

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sublimaze®

50 micrograms/ml solution for injection or infusion

Fentanyl citrate

This medicine contains Fentanyl Citrate, which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

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
2. What you need to know before you take Sublimaze
3. How to take Sublimaze
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

This medicine has been prescribed for you for pain relief. It contains Fentanyl citrate which belongs to a class of medicines called opioids, which are 'pain relievers'. This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it and when it is appropriate to stop, and how to do it safely.

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
- 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. It can also be used to relieve severe pain such as during a heart attack.

2. 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'. You may only be able to have Sublimaze if your breathing is helped by a machine called a ventilator
- You are in labour or before the cord is clamped during a Caesarean section, Sublimaze may affect the baby's breathing.

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

Warnings and precautions

Talk to your prescriber before taking this medicine if you:

- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Sublimaze to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.

Addiction can cause withdrawal symptoms when you stop taking this medicine. 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 prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

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

- Problems with your lungs, liver or kidneys
- An underactive thyroid gland
- Problems with alcohol (alcoholism)

- A muscle weakness called 'myasthenia gravis'
- Long-term treatment with strong painkillers
- Low blood volume
- A recent head injury
- If you are elderly 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 nurse before having Sublimaze.

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).

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

If this applies to you, do not have Sublimaze

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

- Selective Serotonin Reuptake Inhibitors (SSRIs) or Serotonin Norepinephrine Reuptake Inhibitors (SNRIs) for depression (such as citalopram, duloxetine, escitalopram, fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine)

The effects of Sublimaze or any of these medicines may be increased when they are taken together

- Other strong medicines for pain, for example 'opioid analgesics' such as morphine or codeine
- Medicines for putting you to sleep called 'anaesthetic agents'
- Medicines for anxiety or to help you sleep such as tranquillisers or sleeping pills
- Medicines that affect your central nervous system (CNS depressants) such as medicine for mental disorders or alcohol
- Medicines for HIV infection (called antiviral protease inhibitors) such as ritonavir, indinavir or saquinavir
- Medicines for treating a fungal infection such as fluconazole or voriconazole

The dose of etomidate and midazolam may need to be reduced if given together with Sublimaze.

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.

Sublimaze with benzodiazepines

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.

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.

This medicine can affect your ability to drive as it may make you sleepy or dizzy.

- Do not drive while taking this medicine until you know how it affects you.

- It is an offence to drive if this medicine affects your ability to drive.
- However, you would not be committing an offence if:
 - The medicine has been prescribed to treat a medical or dental problem and
 - You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
 - It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Sublimaze contains sodium

For Sublimaze 2 ml ampoules: 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.

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 to take Sublimaze

Sublimaze is given 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 a drip (infusion) or injection into a vein or a muscle
- 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 in kilograms
- Your general health
- Your age
- The reason you are being given it
- Other medication

Sublimaze given by injection

If you are to breathe by yourself

- adults and children aged 12 to 17 years old:

- You will usually be given an initial dose of 50 - 200 micrograms
- If necessary, you will be given further injections of 50 micrograms during the operation

- children aged 2 to 11 years old:

- You will usually be given an initial dose of 1 - 3 micrograms per kilogram

- If necessary, you will be given further injections of 1 - 1.25 microgram per kilogram during the operation

When your breathing is helped by a machine (ventilator)

- adults and children aged 12 to 17 years old:

- The initial dose will be 300 - 3500 micrograms
- If necessary, further injections of 100 - 200 micrograms will be given during the operation

- children aged 2 to 11 years old:

- You will usually be given an initial dose of 1 - 3 micrograms per kilogram
- If necessary, you will be given further injections of 1 - 1.25 micrograms per kilogram during the operation

Sublimaze given as a drip (infusion)

- The dose of Sublimaze is based on body weight in kilograms
- You may be given an initial dose of 1 microgram per kilogram during each minute for the first 10 minutes
- If necessary, this may be followed by 0.1 micrograms per kilogram during each minute of your operation
- The drip will normally be stopped 40 minutes before the end of your operation

Elderly patients

Less Sublimaze may be used in patients that 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 monitored during your operation. The overdose symptom include: A brain disorder (known as toxic leukoencephalopathy)

Your prescriber should have discussed with you, how long the course of drip (infusion) will last.

They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

If you stop taking Sublimaze

Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

Pregnancy and breast-feeding

Do not take Sublimaze if you are pregnant or think you might be pregnant unless you have discussed this with your prescriber and the benefits of treatment are considered to outweigh the potential harm to the baby.

If you use Sublimaze during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

Do not take Sublimaze while you are breastfeeding as fentanyl passes into breast milk and will affect your baby.

4. 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)

- Agitation
- 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
- Stopping breathing for a short period of time. If necessary, your breathing will be helped by a machine (ventilator)
- Skin rash
- Confusion after the operation

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
- Swelling and clotting in a vein
- Hiccups
- Feeling of extreme happiness

Other side effects (frequency not known):

- Serious allergic reaction which may cause difficulty in breathing or dizziness, and hives or nettle rash (urticaria)
- Convulsions (fits or seizures)
- Loss of consciousness
- 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

Unknown frequency:

dependence and addiction (see section "How do I know if I am addicted?").

Drug Withdrawal

When you stop taking Sublimaze, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?

If you notice any of the following signs whilst taking Sublimaze, it could be a sign that you have become addicted.

- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard

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

5. How to store Sublimaze

Sublimaze is kept out of the sight and reach of children. It is stored in a Controlled Drug Store in the hospital pharmacy. Do not store above 30°C. Keep the ampoules in the outer carton to protect from light.

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

6. Contents of the pack and other information

What Sublimaze contains

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

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 Limited
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