

**1.4.3. PATIENT INFORMATION LEAFLET (PIL)**

**VERMOR-10**

**Morphine Sulphate Injection BP 10mg/ml-1ml**

**Read all of this leaflet carefully before you start receiving 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.
- 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.

**This medicine contains morphine which is an Opioid, which can cause addiction. You can get withdrawal symptoms if you stop receiving it suddenly.**

What is in this leaflet?

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

**1. What Morphine Injection is and what it is used for**

This medicine has been prescribed for you to relieve severe or very severe pain.

It contains morphine 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 receiving it suddenly. Your prescriber should have explained how long you will be receiving it for and when it is appropriate to stop, how to do this safely.

## **2. What you need to know before you are given Morphine Injection**

### **You must NOT be given Morphine Injection:**

- If you are allergic to morphine or any of the other ingredients of this medicine (listed in section 6)
- If you have a breathing disorder
- If you have a head injury or raised pressure around your brain.
- If you have a convulsive disorder (epilepsy) or suffer from fits (seizures).
- If you have acute alcohol poisoning (intoxication).
- If you suffer from liver or kidney failure • if you have a narrowing of the tubes leading to your bladder.
- If you have inflammation of your pancreas
- If you have impaired function of your gallbladder.
- If you have an inflammation of your bowel or a bowel obstruction.
- If you have low blood pressure with a lack of adequate circulatory filling
- If you suffer from an enlarged prostate gland. • if you have a thyroid problem
- If you have Phaeochromocytoma - a tumour of the adrenal gland
- If you are taking any of the antidepressant medicines known as monoamine oxidase inhibitors (MAOIs) or have taken them during the last two weeks.
- If you are unconscious (coma).

**Warnings and precautions:** Tell your doctor or nurse before being given Morphine Injection:

- If you have low blood pressure
- If you have an under-active thyroid gland
- If you have asthma or other breathing difficulties
- If you have kidney or liver disorders
- If you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.

- If you have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.

Talk to your doctor or nurse if you experience any of the following symptoms while using Morphine Injection:

- Increased sensitivity to pain despite the fact that you are using increasing doses (hyperalgesia). Your doctor will decide whether you will need a change in dose or a change in strong analgesic (“painkiller”), (see section 2).
- Weakness, fatigue, lack of appetite, nausea, vomiting or low blood pressure. This may be a symptom of the adrenals producing too little of the hormone cortisol, and you may need to take a hormone supplement.
- Loss of libido, impotence, cessation of menstruation. This may be because of decreased sex hormone production.
- If you feel you need to take more of Morphine Injection 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.

Receiving this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be receiving 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 receiving 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 receiving the medicine suddenly as you will be more likely to experience withdrawal symptoms.

Opioid 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.

**Children:**

This medicine is not recommended for use in children under 12 years of age. If you have any concerns ask your doctor or pharmacist.

**Other medicines and Morphine Injection:** Tell your doctor or nurse if you are using or have recently used or might use any other medicines, including medicines obtained without a prescription. This is especially important if you are taking any of the medicines mentioned below or medicines for:

- Rifampicin to treat e.g. tuberculosis
- Concomitant use of Morphine Injection and sedative medicines such as benzodiazepines or related drugs 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 Morphine Injection together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

- Monoamine oxidase inhibitors - MAOIs (medicines used for depression) or if you have taken them during the last two weeks.
- Drugs that depress the nervous system (your doctor or pharmacist will know what these are).
- Other painkillers - especially pentazocine, nalbuphine, or buprenorphine.
- Muscle relaxants.
- Diuretics (water tablets) - drugs that increase urine excretion.
- Cimetidine - an anti-ulcer treatment
- Antiarrhythmics - drugs to control heart rhythm or rate (e.g. mexiletine).
- Drugs used to treat depression.
- Drugs used to treat anxiety.
- Medicines to help you sleep.
- Drugs for treatment of digestive tract disorders (e.g. cisapride).

- Drugs used for Parkinson's Disease
- Drugs used to treat vomiting or indigestion (e.g. domperidone or metoclopramide).
- Some medicines used to treat blood clots (e.g. clopidogrel, prasugrel, ticagrelor) may have delayed and decreased effect when taken together with morphine

**Morphine Injection and alcohol:**

Alcohol should be avoided during treatment.

**Pregnancy and breast feeding:**

You should not be given Morphine Injection 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 receive Morphine Injection during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.

You should not be given Morphine Injection while you are breastfeeding as morphine passes into breast milk and will affect your baby.

**Driving and using machines:** You should not drive or use machinery while receiving Morphine Injection.

The 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.

**3. How Morphine Injection is given**



Your nurse or doctor will give you the injection. Your doctor will decide the correct dosage for you and how and when the injection will be given.

Your prescriber should have discussed with you, how long the course of Morphine 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 are given more Morphine Injection than you should**

Since the injection will be given to you by a doctor or nurse, it is unlikely that you will be given too much. People who have taken an overdose may get pneumonia from inhaling vomit or foreign matter; symptoms may include breathlessness, cough and fever. People who have taken an overdose may also have breathing difficulties leading to unconsciousness or even death. If you think you have been given too much, you must tell the person giving you the injection. Tell your doctor or nurse immediately if any of the following symptoms of overdose occur:

- Shallow breathing
- Blue skin
- Contraction of the pupils
- feeling extremely sleepy
- Muscle weakness
- Cold and clammy skin
- Very slow heart rhythm
- Fall in blood pressure

**If you stop being given Morphine Injection**

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.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Important side effects or symptoms to look out for and what to do if you are affected:

- **Serious allergic reaction which causes difficulty in breathing or dizziness; swelling of the eyelids, face or lips; rash or itching (especially affecting your whole body).**

If you are affected by these important side effects contact a doctor **immediately**.

The **other** following side effects have been reported:

#### **Very common: may affect more than 1 in 10 people**

- Feeling sick (nausea)• vomiting
- Shallow breathing
- Constipation
- Sleepiness
- Not knowing where you are (disorientation)
- sweating
- A perception of seeing or hearing things (hallucinations)
- Uncomfortable mood• feeling of very intensive happiness and well-being (euphoria)
- Tolerance and dependence (with long-term treatment)

#### **Common: may affect up to 1 in 10 people**

- Irregular skin patches and itching• pain at injection site
- Headache
- Dizziness
- Agitation
- Fits
- Impairment of taste
- Mood changes
- Changes in psychological functions and senses
- Sleeplessness (insomnia)
- High pressure in your brain (you may have a headache and feel sick or vomit)
- Involuntary trembling and quivering

- Muscle cramps
- Contraction of the pupils
- Visual problems
- Dry mouth
- Stomach pain
- Hiccups
- Diarrhea
- Gallbladder spasms with stomach pain
- Flushing
- chills
- Slow or fast heartbeat
- High blood pressure
- Heart failure
- Fluid in the lungs• spasms in the throat
- Asthma-like symptoms
- Decreased ability to cough
- Problems with urination
- Impotence
- swelling of the skin
- feeling hot or cold
- Abstinence symptoms or dependence (for symptoms see section 3: If you stop being given Morphine Injection).

**Not known: frequency cannot be estimated from the available data**

- An increased sensitivity to pain
- Dependence and addiction (see section “How do I know if I am addicted?”)

**Drug Withdrawal**

When you stop receiving Morphine Injection, 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 receiving Morphine Injection, 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 receiving 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

If you think this injection is causing you any problems, or you are at all worried, talk to your doctor, nurse or pharmacist.

**5. How to store Morphine Injection**

Keep this medicine out of the sight and reach of children. Store at a temperature not exceeding 30°C. Protect from light.

**6. Contents of the pack and other information what Morphine Injection contains:**

The active substance is morphine sulfate. In Morphine Injection, each 1 ml of solution contains 10 mg of morphine sulfate.

The other ingredients are:

Di Sodium E.D.T.A

Sodium Chloride

Tri sodium Citrate Dihydrate

Citric Acid (anhydrous)

Water for Injection.

**What Morphine Injection looks like and contents of the pack:**

A colourless or almost colourless solution filled in 1 ml amber glass ampoules.

**MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESSES**

**Marketing Authorization Holder**

Verve Human Care Laboratories

15-A, Pharmacy,

Selaqui, Dehradun-248011

India

**Manufacturing Site:**

Verve Human Care Laboratories

15-A, Pharmacy,

Selaqui, Dehradun-248011

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VERVE



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