbeat; cardiac arrest (heart attack)
- convulsions (fits/seizures).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Very common side effects:

- muscle stiffness or involuntary muscle movements, including slow, stiff or jerking movements
- feeling sick (nausea) and being sick (vomiting).

Common side effects:

- agitation
- difficulty with body movements (dyskinesia)
- drowsiness (sedation)
- dizziness
- problems with vision
- low or high blood pressure
- pain in your veins
- choking caused by cramping (spasm) of the muscles in your throat
- skin rash
- confusion after the operation.

Uncommon side effects:

- changes in blood pressure
- fall in body temperature below normal or chills

- headache
- swelling and clotting in a vein
- hiccups
- feeling of extreme happiness
- difficulty in swallowing.

Side effects with an unknown frequency:

- delirium (characterised by symptoms such as a combination of agitation, restlessness, disorientation, confusion, fear, seeing or hearing things that are not really there, sleep disturbance, nightmares)
- addiction to or dependence on drugs
- loss of consciousness
- muscle twitching
- withdrawal syndrome (characterised by nausea, vomiting, diarrhoea, anxiety, chills, tremor and sweating).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SUBLIMAZE.

5. How to store SUBLIMAZE

- Store at or below 25 °C. Protect from light.
- Your doctor or health care provider will store SUBLIMAZE and will not keep SUBLIMAZE after the date (month and year) printed after “EXP”.

- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

6. Contents of the pack and other information

What SUBLIMAZE contains

The active ingredient in SUBLIMAZE is fentanyl.

Each 1 mL of solution contains 0,05 mg (50 µg) fentanyl as fentanyl citrate. The other ingredients are sodium chloride and water for injection.

What SUBLIMAZE looks like and contents of the pack

A clear, colourless solution.

Packed in cartons of 5 ampoules each.

Holder of Certificate of Registration

Piramal Critical Care (Pty) Ltd

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Kiepersol House

Stonemill Office Park

300 Acacia Road

Darrenwood 2194

Tel: 011 678 1948

This leaflet was last revised in

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Registration numbers

SUBLIMAZE 2 mL: B/2.7/1014

SUBLIMAZE 10 mL: Q/2.7/34

Piramal Critical Care South Africa (Pty) Ltd
SUBLIMAZE® 2 mL & 10 mL

Solution for injection
0,05 mg (50 µg) fentanyl (as fentanyl citrate) per 1 mL

Dates of registration

SUBLIMAZE 2 mL: 19 April 1984

SUBLIMAZE 10 mL: 21 January 1983