

**PROPOSED PATIENT INFORMATION LEAFLET: April 2017****Read all of this leaflet carefully before you start using this medicine**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**S6****SUBLIMAZE®**

SUBLIMAZE® 2 ml injection

SUBLIMAZE® 10 ml injection

**1. WHAT SUBLIMAZE CONTAINS**

The actual medicine in SUBLIMAZE is also called fentanyl. It belongs to the strong painkillers, which are also called opioids.

Each ml contains 0,0785 mg (78,5 µg) fentanyl citrate equivalent to 0,050 mg (50 µg) fentanyl base and sodium chloride and water.

**2. WHAT SUBLIMAZE IS USED FOR**

SUBLIMAZE is a strong painkiller that is used in hospitals.

SUBLIMAZE also strengthens the state of general loss of feeling (narcosis or anaesthesia) during surgery.

### **3. BEFORE YOU USE SUBLIMAZE**

#### **Do not use SUBLIMAZE:**

You should not be given SUBLIMAZE if you have previously had an allergic reaction to SUBLIMAZE or a similar painkiller.

You should not be given SUBLIMAZE if you are suffering from bronchial asthma or are in heart failure secondary to chronic lung disease.

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

#### **Take special care with SUBLIMAZE:**

Important!

SUBLIMAZE is a strong painkiller and should be given only by competent persons.

As with similar painkillers, SUBLIMAZE may weaken breathing. This may also occur sometime 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 nurse immediately.

#### **Lung diseases or breathing problems, brain disorders, impaired thyroid, liver or kidney function:**

Always inform your doctor to ensure optimal care.

#### **Pregnancy**

If you are pregnant, you should inform your doctor, who will decide if you should be given SUBLIMAZE.

**Breast-feeding**

If you are breast-feeding 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 breast-feeding following administration of SUBLIMAZE.

**Driving and operating machinery**

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

**Other medicines and alcohol**

You should always inform your doctor if you are taking other medicines on a regular basis, including complimentary or traditional medicines, the use of SUBLIMAZE with these medicines may cause undesirable interactions. Occasionally, it is necessary to adapt the dose in the case of combined use. Please consult your doctor, pharmacist or other healthcare professional for advice.

- Certain medicines for depression called MAO-inhibitors should not be combined with SUBLIMAZE. These medicines should not be taken in the 2 weeks before SUBLIMAZE is given.
- If you have been taking other strong painkillers for a long time, you should mention this to your doctor. The dose may have to be adapted.
- Tell your doctor if you are taking the protease inhibitor ritonavir, as you may need less SUBLIMAZE.
- You should also inform your doctor if you use alcohol or drugs regularly or if you are taking a medicine that slows your reactions (for example, sleeping pills, tranquillizers, medicine for mental disorders).

- Your doctor will need to know if you are using certain medicines for infections caused by fungi (e.g. fluconazole, ketoconazole) and other medicines e.g. erythromycin, diltiazem and cimetidine. The dose of SUBLIMAZE may need adjustment.

Not all side effects reported for this medicine is included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or healthcare professional for advice.

#### **4. HOW TO USE SUBLIMAZE**

SUBLIMAZE is injected into a vein (intravenous use).

The amount of SUBLIMAZE depends on the situation. Your doctor will determine how much SUBLIMAZE you need based on your weight, age and medical condition.

#### ***Information for the person administering SUBLIMAZE:***

See instructions at the end.

#### **5. POSSIBLE SIDE EFFECTS**

Undesired effects, if any, occur mainly during the operation and are managed by your doctor. Some may also occur shortly afterwards; therefore, you will remain under supervision for a while after the operation.

Examples include:

- abnormally slow and/or weak breathing or increased breathing rate or a temporary stopping of breathing; spasms of the breathing passages and voice box; hiccups;
- slow, fast or irregular heart beat or cardiac arrest; low or high or variable blood pressure;
- muscle stiffness or involuntary muscle movements, including slow, stiff or jerking movements;
- dizziness, nausea and vomiting may also occur;
- feeling of well-being or elation; sedation; headache; convulsions; or loss of consciousness;
- allergic reactions occur rarely and can be recognized, for instance, by skin rash or redness, itching, shortness of breath or swollen face;
- other complications relating to your procedure such as postoperative confusion or agitation, neurological complications or airway complications of the anaesthesia may also occur;
- undesirable effects such as vein pain or inflammation; chills or lowered body temperature or visual disturbance.

Do not hesitate to tell your doctor or the nurse about any bothersome or undesirable effects.

**OVERDOSE**

In the unlikely event that an overdose has been given, your doctor will take the necessary action. The main symptom is markedly weakened breathing.

***Information for the doctor in case of overdose******Immediate measures:***

*In case of hypoventilation or apnoea, administer oxygen and assist or control respiration.*

*Naloxone should be used to control respiratory depression. Bear in mind that additional doses may be required.*

***Other measures:***

*If muscular rigidity accompanies the depressed respiration, an intravenous neuromuscular blocking agent might be required.*

*If hypovolaemia contributes to severe or persisting hypotension, administering parenteral fluid should be considered.*

*Monitor patient carefully and provide additional supportive measures as required.*

**In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.**

**6. STORING OF SUBLIMAZE**

Store below 25 °C. Protect from light.

This medicine can be kept for only a limited period. Do not use SUBLIMAZE after the date (month and year) printed after "EXP", even it has been stored properly.

Keep all medicines out of the reach and sight of children

**7. PRESENTATION OF SUBLIMAZE**

2 ml ampoules packed in cartons of 5 and 30 ampoules.

10 ml ampoules packed in cartons of 5 ampoules.

**8. IDENTIFICATION OF SUBLIMAZE**

A clear, colourless solution.

**9. REGISTRATION NUMBER/ REFERENCE NUMBER**

2 ml: B/2.7/1014

10 ml: Q/2.7/34

**10. NAME AND ADDRESS OF REGISTRATION HOLDER**

Piramal Critical Care South Africa (Pty) Ltd

Office 2, Ground Floor, Kiepersol House,

300 Acacia Road, Darrenwood, 2194

**11. DATE OF PUBLICATION**

17 November 2009.

As per CCC  
Recommendations  
17 November  
2009.

## **INFORMATION FOR THE PERSON ADMINISTERING SUBLIMAZE**

### **DIRECTIONS FOR USE**

*The dosage of SUBLIMAZE should be individualized according to age, body weight, physical status, underlying pathological condition, use of other drugs, and type of surgery and anaesthesia.*

*The initial dose should be reduced in the elderly and in debilitated patients. The effect of the initial dose should be taken into account in determining supplemental doses.*

*To avoid bradycardia, it is recommended to administer a small intravenous dose of an anti-cholinergic just before induction. Droperidol may be given to prevent nausea and vomiting.*

#### **- Use as an analgesic supplement to general anaesthesia**

*Low dose: 2 µg/kg.*

*SUBLIMAZE in small doses is most useful for minor, but painful, surgery.*

*Moderate dose: 2-20 µg/kg*

*Where surgery becomes more complicated, a larger dose will be required. The duration of activity is dependent on dosage.*

*High dose: 20-50 µg/kg*

*During major surgical procedures, in which surgery is longer, and during which the stress response would be detrimental to the well-being of the patient, dosages of 20-50*

*µg/kg of SUBLIMAZE with nitrous oxide/oxygen have been shown to have an attenuating effect. When dosages in this range have been used during surgery, post-operative ventilation and observation are essential in view of the possibility of extended post-operative respiratory depression.*

*Supplemental doses of 25-250 µg (0.5-5 ml) should be tailored to the needs of the patient and to the anticipated time until completion of the operation.*

**- Use as an anaesthetic agent**

*When attenuation of the response to surgical stress is especially important, doses of 50-100 µg/kg may be administered with oxygen and a muscle relaxant. This technique provides anaesthesia without necessitating the use of additional anaesthetic agents. In certain cases, doses up to 150 µg/kg may be required to produce this anaesthetic effect. SUBLIMAZE has been used in this fashion for open heart surgery and certain other major surgical procedures in patients for whom protection of the myocardium from excess oxygen demand is particularly indicated.*

**- Use in the elderly**

*As with other opioids, the dose should be reduced in elderly or debilitated patients.*

**- Use in children**

*For induction and maintenance in children aged 2-12 years, a dose of 2-3 µg/kg is recommended.*

**INSTRUCTIONS FOR USE**

*If desired, SUBLIMAZE may be mixed with sodium chloride or glucose intravenous infusions. Such dilutions are compatible with plastic infusion sets. These should be used within 24 hours of preparation.*