**Professional Information**

**SCHEDULING STATUS**

**S2**

## 1 NAME OF THE MEDICINE

Norflex 100mg tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Orphenadrine citrate 100 mg.

Contains sugar: lactose monohydrate 167 mg/tablet.

For full list of excipients, see Section 6.1

## 3 PHARMACEUTICAL FORM

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

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Conditions involving skeletal muscle spasm such as low back pain and torticollis and also those resulting from trauma such as whiplash injury.

### 4.2 Dose and method of administration

One tablet two or three times daily with water.

## 4.3 Contraindications

Norflex should be used with caution in the presence of glaucoma, tachycardia and urinary retention. Safe use in pregnancy has not been established; therefore Norflex should not be used in pregnant women.

Orphenadrine shows some anticholinergic activity and should not be used in patients with achalasia, prostatic hypertrophy, bladder neck obstruction, myasthenia gravis, peptic ulcer stenosing, pyloric or duodenal obstruction or porphyria.

## 4.4 Special warnings and precautions for use

Orphenadrine citrate should be used with caution in patients with cardiac decompensation, coronary insufficiency, cardiac arrhythmias, CNS depression, or hepatic or renal function impairment.

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.

Contains lactose which may have an effect on the glycaemic control of patients with diabetes mellitus. Patients with the rare hereditary conditions of galactose intolerance e.g. galactosemia, Lapp lactase deficiency, glucose-galactose malabsorption or fructose intolerance should not take NORFLEX.

### Use in the elderly

No data available

### Paediatric use

No data available

## 4.5 Interactions with other medicines and other forms of interactions

Alcohol and CNS depression – producing medications: Concurrent use with orphenadrine may result in additive CNS depressant effects; caution is recommended and dosage of one or both agents should be reduced.

Anticholinergic or other medications with anticholinergic action:

Anticholinergic effects may be intensified when these medications are used concurrently with orphenadrine because of the secondary anticholinergic activity of orphenadrine.

Orphenadrine is an inhibitor of the cytochrome P450 isoenzyme CYP2B6, which is involved in the metabolism of bupropion to its major metabolite; NORFLEX should be used with caution in patients also receiving bupropion.

**4.6 Fertility, pregnancy and lactation**

**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.

**Breastfeeding**

No data available

**Fertility**

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, and urinary retention. 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.

Other possible side effects are as follows:

Blood and the lymphatic system disorders

Less frequent: Aplastic anaemia

Frequency unknown: Agranulocytosis, anaemia, haemolytic anaemia, leukopenia, thrombocytopenia, eosinophilia.

Immune system disorders

Frequency unknown: Anaphylactic or anaphylactoid reaction.

Nervous system disorders

Less frequent: Fainting, hallucinations, confusion, dizziness or light-headedness, drowsiness, paradoxical stimulation, trembling.

Frequency unknown: Convulsions, mental depression.

Eye disorders

Less frequent: Increased intraocular pressure (eye pain), unusually large pupils, blurred or double vision or any other change in vision.

Frequency unknown: Conjunctivitis, stinging or burning of eyes, Nystagmus.

Cardiac disorders

Less frequent: Fast heartbeat, pounding heart.

Vascular disorders

Frequency unknown: Flushing or redness of face.

Respiratory, thoracic and mediastinal disorders

Frequency unknown: Allergic reaction bronchospastic, nasal congestion.

Gastrointestinal disorders

Frequent: Dryness of mouth.

Less frequent: Abdominal or stomach cramps or pain, constipation, nausea or vomiting.

Frequency unknown: Gastrointestinal bleeding, diarrhoea, heartburn, hiccups.

Hepato-biliary disorders

Frequency unknown: Hepatotoxicity.

Skin and subcutaneous tissue disorders

Frequency unknown: Angioedema, allergic dermatitis, erythema multiforme.

Musculoskeletal, connective tissue and bone disorders

Less frequent: Muscle weakness.

Renal and urinary disorders

Less frequent: Decreased urination, difficult urination.

General disorders and administrative site conditions

Less frequent: Weakness, headache.

Frequency unknown: Allergic fever, clumsiness or unsteadiness.

Reporting suspected adverse effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8. Alternately you can contact iNova Pharmaceuticals (Pty) Ltd at +27 11 087 0000.

**4.9 Overdose**

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**

A.2.10 (Centrally active muscle relaxants).

ATC class: M03BC01 – Muscle Relaxants, Centrally Acting Agents.

Mechanism of action: Skeletal muscle relaxant.

Norflex has a weak antihistaminic action and a mild local anaesthetic effect, neither of which are of practical importance. Its most important action is that of relaxing skeletal muscle spasm, without affecting normal muscle tone. This results from the central action of Norflex. Norflex also exerts a mild euphoriant action. By relaxing skeletal muscle spasm, Norflex will alleviate pain resulting from the spasm.

### 5.2 Pharmacokinetic properties

Orphenadrine is readily absorbed from the gastrointestinal tract. After a single dose, peak concentration is obtained after 6 to 8 hours. It is almost completely metabolised to at least 8 metabolites. It is mainly excreted in the urine as metabolites and small amounts of unchanged drug. The half-life of orphenadrine has been reported to be 14 hours.

### 5.3 Preclinical safety data

**Genotoxicity:** No data available.

**Carcinogenicity:** No data available.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

- Colloidal anhydrous silica
- ethyl cellulose
- lactose monohydrate
- magnesium stearate.

### 6.2 Incompatibilities

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

### 6.3 Shelf life

36 months.

### 6.4 Special precautions for storage

Store at or below 30 ºC in a cool dry place.

KEEP OUT OF REACH OF CHILDREN

### 6.5 Nature and contents of the container

White, plastic bottles with a screw cap or PVC/PVCD and aluminium blister strips in a box containing 20 or 50 tablets.

### 6.6 Special precautions for disposal

No special requirements.

## 7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road, Bedfordview 2007

South Africa

## 8 REGISTRATION NUMBER

H 1612 (Act 101 1965)

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21 February 1985

## 10 DATE OF REVISION OF THE TEXT

19 September 2021