SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dimenhydrinate

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Dimenhydrinate BP 50.00 mg

3 PHARMACEUTICAL FORM

Tablet

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Dimenhydrinate is used mainly as an anti-emetic in the prevention and treatment of motion sickness; irradiation sickness, postoperative vomiting, drug-induced nausea and vomiting, and the symptomatic treatment of nausea and vertigo due to Meniere's disease and other labyrinthine disturbances.

4.2 Posology and method of administration

Adults:

For motion sickness it is usually given in doses of 50 mg three times daily, the first dose for preventing motion sickness being taken about 30 minutes before the journey.

For other treatment, 4-hourly administration may be required. Doses of 100 mg may be required but a daily total of 300 mg should not usually be exceeded.

Children:

2 to 6 years - 12.5 to 25 mg two to three times daily. Not more than 75 mg should be given in any 24 hours. Do not exceed the stated dose.

7 to 12 years - 25 to 50 mg two to three times daily. Not more than 150 mg should be given in any 24 hours. Do not exceed the stated dose.

Elderly:

Same as adult dose.

Route of administration: Oral.

4.3 Contraindications

Sensitivity to Dimenhydrinate or any of the other ingredients of the tablet.

In patients with porphyria.

Children under 2 years old.

4.4 Special warnings and precautions for use

Dimenhydrinate should be used with caution in patients with

- epilepsy
- prostatic hypertrophy or urinary retention
- glaucoma
- hepatic diseases
- pyloroduodenal obstruction

In patients with renal impairment, a reduction in the dose of any antihistamine (e.g. dimenhydrinate) may be necessary.

Use in children under 6 years old should only be under professional advise. Diphenhyramine should not be taken with cough and cold medicines in children aged 2-6 years old.

Children and the elderly are more susceptible to the side effects.

It has been suggested that Dimenhydrinate could mask warning symptoms of damage caused by ototoxic drugs such as the amino-glycoside antibiotics.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Dimenhydrinate will interact with anticholinergic, anti-depressant (tricyclic and MAOIs) and anti-parkinsonian drugs such as Trihexyphenidyl, increasing the anticholinergic side effects, dry mouth, urine retention, confusion, etc.

The effects of Betahistine may be antagonized.

Sedating antihistamines may enhance the sedative effects of CNS depressants including alcohol, other sedating antihistamines, barbiturates, hypnotics, opiods, anxiolytic sedatives and antipsychotics.

It is important that the dose of Neperidine, Morphine or other narcotic analgesics and of barbiturates be reduced by ¼ or ½ when used concomitantly.

4.6 Pregnancy and lactation

Dimenhydrinate should not be used in pregnancy unless the physician considers it is essential. There was a significant incidence of cleft palate and clefts with other defects in children whose mothers have taken diphenhydramine (a component of Dimenhydrinate).

Dimenhydrinate is excreted in breast milk to such an extent that effects on the suckling child are likely if therapeutic doses of Dimenhydrinate are administered to breast-feeding women.

4.7 Effects on ability to drive and use machines

Patients undergoing treatment with Dimenhydrmnate should not take charge of vehicles, other means of transport or machinery where loss of attention may lead to accidents because Dimenhydrinate may cause drowsiness and dulling of mental alertness.

4.8 Undesirable effects

Adverse effects with Dimenhydrinate may vary in incidence and severity from patient to patient. The most common effect is sedation which may vary from slight drowsiness to deep sleep. The drug may be associated with inability to concentrate, lassitude, dizziness, hypotension, muscular weakness and inco-ordination. When they do occur the sedative effects may diminish after a few days.

Rare with Dimenhydrinate are gastro-intestinal side effects.

Dimenhydrinate may very rarely produce headache, blurred vision, tinnitus, elation or depression, irritability, nightmares, anorexia, difficulty in micturition, dryness in the mouth, tightness in the chest, tingling, heaviness and weakness of the hands.

Although cardio-vascular side effects are rare, minor increases in blood pressure and occasional mild hypotension have been reported. Leucopenia and rarely agranulocytosis, jaundice and extra-pyramidal reactions have also been reported.

Occasionally hypersensitivity reactions have followed its uses by both mouth or topical application. These include bronchospasm, angioedema, rashes and photosensitivity.

4.9 Overdose

In the case of severe overdosage, the stomach should be emptied by gastric lavage. Emetics should not be used.

The patient should be kept quiet, particularly in the case of children, to minimise the excitation which occurs. Convulsions may be controlled with Diazepam preferably given intravenously. Since Dimenhydrinate is rapidly

metabolised with only traces being recoverable in the urine, diuresis is of little, if any, value.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dimenhydrinate is the salt produced by interaction of the antihistimanic base diphenhydramine with the acidic compound 8-chiorotheophylline. Dimenhydrmnate markedly depresses labyrinthine function.

Because of the receptors with which it interacts, Dimenhydrinate is described as an H1-antagonist or the blocker of histamine and belongs to the Theanolamine group.

The mode of action is a result of the binding with high affinity to ‘in the brain. It is not, however, clear whether the anti-motion sickness activity of Dimenhydrinate is related to its ability to block muscarinic receptors.

5.2 Pharmacokinetic properties

Dimenhydrinate is well absorbed from the gastro-intestinal tract after oral dosing with extensive first-pass effect. The drug is metabolised in the liver and excreted usually as metabolites in the urine. The drug is highly bound to plasma proteins and is widely distributed in the body. Following oral administration, the effects develop in about 30 minutes and are maximal within 1-2 hours and last for 3-6 hours.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
Povidone
Sodium Starch Glycollate
Magnesium Stearate

6.2 Incompatibilities

Dimenhydrinate caused precipitation when mixed with solutions of Tetracycline Hydrochloride in dextrose injections and when mixed with Novobiocin Sodium in sodium chloride solution.

Substances which were incompatible with solutions of Dimenhydrinate included phenothiazine derivatives, reserpine, methoxamine hydrochloride, pentobarbitone sodium, thiamylal sodium, nicotinic acid, pyridoxine hydrochloride, and certain antibiotic solutions such as chioramphenicol succinate.

6.3 Shelf life

36 months: High density polystyrene containers with polythene lids and/or polypropylene containers with polypropylene or polythene lids.

24 months: PVC/Aluminium foil packs.

6.4 Special precautions for storage

Keep container well closed. Protect from light. Store below 25ºC.

6.5 Nature and contents of container

High density polystyrene containers with polythene lids and/or polypropylene containers
with polyproylene or polythene lids: 100 and 500

PVC/Aluminium foil packs: 30

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Chelonia Healthcare Limited

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8 MARKETING AUTHORISATION NUMBER(S)

PL 33414/0040

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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17/02/2009