Merck Serono

MERCK

Praxilene® 200 mg

Naftidrofuryl hydrogen oxalate film-coated tablets

Composition

Each film-coated tablet of Praxilene 200 mg contains 200 mg of naftidrofuryl hydrogen oxalate as active ingredient.
Excipients: Eudragit RSPO, Compritol 888, lactose, talc, magnesium stearate, Eudragit NE 30 D, hypromellose, Macrogol 4000.

Properties

Praxilene is a vasodilator and an anti-ischaemic medicine.

Indication

This medicine treats symptoms of:

- peripheral arterial occlusive disease stage II (a disease of the arteries of the legs, responsible for painful cramps when walking),
- minor cerebrovascular disorders associated with ageing,
- Raynaud's syndrome (spasms of the small arteries, most commonly in the fingers and toes).

Contraindications

Praxilene **must not be used** in patients with:

- hypersensitivity to naftidrofuryl or to any excipients,
- history of oxalate crystals in the urine,
- history of recurrent calcium containing kidney stone.

Pregnancy and lactation

Praxilene is mainly for use in elderly subjects. There is no, or inadequate, evidence of the safety of Praxilene in human pregnancy. It is therefore not advisable to use Praxilene in pregnant women.
No information is available in breast-feeding women. Praxilene should not be used in breast-feeding women.

Special warnings and precautions

Taking Praxilene without liquid before going to bed or lying down may injure the oesophagus. It is therefore essential to take the tablets with a large glass of water.
This medicine contains 38 mg of oxalate per 200 mg tablet. The presence of oxalate may modify the urine and increase the risk of kidney stone. It is therefore recommended to drink large volumes of water during the whole treatment period in order to maintain an adequate level of diuresis.
Because Praxilene 200 mg film-coated tablets contain lactose, it is not indicated in case of congenital galactosemia, glucose and galactose malabsorption syndrome or in case of lactase deficiency.

Effects on the ability to drive and use machines

No special information is available on the effect of Praxilene on the ability to drive a vehicle or use machines.

Undesirable effects

Like all medicines, Praxilene can cause side effects, although not everybody gets them. The following undesirable effects were observed in clinical studies or in routine patient management:

Uncommon:

- gastrointestinal disorders (diarrhoea, nausea, vomiting, stomach ache)
- skin rash

Rare: hepatitis

Very rare: calcium oxalate kidney stones

In a few patients who took the medicine without liquid, difficulty in swallowing Praxilene resulted in a local inflammation of the oesophagus.

Patients must report any undesirable or distressing effect to their doctor. To prevent serious reactions, patients must speak to their doctor immediately, if an undesirable effect is severe, occurred suddenly, or gets worse rapidly.

Interactions

As a general rule, patients have to consult their doctor, if they are taking or have recently taken another medicine, including over-the-counter medicines.

Dosage and Administration

One tablet two or three times per day.
The tablet has to be swallowed during meals without biting it, and always with a large glass of water.
In case of missed dose, patients have to take the next dose at the usual time. Patients must not double the dose of Praxilene.

Overdose

Depression of cardiac conduction, confusion and convulsions may occur. In the event of an overdose, the stomach has to be emptied by gastric lavage and emesis. Activated charcoal may be administered if necessary. Cardiovascular function has to be monitored and symptomatic treatment may be considered. Convulsions may be managed by diazepam.

Storage and Stability

Store below 25°C in a dry place.
Do not use after the expiry date stated on the outer packaging.

Keep medicines out of the reach of children.

Pharmaceutical form and presentations

Praxilene 200 mg film-coated tablets are white.
Box of 20 film-coated tablets in blister pack.

Date of Information: July 2006

31036730