# NEW ZEALAND DATA SHEET
# NORFLEX™

## 1 PRODUCT NAME
NORFLEX 100 mg slow release tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION
Each slow release tablet contains orphenadrine citrate 100 mg.

Excipient with known effect:

Lactose monohydrate

For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM
Slow release tablet

White, round, biconvex tablets marked **N/X** on one face and no markings on the other face.

## 4 CLINICAL PARTICULARS
### 4.1 Therapeutic indications
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.

### 4.2 Dose and method of administration
Adults

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

Children

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

Special Populations

*Elderly*

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

### 4.3 Contraindications
- Hypersensitivity to the active substance or any of the excipients listed in section 6.1.
- Glaucoma
- Paralytic ileus
- Pyloric or duodenal obstruction

- Stenosing peptic ulcers
- Prostatic hypertrophy or obstruction of the prostate or bladder neck
- Oesophageal spasm (megaesophagus)
- Myasthenia gravis.

## 4.4 Special warnings and precautions for use

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.

## 4.5 Interaction with other medicines and other forms of interaction

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.

## 4.6 Fertility, pregnancy and lactation

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.

Lactation

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

## 4.7 Effects on ability to drive and use machines

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.

## 4.8 Undesirable 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 reactions are listed below according to system organ class and frequency. Frequencies are defined according to the following convention:

Very common (≥1/10), Common (≥1/100 to <1/10), Uncommon (≥1/1,000 to <1/100), Rare (≥1/10,000 to <1/1,000), Very rare (<1/10,000), Not known (cannot be estimated from the available data).

**Cardiac disorders**
Frequency unknown: Tachycardia, palpitation.

**Eye disorders**
Frequency unknown: Blurred vision, dilation of pupils, increased ocular tension.

**Nervous system disorders**
Frequency unknown: Headache, dizziness, drowsiness, tremor, transient episodes of light-headedness, syncope.

**Psychiatric disorders**
Frequency unknown: Hallucinations, agitation, mental confusion.

**Immune system disorders**
Frequency unknown: Hypersensitivity reactions.

**Skin and subcutaneous tissue disorders**
Frequency unknown: Pruritus, urticaria and other dermatoses

**Renal and urinary disorders**
Frequency unknown: Urinary hesitancy or retention.

**Gastrointestinal disorders**
Frequency unknown: Nausea, vomiting, constipation, gastric irritation, dryness of mouth.

**Musculoskeletal and connective tissue disorders**
Frequency unknown: Weakness.

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.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/

## 4.9 Overdose

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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Ethers, chemically close to antihistamines. ATC code: M03BC01.

NORFLEX is an analgesic and a muscle relaxant. Orphenadrine citrate is a centrally acting compound which in animals selectively blocks faciliatory 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.

## 5.2 Pharmacokinetic properties

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.

## 5.3 Preclinical safety data

No additional data available.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Colloidal silicon dioxide
Ethycellulose
Lactose monohydrate
Magnesium stearate.

The tablet formulation is colour-free, preservative-free and does not contain gluten.

## 6.2 Incompatibilities

Not applicable

## 6.3 Shelf life

36 months

## 6.4 Special precautions for storage

Store below $30^0$C.

## 6.5 Nature and contents of container

Bottle, HDPE: 100 tablets

### 6.6 Special precautions for disposal and other handling

Keep out of reach of children

## 7 MEDICINE SCHEDULE

Prescription

## 8 SPONSOR

iNova Pharmaceuticals (New Zealand) Limited
c/- Simpson Grierson
88 Shortland Street,
Auckland 1141

Telephone: 0508 375 394

## 9 DATE OF FIRST APPROVAL

31 December 1969

## 10 DATE OF REVISION OF THE TEXT

11 December 2018

## SUMMARY TABLE OF CHANGES

| **Date** | **Changes** |
|---|---|
| 23 April 2018 | Data sheet reformatted<br>Section 4.3: added hypersensitivity to any of the excipients listed in section 6.1<br>Section 4.6: added Pregnancy categorisation Category B2<br>Section 4.8: added standard text on adverse reaction frequency conventions<br>Section 5: Pharmacotherapeutic group and ATC code added. |
| 11 December 2018 | Sections 1, 2 and 3: amended the dosage form to slow release tablet |