Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sea-Legs Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 12.50mg Meclozine Hydrochloride.
Also contains 132.6 mg lactose monohydrate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
White, round biconvex tablet with a scoreline on one side.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

The prevention and treatment of motion sickness.

4.2 Posology and method of administration

Route of administration: Oral

Adults and Children over 12 years

Two tablets (25mg) per 24 hours. The tablets may be taken one hour prior to commencement of journey or, as Sea-Legs can remain active for 24 hours after one dose, the previous night.

Children 6-12 years of age

One tablet (12.5mg) per 24 hours.

Children 2-6 years of age

Half of one tablet (6.25mg) per 24 hours.

4.3 Contraindications

Contraindicated in pregnancy.

4.4 Special warnings and precautions for use

May cause drowsiness, if affected do not drive or operate machinery.

Avoid alcoholic drink.

Sea legs tablets contain Lactose and therefore should not be taken by patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

Contraindicated in pregnancy.

4.7 Effects on ability to drive and use machines

May cause drowsiness, if affected do not drive or operate machinery.

4.8 Undesirable effects

None known.

4.9 Overdose

No specific statement.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Meclozine Hydrochloride is a piperazine derivative with the properties of anti-histamines. It is used for its anti-emetic action, which may last up to 24 hours. Sedative effect are not marked. It is used for the prevention and treatment of motion sickness.

5.2 Pharmacokinetic properties

In general, anti-histamines are readily absorbed from the gastro-intestinal tract, metabolised in the liver and excreted usually as metabolites in the urine.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Maize Starch
Sodium Starch Glycolate (Type A)
Magnesium Stearate
Povidone Powder

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Aluminium foil printed on one side and lacquer laminated against a low density polyethylene on the other, or PVC/PVdC blister packs.

Foil strips and blister packs are presented in cardboard cartons.

Pack sizes are 12 or 28 tablets. Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements

7 MARKETING AUTHORISATION HOLDER

GR Lane Health Products Ltd
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Gloucestershire GL2 0GR
UK

8 MARKETING AUTHORISATION NUMBER

PA00257/073/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 July 2000

Date of last renewal: 21 July 2005

10 DATE OF REVISION OF THE TEXT

February 2015