Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Praxilene 100 mg Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains 100 mg naftidrofuryl hydrogen oxalate.

For a full list of excipients, see 6.1.

3 PHARMACEUTICAL FORM

Capsule, hard (capsule)
Pale pink hard gelatin capsules overprinted with Praxilene Lipha.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the treatment of:

Peripheral vascular disease with such symptoms as intermittent claudication and cold extremities. As with all such drugs, Praxilene capsules are not suitable for the treatment of advanced disease symptoms, such as pain at rest.

4.2 Posology and method of administration

Posology:
The usual dose is 100-200mg (1-2 capsules) three times a day (t.i.d).

Method of Administration:

For oral administration. The capsules should be swallowed whole during meals with a sufficient amount of water (minimum of one glass).

Paediatric population

This drug is not indicated for use in children.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Patients with a history of hyperoxaluria or recurrent calcium-containing kidney stones.

4.4 Special warnings and precautions for use

When Praxilene is used concomitantly with anti-hypertensive drugs, adjustment of dosage of the latter may be necessary.

The product should be used with caution in patients with renal or hepatic insufficiency.

Cases of liver damage have been reported. In the event of symptoms suggesting liver damage, Praxilene must be discontinued.

In view of the oxalate content of each capsule, a sufficient amount of liquid should be taken during treatment to maintain an adequate level of diuresis and avoid the development of calcium oxalate kidney stones.

The administration of Praxilene without liquid before going to bed may cause local oesophagitis. Therefore, it is essential to always take the capsule with a sufficient amount of water.

4.5 Interaction with other medicinal products and other forms of interactions

When Praxilene is used concomitantly with anti-hypertensive drugs, adjustment of dosage of the latter may be necessary.

4.6 Fertility, pregnancy and lactation

Pregnancy

In the absence of any relevant clinical data, the use of Praxilene is not advisable during pregnancy.

Breast-feeding

In the absence of specific data concerning the excretion of the drug in human milk, Praxilene should not be used by breast-feeding women.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

According to information collected during clinical trials and spontaneous reports since marketing authorisation, the following undesirable effects may occur under treatment with naftidrofuryl.

The following definitions apply to the frequency terminology used hereafter:
very common ≥1/10
common ≥1/100, <1/10
uncommon ≥1/1,000, <1/100
rare ≥1/10,000, <1/1,000
very rare <1/10,000
frequency not known: cannot be estimated from the available data

Gastro-intestinal disorders:
Uncommon: Diarrhoea, nausea, vomiting and epigastric pain.
Frequency not known: In some patients who took the medicinal product without liquid before going to bed, the capsule being stuck in the throat led to local oesophagitis.

Renal and urinary disorders:
Very rare: Calcium oxalate kidney stones (see section 4.4).

Skin and subcutaneous tissue disorders:
Uncommon: Skin rash.

Hepatobiliary disorders:
Rare: Liver damage

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions 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

4.9 Overdose

Signs and symptoms: Depression of cardiac conduction, convulsions or confusion may occur.

Treatment: The stomach should be emptied by gastric lavage and emesis. Activated charcoal may be employed if necessary. Cardiovascular function and respiration should be monitored and, in severe cases, electrical pacemaking or the use of isoprenaline should be considered. Convulsions may be managed by diazepam.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: peripheral vasodilator, ATC code: C04AX21
Praxilene has been shown to exert a direct effect on intracellular metabolism. Thus it has been shown in man and animals that it produces an increase of ATP levels and a decrease of lactic acid levels in ischaemic conditions, evidence for enhancement of cellular oxidative capacity. Furthermore, Praxilene is a powerful spasmolytic agent.

5.2 Pharmacokinetic properties

Naftidrofuryl oxalate is well absorbed when given orally. Peak plasma levels occur about 30 minutes after dosing with Praxilene capsules and the half life is about one hour, although intersubject variation is relatively high. Accumulation does not occur at a dose level of 200mg three times daily.
The drug becomes extensively bound to plasma proteins and is excreted principally via the urine, all in the form of metabolites.

5.3 Preclinical safety data

No toxic effects were seen in animal studies which provide additional information to that obtained in man. In repeated dose studies the no effect level was 25mg/kg/day or greater. There was no evidence of effects on reproduction below doses which caused maternal toxicity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Talc
Magnesium stearate

Capsule Shells:
Erythrosine E127
Titanium dioxide E171
Gelatin

Printing Ink:
Black iron oxide E172

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25^{o} C.
Store in the original package in order to protect from light and moisture.

6.5 Nature and contents of container

High density polyethylene tablet containers or polypropylene tubs with tamper evident polyethylene closures, containing 100 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Merck Serono (Ireland) Limited
4045 Kingswood Road
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA2286/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 April 1980

Date of last renewal: 01 April 2010

10 DATE OF REVISION OF THE TEXT

June 2021