GRAVINATE
(Dimenhydrinate)

Tablet & Liquid

COMPOSITION

Each tablet contains:

Dimenhydrinate ……50 mg

Each 4ml contains:

Dimenhydrinate 12.5mg

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.

DOSAGE AND ADMINISTRATION

Adults:
It is usually given in doses of 50 mg thrice daily, the first dose for preventing motion sickness being taken about 30 minutes before the journey. For 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 or three times daily. Max: 75 mg daily.
7 to 12 years - 25 to 50 mg two or three times daily. Max: 150 mg daily.
≥12 years Same as adult dose.

Elderly:
Same as adult dose.

Method of Administration

Oral

CONTRAINDICATIONS

Sensitivity to Dimenhydrinate or any of the other ingredients.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Dimenhydrinate should be used with caution in epilepsy, prostatic hypertrophy, glaucoma and hepatic diseases. It has been suggested that Dimenhydrinate could mask warning symptoms of damage caused by ototoxic drugs such as the amino-glycoside antibiotics.

DRUG INTERACTIONS

Dimenhydrinate will interact with anticholinergic and anti-parkinsonian drugs such as Benzhexol, increasing the anticholinergic side effects, dry mouth, urine retention, confusion, etc. Patients should be warned not to take alcohol while under treatment with drugs affecting the Central Nervous System, in particular anti-histamines such as Dimenhydrinate. Because of the potentiating threat of Dimenhydrinate on the action of the Central Nervous System depressants 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.

EFFECTS ON ABILITY TO DRIVE

Patients undergoing treatment with Dimenhydrinate 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.

FERTILITY, 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).

ADVERSE DRUG REACTIONS

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 incoordination. 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 and topical application.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions at pv@searlecompany.com

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 minimize the excitation which occurs. Convulsions may be controlled with Diazepam preferably given intravenously. Since Dimenhydrinate is rapidly metabolized with only traces being recoverable in the urine, diuresis is of little, if any, value.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties

Dimenhydrinate is the salt produced by interaction of the antihistaminic base diphenhydramine with the acidic compound 8-chlorotheophylline. Dimenhydrinate 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 H1 - receptors 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.

Pharmacokinetic properties

Dimenhydrinate is well absorbed from the gastro-intestinal tract after oral dosing with extensive first-pass effect. The drug is metabolized 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.

PRECLINICAL SAFETY DATA

No relevant information additional to that contained elsewhere in the SPC.

PRESENTATION

Gravinate Tablets are available as a Boxes of 100 tablets (10 x 10's blister strips)

Gravinate Liquid is available as Bottle of 60ml

INSTRUCTIONS

- *To be sold on the prescription of a registered medical practitioner only.*

- *Protect from sunlight, moisture and heat.*

- *Store below 30°C.*

- *Keep all medicines out of sight & reach of children.*

- *Product contains lactose.*

REGISTRATION NUMBER

Gravinate Tablets: 014407

Gravinate Liquid: 014409

MANUFACTURING LICENCE NO. 000647

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Manufactured by:

The Searle Company Limited

32-Km, Multan Road, Lahore-Pakistan.

DATE OF PUBLICATION OF THE PACKAGE INSERT

June 2021

SPL/SPC-GRA.T&S/621-000(001)