

MERCK

Praxilene® 100 mg Capsules

naftidrofuryl hydrogen oxalate

The name of your medicine is Praxilene 100 mg capsules, which will be referred to as Praxilene throughout this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Praxilene is and what it is used for

Praxilene belongs to a group of medicines known as 'metabolic activators'. These are used to treat different types of blood circulation problems.

Praxilene allows your body to make better use of the oxygen in your blood.

Praxilene is used to treat peripheral vascular disorders (blood circulation problems outside the brain and heart).

Praxilene is used to treat the following symptoms of these disorders:

- cramp-like pains, usually in your calves when you walk (intermittent claudication)
- cramps in your legs at night
- pale or blue fingers or toes which get worse when it is cold

2. What you need to know before you take Praxilene



Do not take Praxilene if you:

- are allergic (hypersensitive) to naftidrofuryl hydrogen oxalate or any of the other ingredients of this medicine (listed in section 6)

- have had kidney stones or other urinary problems in the past

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Praxilene

If you have any liver or kidney conditions tell your doctor before taking Praxilene.

Always swallow Praxilene capsules with a large glass of water, as this will help to prevent any irritation in the throat.

While taking Praxilene, you should drink plenty of fluids. This will help to prevent the formation of kidney stones.

Cases of liver damage have been reported with Praxilene. If you show signs of liver damage (you would see a yellowing of the skin and eyes, you may experience itching, loss of appetite accompanied by nausea and vomiting), you must stop taking Praxilene and see your doctor immediately.

Children

This medicine is not recommended for children.

Other medicines and Praxilene

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor if you take any medicines used for high blood pressure as this can affect how Praxilene and the other medicine works

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Driving and using machines

This medicine has no effect on the ability to drive or use machinery.

3. How to take Praxilene

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one or two capsules three times a day.

Your doctor may tell you to take a different dose. If this is the case, you must follow his or her advice. Swallow the capsules whole, **do not chew them**. Always take your capsules with a large glass of water. Praxilene should be taken with food.

If you stop taking Praxilene

Do not stop taking Praxilene unless your doctor tells you to, even if you feel better.

If you take more Praxilene than you should

If you take too much Praxilene, go to your local hospital.

Overdose may cause heart problems, convulsions or confusion.

If you forget to take Praxilene

Do not take a double dose to make up for a forgotten dose. If you forget to take a dose, just take the next dose at the right time.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects with Praxilene, STOP taking the capsules, contact your doctor immediately and consider attending hospital casualty: A severe allergic reaction, such as itching, swelling of the face, lips, tongue, mouth, or throat, which may cause shortness of breath, wheezing, or difficulty breathing.

The following side-effects have been reported:

Uncommon (affects less than 1 in 100 patients):

- diarrhoea
- feeling sick
- vomiting
- stomach ache
- skin rash

Rare (affects less than 1 in 1000 patients):

- liver damage - you would see a yellowing of the skin and eyes and you should see your doctor immediately in this case

Very rare (affects less than 1 in 10,000 patients):

- kidney stones

Unknown frequency:

- irritation in the throat when Praxilene is taken without a glass of water

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance

Earlsfort Terrace

IRL - Dublin 2

Tel: +353 1 6764971

Fax: +353 1 6762517

Website: www.hpra.ie

E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Praxilene

Keep this medicine out of the sight and reach of children.

Do not use the medicine after the expiry date which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month. Do not store Praxilene above 25°C.

Store Praxilene in its original container in order to protect the capsules from light and moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information



What Praxilene contains

The active substance is 100 milligrams (mg) of naftidrofuryl hydrogen oxalate.

The name of this ingredient has changed (it used to be called 'naftidrofuryl oxalate'), but your medicine has not changed.

The other ingredients are magnesium stearate (E572), talc (E553 (b)), three common food colours (erythrosine E127, titanium dioxide E171 and black iron oxide E172), and gelatine.

What Praxilene looks like and contents of the pack

The capsules are pink and have 'Praxilene' and 'Lipha' written on them.

Praxilene comes in packs containing 100 capsules. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Merck Serono (Ireland) Limited,
4045 Kingswood Road,
Citywest Business Campus, Dublin,
D24 V06K, Ireland.

Manufacturer

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HELPFUL INFORMATION



As well as taking Praxilene there are several other things you can do to help improve your blood circulation problems:



Stop smoking

Smoking makes your circulation worse. If you stop smoking, your circulation will improve.



Exercise regularly

A walk every day will help to improve your circulation.



Eat and drink sensibly

Try not to eat too many fatty and sugary foods. Also do not drink too much alcohol.