Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Serc 8 mg Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 8 mg of betahistine dihydrochloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
Product imported from France and Spain:
White, round, flat tablets, imprinted ‘256’ on one face and ‘S’ on the reverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the management of vertigo, tinnitus, and hearing loss associated with Meniere’s disease.

4.2 Posology and method of administration

Route of administration: Oral

Adults only:
The usual dose is 8 to 16mg, three times daily preferably with meals

4.3 Contraindications

- Hypersensitivity to any component of the product
- Use concurrently with antihistamines.
- Use in children.
- Use in phaeochromocytoma.

4.4 Special warnings and precautions for use

Caution is advised in the treatment of patients with a history of peptic ulcer. Clinical intolerance to Serc in bronchial asthma patients has been shown in a relatively few patients and therefore caution should be exercised when administrating betahistine to patients with bronchial asthma.

4.5 Interaction with other medicinal products and other forms of interaction

Although an antagonism between Serc and antihistamines could be expected on a theoretical basis, no such interactions have been reported.

4.6 Pregnancy and lactation

Betahistine should only be used in pregnancy if considered essential by the physician.

4.7 Effects on ability to drive and use machines

It has been shown that at over 4 times the recommended daily dose, betahistine does not affect driving or psychomotor ability.

4.8 Undesirable effects

Gastrointestinal disorders
In some cases mild gastric complaints have been observed. These can normally be dealt with by taking the dose during meals or by lowering the dose.

Nervous system disorders
In some cases headaches have been reported.

Skin and subcutaneous tissue disorders
In very rare cases cuntaneous hypersensitivity reactions have been reported, in particular rash, purities and urticaria.

4.9 Overdose

A few overdose cases have been reported. In most cases no overdose symptoms were reported. Some patients experienced mild to moderate symptoms at doses above 200 mg. At a dose of 728 mg a convulsion was reported. In all cases recovery was complete. Treatment of overdose should include standard supportive measures.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

The mechanism of action of betahistine is not known. Pharmacological testing animals has shown that the blood circulation in the striae vascularis of the inner ear improves, probably by means if a relaxation of the precapillary sphincters of the microcirculation of the inner ear.

In pharmacological studies, betahistine was found to have weak H1 receptor agonistic and considerable H3 antagonistic properties in the CNS and autono-mic nervous system. Betahistine was also found to have a dose-dependent inhibiting effect on spike generation of neurons in lateral and medial vestibular nuclei. The importance of this observation in the action against Méniére’s syndrome or vestibular vertigo, however, remains unclear.

5.2 Pharmacokinetic properties

Betahistine dihydrochloride is completely absorbed after oral administration. Only one metabolite 2-pyridylacetic acid, which is excreted in the urine, is known.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the presciber which are additional to that already including in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline cellulose
Mannitol (E421)
Citric acid monohydrate
Colloidal anhydrous silica
Talc

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

The shelf life expiry date for this product is the date shown on the container and outer package of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C.
Store in the original package.

6.5 Nature and contents of container

Blister packs containing 60 and 90 tablets contained in an outer cardboard carton**.**

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 Parallel Product Authorisation Holder

PCO Manufacturing Limited
Unit 10, Ashbourne Business Park
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Ashbourne
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8 Parallel Product Authorisation Number

PPA 0465/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authroisation: 12 August 1987

Date of last renewal: 12 August 2007

10 DATE OF REVISION OF THE TEXT

October 2008