Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Serc 16mg Tablets.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 16mg betahistine dihydrochloride.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

Product imported from Belgium and Spain:
Circular, flat, white to almost white tablets imprinted with '267' on either side of a Breakline on one side and **S** on the reverse.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Vertigo, tinnitus and hearing loss associated with Ménière's syndrome.

4.2 Posology and method of administration

Initially 16 mg three times daily taken preferably with meals. Maintenance doses are generally in the range 24-48 mg daily.

4.3 Contraindications

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

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 administering betahistine to patients with bronchial asthma.

4.5 Interaction with other medicinal products and other forms of interaction

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

4.6 Pregnancy and lactation

There is insufficient data on the use of this drug during pregnancy to evaluate possible harmful effects. There are no indications of harmful effects in animal testing.
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 cutaneous 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 in animals has shown that the blood circulation in the striae vascularis of the inner ear improves, probably by means of a relaxation of the precapillary sphincters of the microcirculation of the inner ear.

In pharmacological studies, betahistine was found to have weak H_1 receptor agonistic and considerable H_3 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 Ménière'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

Results from preclinical studies do not add to the information required by the prescriber.

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 of this product shall be 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 30 or 42 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
Rath
Ashbourne
Co. Meath

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA 0465/005/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30 September 2005
Date of last renewal: 30 September 2010

10 DATE OF REVISION OF THE TEXT

October 2010