

Professional Information Leaflet (PIL)

For Medicines for Human Use

MORPHINE 10 mg UNIMED (Injection)

MORPHINE 15 mg UNIMED (Injection)

SCHEDULING STATUS

S6

MORPHINE 10 mg UNIMED

Morphine Sulphate 10 mg per 1 ml

MORPHINE 15 mg UNIMED

Morphine Sulphate 15 mg per 1 ml

Sugar free

Read all of this leaflet carefully before you are given MORPHINE UNIMED

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

What is in this leaflet:

1. What **MORPHINE UNIMED** is and what it is used for
2. What you need to know before you receive **MORPHINE UNIMED**
3. How to receive **MORPHINE UNIMED**
4. Possible side effects

5. How to store **MORPHINE UNIMED**

6. Contents of the pack and other information

1 WHAT MORPHINE UNIMED is and what it is used for

MORPHINE UNIMED contains the active ingredient morphine sulphate. MORPHINE UNIMED belongs to a group of medicines called opioid analgesics. It works by blocking the pain signals from reaching your brain.

MORPHINE UNIMED is used for the treatment of:

Relief of severe and persistent pain associated with cancer, heart attacks and after surgery.

2 What you need to know before you receive MORPHINE UNIMED

MORPHINE UNIMED should not be administered to you if you are or have:

- if you are hypersensitive (allergic) to Morphine sulphate or any of the other ingredients of MORPHINE UNIMED (listed in section 6).
- if you are currently taking medicines used to treat depression known as monoamine oxidase inhibitors (MAOIs) (e.g phenelzine, tranylcypromine, moclobemide or selegiline) or have taken them in the last 14 days.
- if you have difficulty in breathing, shortness of breath, suffer from chronic asthma, chronic lung disease and any obstructive airway disease
- if you have excessive bronchial secretion
- if you are an alcoholic

- if you have convulsive disorders (fits and seizures)
- if you have head injuries or increased pressure in the head
- if you suffer from heart problems
- if you have severe stomach cramps caused by a condition known as biliary colic
- if you are at risk of having a blocked intestine (paralytic ileus)
- if you are suffering from a tumour of the adrenal gland known as a phaeochromocytoma
- if you suffer from severe diarrhoea

Warnings and precautions

Special care should be taken with MORPHINE UNIMED

Tell your doctor if you have any of the following medical conditions:

- If you suffer from an opioid addiction;
- If you suffer from hypothyroidism (under active thyroid gland);
- If you suffer from adrenocortical insufficiency (a lack of hormones produced by the adrenal gland);
- If you have problems with your kidneys or liver;
- if you are a male and suffer from problems with your prostate;
- if you have epilepsy (a condition causing seizures);
- if you suffer from shock (the symptoms of which include sweating, a fast pulse and cold, clammy skin);
- if you suffer from problems with your bowel;
- if you have weak muscular movement and rapid fatigue of muscles under voluntary control (myasthenia gravis);
- if you have lung and/or breathing disorders;

- if you suffer from hypotension-low blood pressure (the symptoms of which include dizziness or light-headedness);
- if you suffer from problems with your gallbladder
- If you are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- if you have a history of mental health disorders (difficulty in thinking, understanding and judging clearly which causes loss of touch with reality), if you have depression, anxiety and suffer from alcohol or drug abuse.

Taking opioids or receiving opioids (as contained in MORPHINE UNIMED) over a long period of time:

- Produces tolerance (where you develop a requirement for increased doses of MORPHINE UNIMED to achieve the same pain-relieving effects).
- Produces dependence, such that when people stop taking/receiving opioids, they have physical and psychological symptoms of withdrawal (such as muscle cramping, diarrhoea, and anxiety).
- Maybe associated with decreased sex hormone levels and increased prolactin. Symptoms may include loss of libido, erectile dysfunction in men and cessation of menstruation in females.

Opioid addiction can cause life-threatening health problems, including the risk of overdose.

Speak to your doctor if you experience any of these effects or if you are concerned.

Other medicines and MORPHINE UNIMED

Always tell your healthcare professional if you are taking other medicine. (This includes complementary or traditional medicines).

Some medicines and MORPHINE UNIMED may interfere with each other. Tell your doctor if you are taking or receiving any other medicine, including any non-prescription medicine that you may have purchased from your pharmacy. These include:

- Medicines used to treat depression, e.g. antidepressants.
- Consuming alcohol
- Medicines used to help you sleep, e.g. sleeping tablets.
- Medicines used to treat anxiety, tension, seizures, panic or sleep disorders, e.g. sedatives.
- Medicines used to control heart rhythm or rate, e.g. mexiletine.
- Medicines used to treat diarrhoea e.g. Loperamide, kaolin
- Medicines used to treat bacterial infections, e.g. ciprofloxacin.
- Medicines used to treat psychiatric or mental disorders (such as phenothiazines).
- Medicines used to treat diarrhoea, e.g. loperamide, kaolin.
- Medicines used as premedication before operations and after heart attacks, e.g. atropine.
- Medicines used to treat nausea and vomiting, e.g. metoclopramide, domperidone.
- Medicines used to treat blood clots, e.g. clopidogrel, prasugrel, ticagrelor.
- Medicines used to treat tuberculosis, e.g. rifampicin.
- Medicines used to treat heartburns, e.g. cimetidine.
- Medicines used to treat HIV/AIDS infections, e.g. ritonavir.

Concomitant use of MORPHINE UNIMED 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 UNIMED 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.

MORPHINE UNIMED with Alcohol

You should not drink alcohol whilst being given MORPHINE UNIMED, as it will increase its effect.

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 other healthcare provider for advice before receiving MORPHINE UNIMED.

Driving and using machines

MORPHINE UNIMED can affect your ability to drive and operate machinery as it may make you sleepy or dizzy. You should not drive a vehicle or use machinery while receiving Morphine Unimed.

3. How to receive MORPHINE UNIMED

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself MORPHINE UNIMED. It will be given to you by a person who is qualified to do so.

Your doctor will decide what the dose is and for how long you will receive MORPHINE UNIMED. This will vary from patient to patient. It will depend on the reason for receiving MORPHINE UNIMED and other factors, such as your physical condition, weight, age as well as other medications that you are taking at the time or after.

For most conditions, MORPHINE UNIMED is usually given as a continuous intravenous infusion or in divided doses throughout the day. However, in certain cases a single dose is required for the control of pain. MORPHINE UNIMED injection is administered either

- directly into the muscle (intramuscular) or beneath the skin (subcutaneous)
- as a slow injection directly into the vein (intravenous)
- as a slow intravenous infusion directly into the vein as a continuous basis.

If you receive more MORPHINE UNIMED than you should

Since a healthcare provider will administer MORPHINE UNIMED, he/she will control the dosage. However, in the event of overdosage, your doctor will manage the overdosage.

In the unlikely event of an overdose, you may experience any or the following symptoms:

- Cold, clammy skin.
- Confusion.
- Convulsions.
- Dizziness.
- Drowsiness.
- Low blood pressure.

- Nervousness or restlessness.
- Pinpoint pupils of eyes.
- Slow heartbeat.
- Slow or troubled breathing.
- Unconsciousness.
- Severe weakness.

If you forget to use MORPHINE UNIMED

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

4. Possible side effects

MORPHINE UNIMED can have side effects.

Not all side effects reported for MORPHINE UNIMED are included in this leaflet. Should your general health worsen while receiving MORPHINE UNIMED please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking MORPHINE UNIMED and tell your doctor 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 MORPHINE UNIMED. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go the casualty department at your nearest hospital if you notice any of the following:

- Changes in heart rate and/or an awareness of your heart beating.
- Collapsed lung, wheezing, difficulty in speaking.
- Slow or troubled breathing.
- Convulsions (fits or seizures).
- Withdrawal symptoms or dependence (symptoms may include body aches, shaking, flu-like symptoms, large pupils, an intense feeling of unsatisfaction, anxiety and irritability).

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

Tell your doctor if you notice anything of the following:

Frequent side effects:

- A feeling of light-headedness (which would be due to lowering of blood pressure) especially when standing,
- Increased sweating,
- Warm sensation of the face,
- Drowsiness,
- Nausea (feeling sick), vomiting (being sick), constipation,
- Unusual tiredness or weakness.
- Difficulty in emptying bladder (urinary retention),
- Inability to get an erection,

Less frequent side effects:

- Loss of appetite,

- False sense of well-being (unpleasant or uncomfortable mood),
- A general feeling of discomfort or illness,
- Nervousness or restlessness,
- A feeling of restless,
- Decreased in sexual drive, inability to get an erection,
- Sleeplessness,
- Confusion,
- Hallucinations (seeing, feeling or hearing things that are not there),
- Depression,
- Decreased in sexual drive,
- Mood swings,
- Headache,
- Unusual excitement or restlessness, especially in children,
- Feeling of spinning or moving (vertigo),
- Contraction of the pupil of the eye and rapid, repetitive, uncontrolled movements of the eyes,
- Dry mouth,
- Stomach cramps or pain,
- A condition when the bowel does not work properly (paralytic ileus),
- Inflammation of the colon,
- Feeling faint when getting up from a seated position, (orthostatic hypotension),
- Low blood pressure,
- Increase in liver enzymes,
- Difficulty or painful urination, frequent urge to urinate,
- Biliary spasm (spasms in the lower stomach area),
- Rash

- Muscle rigidity (muscle stiffness),
- Trembling or uncontrolled muscle movements,
- Difficulty in urinating,
- Pain and irritation at the site of injection.
- Abdominal pain, including inflamed and irritated pancreas.

Side effects with frequency unknown

- Nightmares or unusual dreams,
- Convulsions,
- Blurred vision or double vision,
- Rapid heartbeats,
- Increased blood pressure,
- Dependence,
- Mood changes,
- Sensation of whirling and loss of balance (vertigo),
- Increased sensitivity to pain,
- Feeling of extreme happiness,
- The pupil of your eye becomes smaller,
- Ringing or buzzing in the ears (tinnitus),
- Changes in body temperature from feeling cold to sweating.
- Liver damage
- Breakdown of muscles (Rhabdomyolysis),
- Renal failure

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 your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of this MORPHINE UNIMED.

5. How to store MORPHINE UNIMED

- Store at or below 25 °C.
- Protect from light.
- Keep out of the reach of children
- Store in the original package.
- Do not use after the expiry date stated on the pack.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What MORPHINE UNIMED contains

The active substance is Morphine Sulphate

Each 1 ml ampoule contains 10 mg morphine sulphate

Each 1 ml ampoule contains 15 mg morphine sulphate

Other ingredients

Sodium chloride

Nitrogen

Water for injection

Antioxidant: Sodium metabisulphate 0,1 % *m/v*.

Contains no sugar or preservatives

Applicant: Unimed Healthcare (Pty) Ltd

Module 1.3.2.2

Product Name: Morphine 10 mg Unimed
Morphine 15 mg Unimed

Dosage form and strength: Each 1,0 ml solution contains Morphine Sulphate 10,0 mg
Each 1,0 ml solution contains Morphine Sulphate 15,0 mg

What MORPHINE UNIMED looks like and contents of the pack

Polystyrene containers or cartons with 10 x 1 ml amber glass ampoules.

Holder of Certificate of Registration

Unimed Healthcare (Pty) Ltd

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Anchorville

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MORPHINE 10 mg UNIMED: 30/2.9/0181

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