SCHEDULING STATUS: **S6**

PROPRIETARY NAME (AND DOSAGE FORM):

MORPHINE 10 mg UNIMED (Injection)

MORPHINE 15 mg UNIMED (Injection)

COMPOSITION:

MORPHINE 10 mg UNIMED: 10 mg morphine sulphate per 1 ml.

MORPHINE 15 mg UNIMED: 15 mg morphine sulphate per 1 ml.

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

Sugar free.

PHARMACOLOGICAL CLASSIFICATION:

A 2.9 Other analgesics.

PHARMACOLOGICAL ACTION:

MORPHINE UNIMED is an opioid analgesic. The major effects are produced on the central nervous system and the bowel.

After intramuscular or subcutaneous administration, the onset of action is 10 - 30 minutes. The duration of action is 4 - 5 hours. **MORPHINE UNIMED** is eliminated by glomerular filtration. 90 % of total excretion takes place during the first day. Enterohepatic circulation of morphine and its glucuronides occurs, which accounts for small amounts of morphine in the faeces and in the urine for several days after the last dose.

INDICATIONS:

MORPHINE UNIMED is an analgesic for the symptomatic relief of severe pain especially that associated with neoplastic disease, myocardial infarction and surgery.

CONTRA-INDICATIONS:

Hypersensitivity to any of the ingredients. **MORPHINE UNIMED** is not usually given pre-operatively to children under 1 year of age. **MORPHINE UNIMED** is contra-indicated in respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion. It is also contra-indicated in the presence of acute alcoholism, head injuries and conditions in which intracranial pressure is raised. It should not be given during an attack of bronchial asthma or in heart failure secondary to chronic lung disease.

As serious and sometimes fatal reactions have occurred following administration of morphine to patients receiving monoamine oxidase inhibitors, morphine and related medicines are contra-indicated in patients taking monoamine oxidase inhibitors or within 14 days of stopping such treatment; **MORPHINE UNIMED** and other opioid analgesics should be given with extreme caution.

Pregnancy and lactation: The administration of opioid analgesics during labour may cause respiratory depression in the newborn infant.

WARNINGS:

MORPHINE UNIMED is liable to be subject to abuse.

It should be given with extreme care to newborn or premature infants for other conditions. The dosage should be reduced in elderly and debilitated patients. It should be given with caution or in reduced doses to patients with hypothyroidism, adrenocortical insufficiency, impaired kidney or liver function, prostatic hypertrophy, or shock. It should be used with caution in patients with obstructive bowel disorders. Opioid analgesics should be used with caution in patients with myasthenia gravis.

DOSAGE AND DIRECTIONS FOR USE:

The usual dose by subcutaneous or intramuscular injection is 5 to 20 mg every 4 hours. Children up to 1 month of age may be given 150 µg per kg body mass every 4 hours; those aged 1 to 12 months: 200 µg per kg; 1 to 5 years: 2,5 to 5 mg; 6 to 12 years: 5 to 10 mg.

Doses of up to 15 mg have been given by slow intravenous injection sometimes as a loading dose for continuous or patient-controlled infusion. For continuous intravenous administration, maintenance doses have generally ranged from 0,8 to 80 mg per hour although some patients have required and been given much higher doses.

Note: Facilities for administration of oxygen and assisted respiration should be available if morphine is given intravenously.

Morphine salts are sensitive to changes in pH and morphine is liable to be precipitated out of solution in an alkaline environment. Incompatibilities with other drugs in solution have been reported.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

In normal doses, the most common side-effects of **MORPHINE UNIMED** are nausea, vomiting, constipation, drowsiness and confusion. Micturition may be difficult and there may be ureteric or biliary spasm; there is also an anti-diuretic effect. Dry mouth, sweating, facial flushing, vertigo, bradycardia, palpitations, orthostatic hypotension, hypothermia, restlessness, changes of mood and miosis also occur. These effects occur more commonly in ambulant patients than in those at rest in bed. Raised intracranial pressure occurs in some patients. The euphoric activity of morphine has led to its abuse.

Larger doses produce respiratory depression and hypotension, with circulatory failure and deepening coma. Convulsions may occur in infants and children. Death may occur from respiratory failure. Toxic doses vary considerably with the individual.

Due to the histamine-releasing effect, reactions such as urticaria and pruritus occur in some individuals. Contact dermatitis has been reported and pain and irritation may occur on injection. Anaphylactic reactions following intravenous injection of **MORPHINE UNIMED** have been reported. Muscle rigidity has been reported following the administration of morphine.

The depressant effects of **MORPHINE UNIMED** are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics and sedatives, tricyclic antidepressants and phenothiazines. The actions of opioids may in turn affect the activities of other compounds. For instance, their gastro-intestinal effects may delay absorption as with mexiletine or may be counteractive as with metoclopramide.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

See **SIDE-EFFECTS AND SPECIAL PRECAUTIONS**. The specific antagonist, naloxone hydrochloride, is used to counteract the severe respiratory depression and coma produced by excessive doses of opioid analgesics. A dose of 0,4 to 2 mg is given intravenously, repeated at intervals of 2 to 3 minutes if necessary, up to 10 mg. Naloxone may also be given by subcutaneous or intramuscular injection. The effect of naloxone may be of shorter duration than that of the opioid analgesic and additional doses may be required to prevent relapses.

IDENTIFICATION:

MORPHINE 10 mg UNIMED: 1 ml amber glass ampoules containing a colourless to almost colourless solution.

MORPHINE 15 mg UNIMED: 1 ml amber glass ampoules containing a colourless to almost colourless solution.

PRESENTATION:

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

STORAGE CONDITIONS:

Store at or below 25 °C.

Protect from light.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBERS:

MORPHINE 10 mg UNIMED: 30/2.9/0181

MORPHINE 15 mg UNIMED: 28/2.9/0587

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Unimed Healthcare (Pty) Ltd

Corner Birch Road & Bluegum Avenue

Anchorville

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South Africa

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