

NORGESIC® PRODUCT INFORMATION

Compositio

Each tablet contains orphenadrine citrate 35mg, paracetamol 450mg.

Actions

Orphenadrine is a skeletal muscle relaxant. Paracetamol is an analgesic and antipyretic.

Indications

Tension headache, occipital headaches associated with spasm of skeletal muscles in the region of the head and neck. Acute and traumatic conditions of the limbs and trunk: sprains, strains, whiplash injuries, acute torticollis, prolapsed intervertebral disc.

Contraindications

Orphenadrine shows some anticholinergic activity and should not be used in patients with glaucoma, prostatic hypertrophy or obstruction at the bladder neck, or myasthenia gravis.

Precautions

Orphenadrine 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.

Orphenadrine citrate should be used with caution in patients with tachycardia, cardiac decompensation, coronary insufficiency, cardiac arrhythmias.

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

Serious skin reactions

Rarely, paracetamol may cause serious skin reactions such as acute generalised exanthematous pustulosis (AGEP), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Patients should be informed about the signs of serious skin reactions, and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Use in Pregnancy

Safe use in pregnancy has not been established, therefore the drug should not be used in pregnant women or those likely to become pregnant unless the expected benefits outweigh the potential risks.

Drug Interactions

The effects of antimuscarinic agents such as orphenadrine maybe enhanced by other drugs with antimuscarinic properties such as

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amantadine, some antihistamines, butyrophenones and phenothiazines, and tricyclic antidepressants. The reduction in gastric motility caused by antimuscarinic agents may affect the absorption of other drugs.

Adverse Reactions

Side effects rarely occur at the recommended dosage. Those encountered are associated with anticholinergic activity and may include nausea, dry mouth, blurring of vision. Rarely, rash or drowsiness may occur. These symptoms disappear rapidly with a reduction in dosage or cessation of medication. No toxic effects have been observed.

Overdosage

Symptoms: Symptoms of orphenadrine overdosage are excitement, confusion, delirium leading to coma. Convulsions and tachycardia with dilated pupils and urinary retention may occur. Paracetamol overdosage may cause acute liver damage, but symptoms may not appear for up to several days after ingestion.

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. It is recommended that the patient be referred to a hospital where early and regular monitoring of plasma paracetamol levels can be carried out. If instituted sufficiently early, treatment with N-acetylcysteine, L-methionine or L-cysteamine will minimise liver damage.

Dosage and Administration

2 tablets three times daily

Presentation

Tablets (white, scored, biconvex, marked N/C on one side, no markings on reverse): Blister pack 600's

Storage Conditions

Store below 30°C

Shelf-Life 4 years

Manufactured by:
Adcock Ingram Limited

No. 49 (C&D), Bommasandra Industrial Area,

Anekal Taluk, Bangalore - 560 099

Revision date: September 2018

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Norgesic Tablets - S/L - English - PIL(Front & Back) Dimension: 153 x 187 mm

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