

Read this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine 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.

SCHEDULING STATUS:

S6

PROPRIETARY NAME

SABAX MORPHINE SULPHATE 10 mg

SABAX MORPHINE SULPHATE 15 mg

SABAX MORPHINE SULPHATE 30 mg

(AND DOSAGE FORM):

INJECTION

WHAT THIS MEDICINE CONTAINS:

Each 1 ml contains:

10 mg, 15 mg or 30 mg of Morphine Sulphate

Contains no sugar.

Preservative free

WHAT THIS MEDICINE IS USED FOR:

Relief of intractable pain not controlled with non-narcotic analgesics.

SABAX MORPHINE SUPHATE is to be given only by or under the immediate supervision of your doctor.

BEFORE TAKING THIS MEDICINE:

If you are taking medicines on a regular basis, using SABAX MORPHINE SUPHATE at the same time with another medicine may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

SABAX MORPHINE SULPHATE is usually not given pre-operatively to children under one year of age. It should not be given in the following cases: respiratory depression especially in the presence of cyanosis and excessive bronchial secretion; acute alcoholism, head injuries and conditions in which intracranial pressure is raised; during an attack of bronchial asthma or in heart failure secondary to chronic lung disease; in patients taking monoamine oxidase inhibitors or within 10 days of stopping such treatment.

There is evidence of drug dependence from repeated administration.

The depressant effects of morphine are enhanced by anaesthetics, hypnotics, sedatives and phenothiazines.

HOW TO TAKE THIS MEDICINE:

Do not share medicines prescribed for you with any other person

Doses should generally be reduced in the elderly or debilitated or in patients with renal impairment.

Subcutaneous or intramuscular injection

Adults: 5 to 20 mg every 4 hours

Children: 1 to 5 years: 2,5 to 5 mg

6 to 12 years: 5 to 10 mg

Slow intravenous injection or as loading dose for continuous or patient controlled infusions:

Adults: up to 15 mg

Maintenance dose for continuous intravenous administration and continuous subcutaneous infusion: From 0,8 to 80 mg per hour.

Intrathecal dose ranges from 0,2 to 1,0 mg and must only be given as a single dose.

SIDE-EFFECTS:

Along with its needed effects, a medicine may cause some unwanted effects.

Check with your doctor immediately if any of the following side-effects occur:

Cardiac disorders:

Less Frequent: Bradycardia, Tachycardia, Pounding heartbeat

Gastrointestinal disorders:

Frequent: Nausea and vomiting, Constipation

Less Frequent: Dry mouth, Gastrointestinal irritation (stomach cramps or pain), paralytic ileus or toxic megacolon

General disorders and administration site conditions:

Frequent: Unusual tiredness or weakness

Less Frequent: Redness, swelling, pain or burning at site of injection

Hepatobiliary disorders:

Less Frequent: Biliary spasm

The following side-effects have been reported but frequencies are unknown: Hepatotoxicity

Immune system disorders:

Frequent: Histamine release (decreased blood pressure, fast heartbeat, increased sweating, redness or flushing of the face, wheezing or troubled breathing)

Less Frequent: Allergic reaction (skin rash, hives, and/or itching; swelling of face)

Metabolism and nutrition disorders:

Less Frequent: Loss of appetite

Musculoskeletal and connective tissue disorders:

Less Frequent: Muscle rigidity (especially in muscles of respiration), trembling or uncontrolled muscle movements

Nervous system disorders:

Frequent: Drowsiness

Less Frequent: Headache, Paradoxical CNS stimulation (unusual excitement or restlessness, especially in children), Blurred or double vision

The following side-effects have been reported but frequencies are unknown: Convulsions, Tinnitus (ringing or buzzing in the ears)

Psychiatric disorders:

Less Frequent: False sense of wellbeing, General feeling of discomfort or illness, Nervousness or restlessness, Insomnia, Confusion, Hallucinations, Mental depression,

The following side-effects have been reported but frequencies are unknown: Nightmares or unusual dreams

Renal and urinary disorders:

Less Frequent: Ureteral spasm (difficult or painful urination, frequent urge to urinate, Antidiuretic effect

Respiratory, thoracic and mediastinal disorders:

Less Frequent: Atelectasis; bronchospastic allergic reaction; laryngeal edema; allergic laryngospasm; respiratory depression

Vascular disorders:

Less Frequent: Dizziness, feeling faint or light-headedness, Hypotension

The following side-effects have been reported but frequencies are unknown: Increased blood pressure

Dosage should be reduced in elderly and debilitated patients. Administer with caution or in reduced doses to patients with hypothyroidism, adrenocortical insufficiency, impaired liver function and prostatic hypertrophy or shock.

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

STORAGE AND DISPOSAL INFORMATION:

Store below 25 °C and protect from light. KEEP OUT OF REACH OF CHILDREN.

Any unused or expired medication may be returned to a pharmacy for disposal.

PRESENTATION:

1 ml or 2 ml amber glass ampoules, containing 1 ml of solution, packed in 5's, 10's, 50's and 100's into unit cartons or polystyrene cartons.

IDENTIFICATION:

The solution is clear, colourless to slightly yellowish brown solution.

REFERENCE NUMBER:

SABAX MORPHINE SULPHATE 10 mg: B1242

SABAX MORPHINE SULPHATE 15 mg: B1243

SABAX MORPHINE SULPHATE 30 mg: B1244

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF

REGISTRATION:

ADCOCK INGRAM CRITICAL CARE (PTY) LTD

1 Sabax Road

Aeroton

Johannesburg

2013

DATE OF PUBLICATION OF THIS PACKAGE INSERT:

To be allocated.