NORFLEX®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using NORFLEX?

NORFLEX contains the active ingredient orphenadrine citrate. NORFLEX is used to help relax certain muscles in your body and to relieve the pain and discomfort caused by sprains, strains, or other injury to your muscles. It is also useful for tension headache and persistent hiccups.

For more information, see Section 1. Why am I using NORFLEX? in the full CMI.

2. What should I know before I use NORFLEX?

Do not use if you have ever had an allergic reaction to NORFLEX or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use NORFLEX? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NORFLEX and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use NORFLEX?

- The usual dose is one tablet twice daily. Follow the instructions provided on the pack.

More instructions can be found in Section 4. How do I use NORFLEX? in the full CMI.

5. What should I know while using NORFLEX?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using NORFLEX. • Contact your doctor if you become pregnant whilst using NORFLEX.
Things you should not do	• Do not give NORFLEX to anyone else even if they have the same condition as you. • Do not take NORFLEX to treat any other complaints unless your doctor tells you to.
Driving or using machines	• NORFLEX may cause drowsiness or blurred vision. Be careful driving or operating machinery until you know how NORFLEX affects you.
Drinking alcohol	• Avoid drinking alcohol while using NORFLEX. • It may increase the occurrence or severity of side effects such as drowsiness.
Looking after your medicine	• Store below 30°C in a cool dry place away from moisture, heat, or sunlight • Keep out of reach of children.

For more information, see Section 5. What should I know while using NORFLEX? in the full CMI.

6. Are there any side effects?

Side effects include nausea, dry mouth, blurred vision, drowsiness, rash, trouble urinating, fainting, fast or pounding heartbeat, hallucinations, trouble breathing, confusion and constipation.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

NORFLEX®

Active ingredient: *Orphenadrine citrate*

Consumer Medicine Information (CMI)

This leaflet provides important information about using NORFLEX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using NORFLEX.**

Where to find information in this leaflet:

1. Why am I using NORFLEX?
2. What should I know before I use NORFLEX?
3. What if I am taking other medicines?
4. How do I use NORFLEX?
5. What should I know while using NORFLEX?
6. Are there any side effects?
7. Product details

1. Why am I using NORFLEX?

NORFLEX contains the active ingredient orphenadrine citrate. NORFLEX is a skeletal muscle relaxant. It acts in the central nervous system to produce its muscle relaxant effects.

NORFLEX is used to help relax certain muscles in your body and to relieve the pain and discomfort caused by sprains, strains, or other injury to your muscles. It is also useful for tension headache and persistent hiccups.

2. What should I know before I use NORFLEX?

Warnings

Do not use NORFLEX if:

- You are allergic to orphenadrine citrate, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- You have any of the following conditions
    - Glaucoma
    - Intestinal blockage, stomach ulcer or oesophageal disease
    - Enlarged prostate or bladder obstruction
    - Myasthenia gravis (muscle weakness).
- The packaging shows signs of tampering.
- NORFLEX has passed its use by date printed on the packaging.

Check with your doctor if you:

- have any other medical conditions including heart, liver or kidney problems.
- take any medicines for any other condition

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with NORFLEX and affect how it works.

These include:

- Phenothiazine medicines used to treat serious emotional and mental disorders
- Medicines used to relieve stomach cramps or spasms
- Medicines which have a sedating effect
- Alcohol.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NORFLEX.

4. How do I use NORFLEX?

How much to take

- The usual dose is one tablet twice a day.
- Follow the instructions provided on the pack and use NORFLEX until your doctor tells you to stop.

When to take NORFLEX

- NORFLEX should be used as directed by your doctor or pharmacist.
- Do not change the dose unless your doctor tells you to do so.

If you forget to use NORFLEX

NORFLEX should be used regularly at the same time each day. If you miss your dose at the usual time and remember within an hour or so of the missed dose, take it straight away.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you use too much NORFLEX

If you think that you have used too much NORFLEX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia or 0800 764 766 in New Zealand**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using NORFLEX?

Things you should do

Call your doctor straight away if you:

- Become pregnant.

Remind any doctor, dentist or pharmacist you visit that you are using NORFLEX.

Things you should do

- NORFLEX may cause dryness of the mouth. For temporary relief use sugarless gum or sweets, melt some ice in your mouth or use a saliva substitute. If dry mouth persists, talk to your dentist.

Things you should not do

- Do not give NORFLEX to anyone else even if they have the same condition as you.
- Do not take NORFLEX to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how NORFLEX affects you.

NORFLEX may cause blurred vision or drowsiness in some people

Drinking alcohol

Tell your doctor if you drink alcohol.

Drinking alcohol whilst using NORFLEX may increase the occurrence or severity of side effects such as drowsiness.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store NORFLEX below 30°C in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• Nausea • Dry mouth • Blurred vision • Drowsiness • Rash • Trouble urinating • Constipation • Fainting • Fast or pounding heartbeat • Trouble breathing • Hallucinations • Confusion	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects that you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What NORFLEX contains

Active ingredient (main ingredient)	Orphenadrine citrate
Other ingredients (inactive ingredients)	Ethylcellulose Lactose monohydrate Magnesium stearate Colloidal anhydrous silica
Potential allergens	Lactose monohydrate

Do not take this medicine if you are allergic to any of these ingredients.

What NORFLEX looks like

NORFLEX is a white, round tablet marked N/X on one side and no markings on the other side. It is packaged in blisters containing 10*, 30* or 100 tablets.

* Not supplied in New Zealand.

Registration number: AUST R 370413.

Who distributes NORFLEX

Australia

iNova Pharmaceuticals (Australia) Pty Limited

Level 10, 12 Help Street

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New Zealand

iNova Pharmaceuticals (New Zealand) Pty Limited

Auckland

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