Patient Information Leaflet

SCHEDULING STATUS

S2

NORFLEX 100mg tablets

Each tablet contains 100mg Orphenadrine Citrate.

Contains sugar: lactose monohydrate 167 mg/tablet

Read all of this leaflet carefully before you start taking NORFLEX

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- NORFLEX has been prescribed for you personally and you should not

  share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What NORFLEX is and what it is used for
2. What you need to know before you take NORFLEX
3. How to take NORFLEX
4. Possible side effects
5. How to store NORFLEX
6. Contents of the pack and other information

1 What Norflex is and what it is used for

NORFLEX contains orphenadrine citrate. Orphenadrine citrate is askeletal muscle relaxant. It acts in the central nervous system to produce its muscle relaxant effects. NORFLEX is used to help relieve skeletal muscle spasms such as low back pain, torticollis (a problem involving the muscles of the neck that causes the head to tilt down) and those resulting from trauma such as whiplash surgery.

2. What you need to know before you take Norflex

Do not take NORFLEX:

- If you are hypersensitive (allergic) to orphenadrine citrate or any of the other ingredients of NORFLEX.
- if you have any of the following medical conditions:
    - Glaucoma (high pressure in the eye)
    - intestinal blockage, stomach ulcer or oesophageal disease
    - enlarged prostate or difficulty passing urine;
    - myasthenia gravis (a disease of the muscles causing drooping eyelids, double vision, difficulty in speaking and swallowing, and sometimes muscle weakness in the arms or legs).
    - porphyria
    - achalasia (a condition affecting your oesophagus)
- Do not give this medicine to a child under the age of 12 years.

Warnings and precautions

Take special care with NORFLEX

- if you have any heart problems
- if you have any liver or kidney problems
- if you are over 65 years old.

Other medicines and NORFLEX

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Some medicines may be affected by NORFLEX. These include:

- anticholinergics (medicines used to relieve stomach cramps or spasms);
- medicines used to treat depression e.g. bupropion;
- other central nervous system depressant medicines, including alcohol. Examples of CNS depressants are antihistamines or medicines for hay fever, other allergies or colds; sedatives or tranquilizers; narcotic analgesics; barbiturates; medicines for seizures; anaesthetics, including some dental anaesthetics; and other muscle relaxants.

Taking NORFLEX with food and drink:

There are no known interactions with food. NORFLEX should be swallowed with cold water. Do not drink alcohol whilst taking NORFLEX.

Pregnancy, breastfeeding and fertility:

NORFLEX is not suitable for use during pregnancy and while breastfeeding at the recommended dosage.

If you are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

Driving and using machinery:

It is not always possible to predict to what extent NORFLEX may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which NORFLEX affects them.

NORFLEX contains lactose monohydrate. This may have an effect on the control of your blood sugar if you have 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.

3. How to take Norflex

Do not share medicines prescribed for you with any other person.

Always take NORFLEX exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The usual dose is:

One tablet two or three times daily.

Swallow the tablets with a sufficient quantity of water.

Do not exceed the recommended dose.

If you take more NORFLEX than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Symptoms of overdosage include excitement, severe confusion leading to coma; convulsions; fast heart rate; dilated pupils and difficulty passing urine. Seek medical attention immediately.

If you forget to take NORFLEX

Do not use a double dose to make up for a forgotten individual dose.

4. Possible side effects

NORFLEX can have side effects.

Not all side effects reported for NORFLEX are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while taking NORFLEX, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor if you notice any of the following:

Frequent side effects:

- dry mouth

Less frequent side effects:

- blood disorders
- hallucinations
- confusion
- fainting
- dizziness or light-headedness
- drowsiness
- trembling
- unusual tiredness,
- muscle weakness
- headache
- fast or pounding heartbeat
- eye pain
- unusually large pupils
- changes in vision, blurred or double vision
- stomach cramps or pain

- constipation
- nausea or vomiting
- decreased urination or difficulty urinating.

Frequency not known:

- Convulsions
- depression
- unsteadiness
- liver damage
- hiccups
- allergic reactions involving fever and difficulty breathing
- conjunctivitis, stinging or burning of eyes, involuntary eye movements (nystagmus)
- flushing or redness of the face
- gastrointestinal bleeding
- diarrhoea
- heartburn
- skin rash, swelling of the skin and/or mucous membranes
- blocked nose.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form” found online under SAHPRA’s publications:

https://www.sahpra.org.za/Publications/Index/8. By reporting side effects,

you can help provide more information about the safety of NORFLEX.

Alternately you can contact iNova Pharmaceuticals (Pty) Ltd at +27 11 087 0000. Website: www.inovapharma.co.za.

5. How to store Norflex

Store all medicines out of reach of children.

Store at or below 30 °C and protect from sunlight and moisture.

Do not use after the expiry date stated on the label/blister and carton.

Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What NORFLEX contains:

The active substance is Orphenadrine citrate 100 mg

The other ingredients are ethyl cellulose, magnesium stearate, colloidal

anhydrous silica. Contains sugar: lactose monohydrate 167 mg/tablet.

What NORFLEX looks like and contents of the pack

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

NORFLEX tablets are packed in white, plastic bottles with a screw cap or a PVC/PVDC blister pack containing 20 or 50 tablets.

Holder of Certificate of Registration

iNova Pharmaceuticals (Pty) Ltd

15E Riley Road

Bedfordview

2007

Tel: +27 11 087 0000

This leaflet was last revised in:

19 September 2021

Registration number

H 1612 (Act 101 1965)

Access to the corresponding professional information for healthcare professionals

Full professional information can be found at www.inovapharma.co.za or can be obtained upon request from iNova Pharmaceuticals.

NAMIBIA Scheduling status: NS1 Registration No: 14/5.4.1/0281	**BOTSWANA** Scheduling status: 2 Registration no: B9308695