

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Hexopal 500 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Inositol Nicotinate 500 mg.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

Round, white tablet, with a bevelled edge, stamped with a logo on one side and a breakline on the other. The scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Hexopal Tablets are indicated for the symptomatic relief of severe intermittent claudication and Raynaud's phenomenon.

4.2 Posology and method of administration

Adults (including the elderly)

The usual dose is 3g daily. The dose may be increased to 4g daily if necessary.

Children

Not recommended.

Oral administration.

4.3 Contraindications

This product should not be given to patients who have suffered a recent cardiac infarction, or in the acute phase of a cerebrovascular accident.

Use in patients with a known hypersensitivity to the active ingredient.

4.4 Special warnings and precautions for use

This product should be used with caution in the presence of cerebrovascular insufficiency.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, pregnancy and lactation

There is no evidence of the safety of Hexopal in human pregnancy nor is there adequate evidence from animal work that it is free from hazard. The use of Hexopal in pregnancy should therefore be avoided unless there is no safer alternative.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Side effects occur rarely and include flushing, dizziness, headache, nausea, vomiting, syncope, paraesthesia, rash, postural hypotension.

4.9 Overdose

Despite extensive clinical usage since 1959, no cases of poisoning or overdosage with inositol nicotinate have been reported. In an emergency, gastric lavage and symptomatic treatment are suggested.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Peripheral Vasodilators, ATC code: CO4A CO3

In addition to a vasodilator effect, thought to be due to the slow release of nicotinic acid, Hexopal has been reported to reduce fibrinogen and blood viscosity and to have a beneficial effect on the fibrinolytic system and on blood lipids.

5.2 Pharmacokinetic properties

Radiolabeled tracer studies indicate that with orally administered inositol nicotinate very low concentrations of nicotinic acid are found in the plasma. These levels appear to be maintained for approximately 24 hours.

5.3 Preclinical safety data

The product appears to be virtually non-toxic to animals even in doses up to 100 times the normal therapeutic level.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pregelatinised starch
Talc
Magnesium stearate
Maize starch
Stearic acid
Sodium laurilsulfate

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

PVC blisters containing 100 or 500 tablets.

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

Clonmel Healthcare Ltd.
Waterford Road
Clonmel
Co. Tipperary

8 MARKETING AUTHORISATION NUMBER

PA 126/144/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 14 March 1983

Date of last renewal: 06 January 2008

10 DATE OF REVISION OF THE TEXT

August 2008