SUMMARY OF PRODUCT CHARACTERISTICS

Betahistine dihydrochloride all pharmaceutical forms and strengths

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BETAHISTINE DIHYDROCHLORIDE

<TRADENAME>

1. NAME OF THE MEDICINAL PRODUCT

Unchanged

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

<Trademark> tablets contain 8 mg betahistine dihydrochloride equivalent to 5.21mg betahistine, 16 mg betahistine dihydrochloride equivalent to 10.42 mg and 24 mg betahistine dihydrochloride equivalent to 15.63mg.

<Trademark> oral solution contains 8 mg betahistine dihydrochloride per ml equivalent to 5.21 mg betahistine per ml.

3. PHARMACEUTICAL FORM

Unchanged

4. CLINICAL PARTICULARS

4.1. Therapeutic Indications

Unchanged

4.2. Posology and Method of Administration

Unchanged

4.3. Contra-indications

Unchanged

4.4. Special Warnings and Precautions for Use

Unchanged

4.5. Interactions with other Medicinal Products and other forms of Interaction

Unchanged

4.6. Fertility, pregnancy and lactation

Pregnancy

There are no adequate data from the use of betahistine in pregnant women.

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity at clinically relevant therapeutic exposure. As a precautionary measure, it is preferable to avoid the use of betahistine during pregnancy.

Lactation

It is not known whether betahistine is excreted in human milk.
Betahistine is excreted in rat milk. Effects seen post-partum in animal studies were limited to very high doses. The importance of the drug to the mother should be weighed against the benefits of nursing and the potential risks for the child.

Fertility

Animal studies did not show effects on fertility in rats.

4.7. Effects on Ability to Drive and Use Machines

Unchanged

4.8. Undesirable Effects

Unchanged

4.9. Overdose

Unchanged

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic Properties

Unchanged

5.2. Pharmacokinetic Properties

Unchanged

5.3. Preclinical Safety Data

Chronic toxicity

Adverse effects in the nervous system were seen in dogs and baboons after intravenous doses at and above 120 mg/kg.

Chronic oral toxicity testing for 18 months in rats at a dose of 500 mg/kg and 6 months in dogs at a dose of 25 mg/kg showed betahistine to be well tolerated with no definitive toxicities.

Mutagenic and carcinogenic potential

Betahistine does not have mutagenic potential.

In an 18 months chronic toxicity study in rats betahistine up to a dose of 500 mg/kg did not show any evidence for carcinogenic potential.

Reproduction toxicity

Effects in reproductive toxicity studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.

6. PHARMACEUTICAL PARTICULARS

6.1. List of Excipients

Unchanged

6.2. Incompatibilities

Unchanged

6.3. Shelf Life

Unchanged

6.4. Special Precautions for Storage

Unchanged

6.5. Nature and Contents of Container

Unchanged

6.6. Special precautions for disposal

Unchanged

7. MARKETING AUTHORISATION HOLDER

Unchanged

8. MARKETING AUTHORISATION NUMBER

Unchanged

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Unchanged

10. DATE OF REVISION OF THE TEXT

DD/MM/YYYY