

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sublimaze[®] 50 micrograms/ml solution for injection

Fentanyl (as citrate)

Sublimaze is a registered trademark

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or nurse
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours
- If you get any side effects talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4

What is in this leaflet

- 1 What Sublimaze is and what it is used for
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What Sublimaze is and what it is used for

Sublimaze contains a medicine called fentanyl citrate. It belongs to a group of medicines called 'opioid analgesics'. Sublimaze is a strong painkiller that works for a short period of time.

Sublimaze is used to prevent or relieve pain during different types of surgery. It can be:

- Used alone for short operations, when you go home on the same day
- Used with other medicines (anaesthetics) to put you to sleep for longer operations when 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 (a machine to help you breathe). During major operations, it is used with a sedative known as a neuroleptic to put you to sleep.

What you need to know before you take Sublimaze

Do not have Sublimaze if:

- You are allergic to anything in Sublimaze (listed in section 6 below)
- You are allergic to other strong medicines for pain called 'opioid analgesics'
- You suffer from breathing difficulties called 'obstructive airways disease' or 'respiratory depression' or you have a large amount of phlegm or asthma
- You are having an operation on your gallbladder

Do not have this medicine if any of the above applies to you. If you are not sure, talk to your doctor or nurse before you are given Sublimaze.

Warnings and precautions

Tell your doctor before using [fentanyl solution of injection product] 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 may result in the drug 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 have concern that you may become dependent on Sublimaze, it is important that you consult your doctor.

In particular, tell your doctor or pharmacist if you are taking:

- Some painkillers for nerve pain (gabapentin and pregabalin).

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

Please tell your doctor if you are pregnant, might become pregnant or are breast-feeding (see Pregnancy section for more information).

Tell your doctor or pharmacist if you have experienced increased sensitivity to pain despite the fact that you are taking increasing doses (hyperalgesia). Your doctor will decide whether you will need a change in dose or stop taking this medicine.

Check with your doctor or nurse before you are given this medicine if you have or have ever had:

- Problems with your lungs, liver or kidneys
- An underactive thyroid gland
- Problems with alcohol (alcoholism)
- Low blood volume
- A recent head injury or problems with blood pressure in the brain
- If you suffer from a condition in which muscles become weak and tire easily, known as myasthenia gravis
- Certain medicines for depression called Selective Serotonin Re-uptake Inhibitors (SSRIs), Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs) or Monoamine oxidase inhibitors (MAOIs), as they may increase the risk of a condition called serotonin syndrome. (See section 4 for the signs and symptoms of serotonin syndrome. Also see section ‘Other medicines and Sublimaze’)

Your doctor will carefully monitor the amount of Sublimaze given to you. If you

are not sure if any of the above applies to you, talk to your doctor or nurse before having Sublimaze.

Special monitoring

- Sublimaze may make you breathe more slowly. Your breathing will be carefully monitored until it returns to normal
- Your blood pressure and heart rate may also be monitored

Other medicines and Sublimaze

Please tell your doctor or nurse if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription or herbal medicines.

In particular, do not have this medicine and tell your doctor or nurse if you have taken:

- Medicines for depression called 'monoamine oxidase inhibitors' (MAOIs) in the past two weeks (such as phenelzine, isocarboxazid, tranylcypromine, moclobemide)

If this applies to you, do **not** have Sublimaze.

It is also important to talk to your doctor or nurse if you are taking any of the following:

- Medicines for depression called Selective Serotonin Re-uptake Inhibitors (SSRIs), Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs) (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine).

See section 'Warnings and precautions' above.

The effects of Sublimaze or any of the following medicines may be increased when they are taken together:

- Other strong painkillers, for example 'opioid analgesics'
- Medicines for anxiety or to help you sleep called tranquillisers or sleeping pills (such as midazolam)
- Medicines that affect your central nervous system (CNS depressants) such as medicines for mental disorders
- Medicines for HIV infection (called antiviral protease inhibitors) such as ritonavir
- Medicines for heart problems or high blood pressure called 'beta-blockers'
- Medicines for fungal infections (such as fluconazole or voriconazole)
- Cimetidine - for ulcers, stomach ache and heartburn

Concomitant use of Sublimaze and benzodiazepines (that can help to reduce anxiety and seizures, relax the muscles, and induce sleep) increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However if your doctor does prescribe Sublimaze together with benzodiazepines and related drugs the dosage and duration of concomitant treatment should be limited by your doctor. Please tell your doctor about all medicines you are taking, and follow your doctor's dosage recommendation closely. It could be helpful to inform friends or relatives to

be aware of sign and symptoms stated above. Contact your doctor when experiencing such symptoms.

Talk to your doctor before having Sublimaze if you are taking any of these medicines. They may have to change the amount of Sublimaze or the other medicines you are given.

The effects of Sublimaze or the following medicines may also be changed when they are taken together, but your doctor will know about these:

- Medicines for putting you to sleep called 'anaesthetics' such as alothane or etomidate
- Medicines to relax the muscles during surgery such as suxamethonium and vecuronium

You should also tell your doctor if you take alcohol regularly.

Pregnancy and breast-feeding

You must tell your doctor before having Sublimaze if you are pregnant or think you may be pregnant.

You may still be able to have Sublimaze if your doctor thinks you need to.

Sublimaze should not be used during childbirth as it can affect the baby's breathing.

Sublimaze may get into breast milk. Do not breast-feed or use breast milk that has been expressed during 24 hours after having Sublimaze.

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

If women receive this drug during pregnancy, there is a risk that their newborn infants will experience neonatal withdrawal syndrome.

Driving and using machines

Do not drive or use any tools or machines for at least 24 hours after having Sublimaze. You may be less alert than usual.

Sublimaze contains sodium

If you need to control your salt intake (controlled sodium diet) be aware that:

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

For SUBLIMAZE 10 ml ampoule: 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.

How to take Sublimaze

Sublimaze is given in hospital by a doctor experienced in using this type of medicine. Check with your doctor or nurse if you are not sure about anything.

How Sublimaze is given

- Sublimaze is given as an injection into a vein or as a drip (infusion)

- You may be given an anaesthetic at the same time
- You may be given other medicines to help with some of the side effects of Sublimaze such as slower heart rate and rigid muscles

How much Sublimaze is given

Your doctor will decide how much Sublimaze you need. This may depend on:

- Your body weight
- Your general health
- Your age
- The reason you are being given it
- Other medication

Sublimaze given during anaesthesia If you are to breathe by yourself

- adults

- The usual dose is 0.5 to 10 micrograms per kilogram of body weight or 0.5 to 5 micrograms per kilogram of body weight per hour given as a drip

- children

- The usual dose is 1 microgram per kilogram of body weight

When your breathing is helped by a machine (ventilator)

- adults

- The initial dose is up to 600 micrograms
- If necessary, further injections of 50 - 200 micrograms will be given during the operation

- children

- The usual dose is 1 microgram per kilogram of body weight

If you are also being given a sedative (neuroleptic)

- adults

- The usual initial dose is 100 micrograms
- If necessary, further injections of 50 micrograms will be given during the operation

Sublimaze given on its own for pain relief

- adults

- The usual initial dose is 100 - 800 micrograms
- If necessary, further injections of 50 micrograms will be given during the operation, with a ventilator to help your breathing

- children

- The usual initial dose is 10 micrograms per kilogram of body weight
- If necessary, further injections of 1 microgram per kilogram of body weight will be given during the operation, with a ventilator to help your breathing

Elderly or weak patients

Less Sublimaze may be used if you are elderly or weak due to ill health.

If you have too much Sublimaze

It is unlikely that you will be given too much Sublimaze. This will be carefully monitored during your operation.

Overdosing can cause a brain disorder (known as toxic leukoencephalopathy).

Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your doctor will monitor these effects during your operation.

Very common (affects more than 1 in 10 people)

- Feeling sick (nausea), being sick (vomiting)
- Muscle stiffness (which may involve your chest muscles)

Common (affects fewer than 1 in 10 people)

- Difficulty with body movements
- Drowsiness
- Dizziness
- Problems with vision
- Irregular heartbeat (slow or fast)
- Low or high blood pressure
- Pain in your veins
- Choking caused by cramping (spasm) of the muscles in your throat
- Difficulty in breathing or wheezing
- Stop breathing for a short period of time. If necessary, your breathing will be helped by a machine (ventilator)
- Skin rash
- Confusion after the operation
- Nervous system complications

Uncommon (affects fewer than 1 in 100 people)

- Changes in blood pressure
- Breathing complications
- Breathing faster than normal
- Fall in body temperature below normal or chills
- Headache
- Agitation after the operation
- Swelling or clotting in a vein
- Feeling of extreme happiness
- Hiccups
- Difficulty in swallowing.

Other side effects (frequency not known):

- Serious allergic reaction which may cause difficulty in breathing, wheezing or coughing, itching, and hives or nettle rash (urticaria)
- Convulsions (fits or seizures)
- Loss of consciousness, semi-consciousness or coma
- Muscle twitching

- Stopping of the heart
- Slow or shallow breathing
- Itching of the skin
- Symptoms of withdrawal syndrome (may manifest by the occurrence of the following side effects: nausea, vomiting, diarrhoea, anxiety, chills, tremor, and sweating)
- Delirium (symptoms may include a combination of agitation, restlessness, disorientation, confusion, fear, seeing or hearing things that are not really there, sleep disturbance, nightmares)

Other side effects when Sublimaze is used together with medicines called neuroleptics, which can be given before or during an operation:

- Shivering and restlessness
- Seeing things that aren't there (hallucinations)
- Unusual movements, including trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk and stiffness of the arms and legs

Using Sublimaze together with certain medicines for depression called Selective Serotonin Re-uptake Inhibitors (SSRIs), Serotonin Norepinephrine Re-uptake Inhibitors (SNRIs) or Monoamine oxidase inhibitors (MAOIs)

The risk of serotonin syndrome may be increased when Sublimaze is used together with some antidepressant medicines (see section 'Other medicines and Sublimaze').

Serotonin syndrome may include:

- Increase in heart rate
- Seeing things that aren't there (hallucinations)
- Fever, shivering and sweating
- Muscle twitching, jerking and stiffness
- Feeling agitated or confused
- Feeling sick or being sick
- Diarrhoea

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

How to store Sublimaze

Keep out of the sight and reach of children. Do not store above 30°C. Keep the ampoules in the outer carton to protect from light.

Sublimaze ampoules are for single use only. The product should be used immediately after opening. Discard any unused contents.

Sublimaze will not be used after the expiry date stated on the carton and label. The expiry date refers to the last day of that month.

Contents of the pack and other information

What Sublimaze contains

- **The active substance** is fentanyl citrate. Each millilitre (ml) contains the equivalent of 50 micrograms of fentanyl.
- **The other ingredients** are sodium chloride and water for injections.

What Sublimaze looks like and contents of the pack

Sublimaze is supplied in a clear glass ampoule containing 2 ml (packs of 10) or 10 ml (packs of 5) of liquid.

Marketing Authorisation Holder:

Piramal Critical Care B.V.

Rouboslaan 32,

2252TR,

Voorschoten,

The Netherlands

Manufacturer:

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**For information in large print, tape, CD or Braille, telephone
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This leaflet was last revised in March 2024.