Orgesic®

Injection

(Buprenorphine HCl)

Composition

Orgesic injection is a colourless liquid containing 0.3 mg/ml buprenorphine, as the hydrochloride, in a 5% dextrose solution, adjusted to pH range 3.5-5.5 with hydrochloric acid. Clear glass snap ampoules of 1 ml (0.3mg).

Orgesic injection contains 50 mg dextrose per ml, but no sodium, potassium or preservative.

Uses

As a strong analgesic for the relief of moderate to severe pain.

Dosage and administration

Adults and children over 12 years old: The recommended dosage is 1 to 2 ml (0.3-0.6mg buprenorphine), by IM or slow IV injection, every six to eight hours or as required. Orgesic injection may be employed in balanced anaesthetic techniques as a premedication at a dose of 0.3 mg intramuscularly or as an analgesic supplement at doses of 0.3-0.45 mg intravenously.

Children under 12 year: Orgesic is suitable for children under 12 at a dose of 3 – 6 microgram / kg body weight every 6-8 hours. In refractory cases up to 9 microgram / kg may be administered. There is no clinical experience in infants below the age of six months.

Elderly

There is no evidence that dosage needs to be modified for the elderly though they may be more susceptible to hallucinations and other psychotomimetic effects.

Contra-indications, warnings, etc

Not to be given to patients who are known to be allergic to Orgesic or other opiates. Controlled human and animal studies indicate that buprenorphine has a substantially lower dependence liability than pure agonist analgesics. In patients abusing opioids in moderate doses substitution with buprenorphine may prevent withdrawal symptoms. In man limited euphroigenic effects have been observed. This has resulted in some abuse of the product and caution should be exercised when prescribing it to patients known to have, or suspected of having, problems with drug abuse.

There is evidence to indicate that therapeutic doses of buprenorphine do not reduce the analgesic efficacy of standard doses of an opioid agonist, and that when buprenorphine is employed within the normal range, standard dose of opioid agonist may be administered before the effects of the former have ended without compromising analgesia. However, in individuals on high doses of opioids, buprenorphine may precipitate abstinence effects due to its properties as a partial agonist.

Orgesic may cause some drowsiness which may be potentiated by other centrally-acting agents, including alcohol, tranquillisers, sedatives and hypnotics. Ambulant patients should be warned not to drive or operate machinery until they are certain they can tolerate Orgesic. Orgesic occasionally causes significant respiratory depression and as with other storng centrally acting analgesics, care should be taken when treating patients with impaired respiratory function or patients who are receiving drugs which can cause respiratory depression. Although volunteer studies have indicated that opioid antagonists may not fully reverse the effects of Orgesic, clinical experience has shown that naloxone may be of benefit in reversing a reduced respiratory rate.

Respiratory stimulants such as doxapram are also effective.

Since buprenorphine is metabolised in the liver, the intensity and duration of its action may be affected in patients with impaired liver function.

Orgesic should be used with caution in patients receiving monoamine oxidase inhibitors, although animal studies have given no indication of interactions.

Use in pregnancy and lactation

Orgesic is not recommended for use during pregnancy. Animal studies indicate that the amounts of buprenorphine excreted in milk are very low and human use are unlikely to be of clinical significance to the baby. There is indirect evidence in animal studies to suggest that Orgesic may cause a reduction in milk flow during lactation. Although this occurred only at doses well in excess of the human dose, it should be borne in mind when treating lactating women.

Interference with laboratory tests

Orgesic has no known effects on diagnostic laboratory test.

Overdosage

Orgesic has a wide safety margin, and in clinical practice doses well in excess of those recommended have been used without untoward effect. Supportive measures should be instituted and, if appropriate, naloxone or respiratory stimulants can be used. The expected symptoms of overdosage would be drowsiness, nausea and vomiting; marked meiosis may occur.

Side-effects

Drowsiness, or sleep from which the patients can be easily arouse, may occur particularly in the post-operative period. In common with other strong analgesics, nausea, vomiting, dizziness, sweating and drowsiness have been reported which may be more frequent in ambulant patients. Should nausea and vomiting occur, concurrent administration of an anti-emetic is advised. Hallucinations and other psychotomimetic effects have occurred although more rarely than with other agonist-antagonists. Hypotension leading to syncope may occur. Rashes, headache, urinary retention and blurring of vision have occasionally been reported. Rarely a serious allergic reaction may occur following a single dose.

Precautions

Orgesic injection, though stable, should be kept cool and protected from light. It may be diluted with 5% Injection Dextrose (B.P.) or Injection Sodium Chloride (B.P.).

Dosage

As prescribed by the physician.

Instructions

To be sold on the prescription of a registered medical practitioner only.
Store at 2-30 °C. Protect from light.
Keep out of the reach of children.

Presentation

Box of 5 x 1 ml ampoules.

M.L. No.: 000024
Manufactured by:
Pharmatec
Pakistan (Pvt) Ltd.
D-86/A S.I.T.E.,
Karachi.

For:
OBS Pakistan (Pvt) Ltd.
C-14, S.I.T.E., Karachi-75700