

Data Sheet

NORFLEX™ injection

Orphenadrine citrate intravenous/intramuscular injection 30 mg/ml

NORFLEX™ tablets

Orphenadrine citrate 100 mg tablets

Presentation

NORFLEX intravenous/intramuscular injection

Orphenadrine citrate 60 mg in Water for Injections BP 2 ml. The injection formulation is colour-free, preservative-free, sugar-free and does not contain gluten or lactose.

NORFLEX tablets

White, round, biconvex tablets marked **N/X** on one face and no markings on the other face. The tablet formulation is colour-free, preservative-free and does not contain gluten.

Uses

Actions

NORFLEX is an analgesic and a muscle relaxant. Orphenadrine citrate is a centrally acting compound which in animals selectively blocks facilitory functions of the reticular formation. Orphenadrine does not produce myoneural block, nor does it affect crossed extensor reflexes. Orphenadrine prevents nicotine induced convulsions but not those produced by strychnine.

The mode of action of orphenadrine has not been clearly identified, but may be related to its analgesic properties. Orphenadrine citrate also possesses anticholinergic activity.

Pharmacokinetics

Orphenadrine is readily absorbed from the gastrointestinal tract and is almost completely metabolised to at least eight metabolites. Orphenadrine and its metabolites are excreted from the body in the urine, with a half life of 14 hours.

Indications

Orphenadrine citrate is indicated for the relief of stiffness and pain resulting from skeletal muscle spasm in sprains and strains, local muscle injury, prolapsed intervertebral disc, lumbago, fibrositis, non-articular rheumatism, acute torticollis, surgery, fractures, anxiety and tension. Orphenadrine citrate has also been shown to be effective for treatment of tension headache and persistent hiccoughs.

Dosage and Administration

Adults

NORFLEX tablets

Two tablets per day; one in the morning and one in the evening.

NORFLEX injection

One 2 ml ampoule (60 mg) intravenously or intramuscularly. May be repeated every 12 hours. Efficacy may be maintained by one NORFLEX tablet twice daily.

Children

Safety and effectiveness in children has not been established. NORFLEX is not recommended for children under 12 years.

Contraindications

Contraindicated in patients with glaucoma, paralytic ileus, pyloric or duodenal obstruction, stenosing peptic ulcers, prostatic hypertrophy or obstruction of the prostate or bladder neck, oesophageal spasm (megaesophagus) and myasthenia gravis.

Contraindicated in patients who have demonstrated a previous hypersensitivity to the drug.

Warnings and Precautions

Orphenadrine citrate should be used with caution in patients with impaired kidney or liver function, tachycardia, cardiac decompensation, coronary insufficiency or cardiac arrhythmias.

Safety of continuous long-term therapy with orphenadrine has not been established. Therefore periodic monitoring of blood, urine and liver function values is recommended if orphenadrine is prescribed for prolonged use.

Pregnancy and lactation

Use in Pregnancy

Safe use of orphenadrine has not been established with respect to adverse effects on foetal development. NORFLEX should therefore be used in women of childbearing potential and particularly during early pregnancy only when in the judgment of the physician the potential benefits outweigh the possible hazards.

Use in Lactation

Orphenadrine is excreted in breast milk and is not recommended for use while breastfeeding.

Effects on ability to drive and operate machinery

NORFLEX may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle. Ambulatory patients should therefore be cautioned accordingly.

Elderly patients

The elderly may be more susceptible to anticholinergic side effects and should be given a reduced dosage.

Adverse Effects

Adverse reactions of orphenadrine are mainly due to the mild anticholinergic action of orphenadrine, and are usually associated with higher doses. Most adverse effects can usually be eliminated by reducing the dose.

Adverse effects by frequency

More common reactions

Known adverse effects include: dryness of mouth, tachycardia, palpitation, urinary hesitancy or retention, blurred vision, dilation of pupils, increased ocular tension, weakness, nausea, vomiting, headache, dizziness,

constipation, drowsiness, hypersensitivity reactions, pruritus, hallucinations, agitation, tremor, gastric irritation, and rarely urticaria and other dermatoses.

Less common reactions

Some patients may experience transient episodes of light-headedness, dizziness or syncope. Infrequently, an elderly patient may experience some degree of mental confusion. These adverse reactions can usually be eliminated by reduction in dosage.

Serious or life threatening reactions

Rare instances of anaphylactic reaction have been reported associated with the intramuscular injection of NORFLEX injection. Very rare cases of aplastic anaemia associated with the use of orphenadrine tablets have been reported. No causal relationship has been established.

Interactions

Confusion, anxiety and tremors have been reported in some patients receiving dextropropoxyphene or dextropropoxyphene combinations and orphenadrine concomitantly. As these symptoms may be due to an additive effect, reduction of dosage and/or discontinuation of one or both agents is recommended in such cases. Interactions have also been reported with phenothiazines and other drugs with anti-muscarinic properties. Avoid concomitant use of alcohol or other CNS depressants.

Overdosage

Symptoms and Signs

Excitement, confusion and delirium leading to coma, convulsions, tachycardia. Dilated pupils, hypersensitivity reactions and urinary retention may occur.

Treatment

Gastric lavage should be carried out immediately regardless of the estimated ingested dose. Convulsions and delirium respond to relatively large doses of diazepam, preferably by mouth. Adequate hydration of the patient is important.

Pharmaceutical Precautions

NORFLEX injection

Store below 25°C.

NORFLEX tablets

Store below 30°C.

Medicine Classification

Prescription Medicine

Package Quantities

NORFLEX injection

Packs of 3 clear glass 2 ml ampoules.

NORFLEX tablets

HDPE bottles of 100 tablets.

Further Information

Nil.

Name and Address

iNova Pharmaceuticals (New Zealand) Limited

C/o Simpson Grierson

88 Shortland Street

Auckland

Distributed by: Douglas Pharmaceuticals Limited, Auckland

Telephone: (09) 835 0660

Facsimile: (09) 835 0685

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