IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0577/070/001
Case No: 2042448

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

McDermott Laboratories Ltd t/a Gerard Laboratories

35/36 Baldoyle Industrial Estate, **Grange Road**, **Dublin 13**, **Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Nagerine 15 mg tablets

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **12/12/2007** until **22/09/2010**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nagerine 15mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Cinnarizine 15mg.

For excipients see Section 6.1.

3 PHARMACEUTICAL FORM

Tablet

White, flat bevel edged tablets marked 'G' on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Cinnarizine is effective in the control of motion sickness.

4.2 Posology and method of administration

Cinnarizine is for oral administration to both adults and children according to the following dosage regime. Tablets may be sucked, chewed or swallowed whole with water.

Motion sickness:
Adults, elderly and children over 12 years:
Two tablets two hours before travel and one tablet every eight hours during journey if necessary.

Children 5-12 years:
One tablet two hours before travel and half a tablet every eight hours during journey if necessary.

Cinnarizine should preferably be taken after meals.

4.3 Contraindications

Contra-indicated in patients with known hypersensitivity to cinnarizine or any other ingredients in Nagerine 15mg Tablets.

4.4 Special warnings and precautions for use

As with other antihistamines, cinnarizine may cause epigastric discomfort; taking it after meals may diminish gastric irritation. Cinnarizine should only be given to patients with Parkinson's disease if the advantages outweigh the possible risk of aggravating this disease.

4.5 Interaction with other medicinal products and other forms of interaction

Concurrent use of alcohol, CNS depressants or tricyclic antidepressants may potentiate the sedative effects of these drugs or cinnarizine.

Cinnarizine may prevent an otherwise positive reaction to dermal reactivity indicators if used within 4 days prior to skin testing as it is an antihistamine.

4.6 Pregnancy and lactation

The safety of cinnarizine in human pregnancy has not been established although studies in animals have not demonstrated teratogenic effects. As with other drugs, it is not advisable to administer cinnarizine in pregnancy.

There are no data on the excretion of cinnarizine in human breast milk. Taking Cinnarizine during lactation should be avoided.

4.7 Effects on ability to drive and use machines

Cinnarizine may cause drowsiness; patients affected in this way should not drive or operate machinery.

4.8 Undesirable effects

Drowsiness and gastro-intestinal disturbances may occur. These are usually transient.

In rare cases, headache, dry mouth, weight gain, perspiration or allergic reactions may be observed. Very rare cases of lichen planus, lupus-like skin reactions and cholestatic jaundice have been reported. These very rare cases and the rare effect of weight gain are more likely to occur during prolonged treatment (e.g. for vestibular symptoms).

Rare cases of aggravation or appearance of extrapyramidal symptoms (sometimes associated with depressive feelings) have been described, predominantly in elderly people during prolonged therapy. The treatment should be discontinued in such cases.

4.9 Overdose

Vomiting, drowsiness, coma, tremor and hypotonia may occur. There is no specific antidote to cinnarizine and in the event of overdosage, gastric lavage is recommended. The administration of activated charcoal may help to reduce absorption of cinnarizine.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Cinnarizine is classed as an antivertigo preparation. Cinnarizine is a piperazine derivative with the actions and uses of the antihistames. It inhibits the transport of calcium ions across cell membranes. It is mainly used for the symptomatic treatment of nausea and vertigo due to Meniere's disease and other labyrinthine disturbances and for the prevention and treatment of motion sickness.

Cinnarizine is reported to possess smooth muscle relaxant properties and to inhibit vasoconstriction, and is thus used in the management of various vascular disorders. Sedative effects are not marked.

5.2 Pharmacokinetic properties

In animals, cinnarizine is extensively metabolised, N-dealkylation being the major pathway. Approximately two thirds of the metabolites are excreted with the faeces, the rest in the urine mainly during the first five days after a single dose.

In man, after oral administration, absorption is relatively slow, peak serum concentrations occurring after 2.6 to 3.4 hours.

Cinnarizine undergoes extensive metabolism but there is considerable interindividual variation in the extent of metabolism. The drug is excreted in the urine unchanged as metabolites and glucoronide conjugates.

5.3 Preclinical safety data

No relevant information additional to that contained elsewhere in the Summary of Product Characteristics.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize starch
Lactose anhydrous
Mannitol
Magnesium stearate
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

No special precautions for storage.

6.5 Nature and contents of container

PVdC coated PVC blister strips with aluminium foil lidding – 4, 6, 8, 10,15, 20, 84 and 100.
Polypropylene container with tamper-evident polyethylene closure – 4, 6, 8, 10,15, 20, 84 and 100.

Not all pack sizes will 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

McDermott Laboratories Limited
t/a Gerard Laboratories
35/36 Baldoyle Industrial Estate
Grange Road
Dublin 13
Ireland

8 MARKETING AUTHORISATION NUMBER

PA 577/70/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 September 2005

10 DATE OF REVISION OF THE TEXT