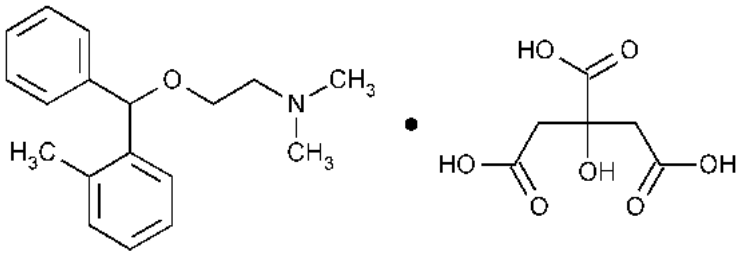
PRODUCT INFORMATION

NORFLEX

NAME OF THE MEDICINE

Orphenadrine citrate



Molecular Formula: $C_{18}H_{23}NO \cdot C_6H_8O_7$

CAS Number: 4682-36-4

DESCRIPTION

NORFLEX Tablets contain orphenadrine citrate 100 mg.

Orphenadrine citrate is white or almost white, crystalline powder. It is sparingly soluble in water, and slightly soluble in alcohol. Its chemical name is (RS)-N,N-Dimethyl-2-[(2-methylphenyl)phenylmethoxy]ethanamine dihydrogen 2-hydroxypropane-1,2,3-tricarboxylate.

Excipients: Ethylcellulose, lactose, magnesium stearate, silica-colloidal anhydrous.

ACTIONS

Skeletal muscle relaxant.

INDICATIONS

Relief of painful muscle spasm associated with fibrositis, whiplash injuries, torticollis, prolapsed intervertebral disc, strains, sprains and similar conditions. Norflex has also been shown to be of value in tension headache and persistent hiccup.

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.

Use in Pregnancy: Category B2

ADVERSE EFFECTS

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.

DOSAGE AND ADMINISTRATION

100mg twice daily. In severe cases, dosage may be increased to 300mg in any 24 hour period.

OVERDOSAGE

For information on the management of overdose, contact the Poison Information Centre on 131126 (Australia).

Symptoms: Symptoms of orphenadrine overdosage are excitement, confusion, delirium leading to coma. Convulsions and tachycardia with dilated pupils and urinary retention may occur.

Treatment: Convulsions and delirium respond to relatively large doses of diazepam, preferably by mouth. Adequate hydration of the patient is important.

PRESENTATION AND STORAGE CONDITIONS

Tablets 100 mg: white, round, biconvex tablet marked N/X on one side and no markings on the other side: 100's. (Polypropylene Bottle)

Store below 30^0C.

NAME AND ADDRESS OF THE SPONSOR

iNova Pharmaceuticals (Australia) Pty Limited
Level 10, 12 Help Street
Chatswood NSW 2067
Australia

POISON SCHEDULE

Prescription Only Medicine

DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS

4 July 1991

DATE OF MOST RECENT AMENDMENT:

28 January 2014