149 mm

197 mm

10 mm

5 mm

5 mm

Merck Semi Serif Bold
22 pt

Merck San Serif Pro Bold
17.6 pt

Merck San Serif Pro
6 pt

PRAXILENE®

Naftidrofuryl Oxalate

Compositions

Each film-coated tablet contains Naftidrofuryl Oxalate 200 mg

Mode of Action

Praxilene has been shown to exert a direct effect on intracellular metabolism. Thus it has been demonstrated in men and animals that it produces an increase ATP levels and a decrease of lactic acid levels in ischaemic conditions, evidence for an enhancement of cellular oxidative capacity.
Furthermore, Praxilene is a powerful spasmolytic agent.

Naftidrofuryl possesses 5-HT2 blocking activity and counteracts both the vasoconstrictor effects in animals and the effects promoting platelet aggregation in animals and in man due to Serotonin.

Indications

Peripheral vascular disorders - painful symptoms of arteritis, intermittent claudication, night cramps, rest pain, incipient gangrene, trophic ulcers, Raynaud's syndrome, diabetic arteriopathy and acrocyanosis.

Dosage and administration

Adult and the elderly :
1 tablet 3 times daily for a minimum of 3 months, or at the discretion of the Physician.

Children :
The drug is not indicated for use in children

Precautions

Caution should be exercised in patients with severe cardiac insufficiency, conduction disorders and renal or hepatic insufficiency. The possibility of an additive effect occurring between Praxilene and anti-arrhythmic and beta adrenergic blocking drugs should be considered.

The administration of Praxilene may modify the composition of the urine, promoting the formation of calcium oxalate kidney stones.
Indeed, the oxalate content is 19 mg per 100 mg of active ingredient. Therefore, a sufficient amount of liquid should be taken during treatment to maintain an adequate level of diuresis.

The administration of Praxilene without liquid before going to bed may cause local oesophagitis. Therefore, it is essential to always take Praxilene with a large glass of water.
Cases of liver damage have been reported. In case of symptoms suggesting liver damage, naftidrofuryl must be discontinued

Drug Interactions

Although naftidrofuryl inhibited in vitro metabolic reactions catalysed by certain cytochrome P450 isoenzymes at very high concentrations, it is unlikely that co-administration of Praxilene will result in clinically significant inhibition of cytochrome P450-mediated metabolism of other drugs.

Pregnancy and lactation

Pregnancy
This medicine is mainly used in elderly subjects, in whom the risk of pregnancy is inexistent. In the absence of any relevant clinical data, the use of Praxilene is not advisable during pregnancy.

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

Side effects

Praxilene is normally well tolerated in the dosage recommended. Occasionally nausea, diarrhea, vomiting and epigastric pain or skin reactions (skin rash) have been noted. In case of disorders of cardiac rhythm, neurological disorders, inform doctor immediately.
In some patients who took the medicinal product without liquid before going to bed, the capsule became stuck in the throat causing local oesophagitis.
In very rare cases, calcium oxalate kidney stones have been noted.
Rarely, liver damage has been reported.

Contraindications

Praxilene must not be used in the following cases:
- Certain disorders of cardiac function
- Atrioventricular block.
- Patients with a history of hyperoxaluria or recurrent calcium-kidney stones

Praxilene is contra-indicated in patients who show a hypersensitivity to naftidrofuryl or to any excipients.

Overdosage

Symptoms
Depression of cardiac conduction, confusion and convulsions 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.

Presentations
Box of 10 x 10 film-coated tablets in blisters

Storage
Store at temperature below 25ºC

Harus dengan resep dokter
"On medical prescription only"

Manufactured by
PT Merck Tbk, Jakarta, Indonesia
under license from
Merck Healthcare KGaA, Darmstadt, Germany

Reg. No. : DKL9415804717B1

Date of revision: 25.09.2017

10470505198V10

Kode Supplier

SPECIFICATION

Material name	: Praxilene 200 FCT Insert
Article No	: 10470505198V10
Dimension	: 149 x 197 mm
Material Quality	: HVS 60 gsm
Varnish & Finishing	: -
Barcode No.	: -
Pharmacode No.	: 126
Color	: Black (5 x 4 mm)

Packing condition, if applicable:	
Length of alufoil	: -
Pcs per roll / sheet	: -
Pcs perbundle	: 100 pcs
Pcs pershipper	: -
Other condition	: Terlipat
(*eg. Folded leaflet*)	Lipat 2, lipat 2 dan lipat 2 tengah
Hasil lipatan	: P x L = 75 mm x 50 mm
Revision History	: Old Design 10470505198V10
- OPI Project	
Prepared by	: ferry

REFERENCE DATE :

File name: Praxilene 200 FCT Insert (10470505198V10)

DISETUJUI OLEH BPOM: 27/09/2024

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