AUSTRALIAN PRODUCT INFORMATION – NORFLEX (ORPHENADRINE CITRATE) SLOW RELEASE TABLETS

1 NAME OF THE MEDICINE

Orphenadrine citrate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

NORFLEX slow release (modified release) tablets contain orphenadrine citrate 100 mg.

Excipients with known effect:

- Sugars as lactose.

For the full list of excipients, see Section 6.1 List of excipients.

3 PHARMACEUTICAL FORM

Slow release (modified release) tablet, 100 mg:

White, round, biconvex tablet. Markings N/X on one side and no markings on the other side.

4 CLINICAL PARTICULARS

4.1 THERAPEUTIC 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.

4.2 DOSE AND METHOD OF ADMINISTRATION

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

4.3 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.

4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

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 the elderly

No data available.

Paediatric use

No data available.

Effects on laboratory tests

No data available.

4.5 INTERACTIONS WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTIONS

Interactions have been reported between orphenadrine and phenothiazines and other drugs with anti-muscarinic properties.

Concomitant use with alcohol or other CNS depressants should be avoided.

4.6 FERTILITY, PREGNANCY AND LACTATION

Effects on fertility

No data available.

Use in pregnancy – Pregnancy Category B2

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.

No data available.

4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

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.

4.8 ADVERSE EFFECTS (UNDESIRABLE 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.

Reporting suspected adverse effects

Reporting suspected adverse reactions after registration of the medicinal product is important. It allows continued monitoring of the benefit-risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at www.tga.gov.au/reporting-problems.

4.9 OVERDOSE

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (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.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACODYNAMIC PROPERTIES

Mechanism of action

Skeletal muscle relaxant.

Clinical trials

No data available.

5.2 PHARMACOKINETIC PROPERTIES

No data available.

5.3 PRECLINICAL SAFETY DATA

Genotoxicity

No data available.

Carcinogenicity

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 LIST OF EXCIPIENTS

Excipients: Ethylcellulose, lactose monohydrate, magnesium stearate, colloidal anhydrous silica

6.2 INCOMPATIBILITIES

Incompatibilities were either not assessed or not identified as part of the registration of this medicine.

6.3 SHELF LIFE

In Australia, information on the shelf life can be found on the public summary of the Australian Register of Therapeutic Goods (ARTG). The expiry date can be found on the packaging.

6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30^0C.

6.5 NATURE AND CONTENTS OF CONTAINER

HDPE Bottle with PP child resistant closure: 100's[#].

Blister pack (PVC/PVDC Al foil): 10's, 30's, 100's

[#] Not marketed

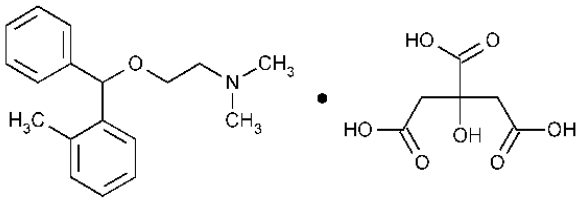
6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

In Australia, any unused medicine or waste material should be disposed of by taking to your local pharmacy.

6.7 PHYSICOCHEMICAL PROPERTIES

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.

Chemical structure



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

CAS number

4682-36-4

7 MEDICINE SCHEDULE (POISONS STANDARD)

Prescription Only Medicine – S4

8 SPONSOR

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

Tel: 1800 630 056

9 DATE OF FIRST APPROVAL

4 July 1991

10 DATE OF REVISION

15 January 2025

SUMMARY TABLE OF CHANGES

Section Changed	Summary of new information
6.5	Addition of 30's pack size – blister pack Bottle presentation status changed to Not marketed.