PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S2**

NORFLEX CO, 35 milligram, 450 milligram, tablets

Orphenadrine citrate, paracetamol

Sugar free.

Read all of this leaflet carefully because it contains important information for you.

NORFLEX CO is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use NORFLEX CO carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NORFLEX CO with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

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

1. What NORFLEX CO is and what it is used for

NORFLEX CO contains orphenadrine citrate and paracetamol.

Orphenadrine citrate is a skeletal muscle relaxant.

It acts in the central nervous system to produce its muscle relaxant effects.

Paracetamol is used to treat or prevent pain and reduce fever.

NORFLEX CO is used to relieve pain due to spasm of voluntary muscle and for the symptomatic treatment of mild to moderate pain and/or fever.

2. What you need to know before you take NORFLEX CO

Do not take NORFLEX CO:

- If you are hypersensitive (allergic) to orphenadrine citrate, paracetamol or any of the other ingredients of NORFLEX CO (listed in section 6).
- If you have any problems such as urinary retention or a weakness and rapid fatigue of muscles under voluntary control
- If you are elderly and have prostatic enlargement
- Do not give this medicine to patients with fever or when the room temperature is high
- If you have any intestinal problems
- If you have glaucoma
- Do not give this medicine to a child
- If you have any problems with your heart
- If you are pregnant
- Liver function impairment

Warnings and Precautions

Take special care with NORFLEX CO:

- if you use for longer than 10 days
- if you have any heart problems
- if you have any liver or kidney problems
- if you are taking other medicines containing paracetamol

Consult a doctor if no relief is obtained from the recommended dosage.

Other medicines and NORFLEX CO

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

Some medicines may be affected by NORFLEX CO. These include:

- anticholinergics (medicines used to relieve stomach cramps or spasms)
- medicines used to treat depression
- other central nervous system depressant (CNS) 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
- medicines used to treat epilepsy or fits
- medicines used to prevent blood clots
- medicines which affect gastric emptying e.g. metoclopramide or propantheline
- chloramphenicol, which is an antibiotic.

NORFLEX CO with food and drink

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

Pregnancy, breastfeeding and fertility

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

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking NORFLEX CO.

Driving and using machines

It is not always possible to predict to what extent NORFLEX CO may interfere with the daily activities of a patient.

You should ensure that you do not engage in the above activities until you are aware of the measure to which NORFLEX CO affects you.

3. How to take NORFLEX CO

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

Always take NORFLEX CO exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

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

The usual dose is:

Two tablets three or four times a day.

Swallow the tablets with a sufficient quantity of water.

Do not exceed the recommended dose.

If you take more NORFLEX CO than you should

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

Overdose with paracetamol containing medicines can lead to liver damage.

Symptoms of overdosage include abdominal pain, vomiting, increased sweating, severe drowsiness, difficulty breathing, cyanosis, excitement, confusion, 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 CO

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

4. Possible side effects

NORFLEX CO can have side effects.

Not all side effects reported for NORFLEX CO are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NORFLEX CO, please consult your healthcare provider for advice.

If any of the following happens, stop taking NORFLEX CO and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to NORFLEX CO. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fast/slow or pounding heartbeat
- hallucinations
- confusion
- mental confusion

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- eye pain
- unusually large pupils
- change in vision, blurred of double vision
- light sensitivity (photophobia)
- dry mouth
- difficulty swallowing

- dizziness or light-headedness
- drowsiness
- reduced mucous secretion
- unusual tiredness
- muscle weakness
- flushing or redness of the face or skin
- decreased urination or difficulty urinating
- stomach cramps or pain
- constipation
- nausea or vomiting
- blood disorders such as low counts for all three types of blood cells: red blood cells, white blood cells, and platelets
- low level of white blood cells in the blood, which can interfere with the ability to fight infection and low level of white cells
- nausea
- heartburn
- skin rash

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 doctoror, pharmacist or nurse. 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 on the safety of NORFLEX CO.

5. How to store NORFLEX CO

- 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 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 CO contains

The active substances in one NORFLEX CO tablet is orphenadrine citrate 35 mg and 450 mg paracetamol.

The other ingredients include colloidal silicon dioxide, magnesium stearate, microcrystalline cellulose, pregelatinized maize starch.

What NORFLEX CO looks like and contents of the pack

White scored tablets with N/C on one side and no markings on the other.

Blister packs of 24 and 48 tablets.

White HDPE Plastic bottles of 120 tablets.

Holder of Certificate of Registration

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