VOTMINE INJECTION 10ML VIAL (50MG/ML)

DESCRIPTION:
VOTMINE INJECTION 10 ML VIAL (50 MG / ML): A clear, colourless solution.
Excipient: Benzyl Alcohol, Propylene Glycol, Sodium Hydroxide, Water for Injection

COMPOSITION:
VOTMINE INJECTION 10 ML VIAL (50 MG / ML): Each ml contains Dimenhydrinate 50 mg in a 10 ml vial.

PHARMACODYNAMICS:
The site of action of dimenhydrinate is not clearly understood. Evidence indicates that dimenhydrinate acts either on the overstimulated labyrinth, depresses transmission of nerve stimuli centrally (to the cerebrum) or acts between the labyrinth and the vomiting center – probably at the chemoreceptor trigger zone.
Antihistamines act by competing with histamines for H1-receptor sites on effector cells. They prevent but do not reverse responses mediated by histamine alone.
Antiemetic; antivertigo agent – Mechanism by which they exert their antiemetic, antimotion sickness and anti-vertigo effects is not precisely known but may be related to their central anticholinergic actions. They diminish vestibular stimulation and depresses labyrinthine function. An action on the medullary chemoreceptive trigger zone may also be involved in the antiemetic effect.

PHARMACOKINETICS:
Dimenhydrinate is the diphenhydramine salt of 8-chlorotheophylline. No human pharmacokinetic data are available. Rhesus monkey orally doses with radioactive diphenhydramine had peak plasma levels (0.25 – 0.3 mcg/mL) of unchanged drug between one to two hours after dosing. Values declined thereafter with an apparent half-life of about one hour. However, plasma levels of total radioactivity reached a peak four hours after dosing (26.0 mcg/mL) and then declined with a half-life of about 12 hours. Ninety-one percent of the labelled material from a four hours plasma sample was identified as the metabolite diphenyl-methoxyacetic acid.
The major urinary metabolites are conjugates of diphenyl-methoxyacetic acid.

INDICATIONS:
Prevention and relief of motion sickness, treatment of vertigo, nausea or vomiting associated with electroshock therapy, anaesthesia and surgery; labirinthine disturbances and radiation sickness.

RECOMMENDED DOSE:
Injection:
Usual Adult and Adolescent Dose: Antiemetic; or Antivertigo agent – Intramuscular, 50 mg repeated every four hours as needed. Intravenous, 50 mg in 10 mL of 0.9% sodium chloride injection, administered slowly over a period of at least two minutes, repeated every four hours as needed.

Usual Pediatric Dose: Antiemetic; or Antivertigo agent – Intramuscular, 1.25 mg per kg of body weight or 37.5 mg per square meter of body surface, every six hours as needed, not to exceed 300 mg per day.
Intravenous, 1.25 mg per kg of body weight or 37.5 mg per square meter of body surface, in 10 ml of 0.9% sodium chloride injection, administered slowly over a period of at least two minutes, every six hours as needed, not to exceed 300 mg per day.
Note: Premature and full-term neonates – Use is not recommended.

Usual Geriatric Dose: See Usual Adult and Adolescent Dose.
Note: Geriatric patients may be more sensitive to the effects of the usual adult dose.

> As this preparation contains benzyl alcohol, its use should be avoided in children under two years of age.
> Not to be used in neonates.

ROUTE OF ADMINISTRATION: Injection: For I.M. and I.V. injection

CONTRAINDICATIONS:
Dimenhydrinate is contraindicated in patients known to be allergic to this drug.

PRECAUTIONS/WARNINGS:
Drowsiness may occur, those affected should not drive or operate machinery. It should be borne in mind that antiemetics should be used with caution since they may mask the presence of underlying organic abnormalities or the toxic effects of other drugs, particularly those drugs causing ototoxicity which may be irreversible.
Prolonged therapy with antihistaminic drugs can produce blood dyscrasias in rare instances.
Pediatric: Newborn or premature infants have an increased susceptibility to anti-cholinergic side effect such as CNS excitation and an increased tendency toward convulsions.
Use in lactation: Small amount of antihistamines are distributed into breast milk; use is not recommended in nursing mothers because of the risk of adverse effects, such as unusual excitement or irritability in infants.
Geriatrics: Dizziness, sedation, confusion and hypotension may be more likely to occur in geriatric patients taking antihistamines. Narrow angle glaucoma and prostate enlargement may be anticipated.
Use cautiously in asthmatic patients.

CAUTION:
Caution is recommended when dimenhydrinate is used, since their antiemetic action may impede diagnosis of such conditions as appendicitis and obscure signs of toxicity from overdose of other drugs.

INTERACTIONS WITH OTHER MEDICAMENTS:
Alcohol or CNS depression-producing medications may potentiate the CNS depressant effects of antihistamines.
Anticholinergics or medications with anticholinergic activity – the anticholinergic effects may be potentiated with concurrent use of antihistamines.
Apomorphine – Prior administration of dimenhydrinate may decrease the emetic response of apomorphine in the treatment of poisoning.
Concurrent use of CNS depression-producing medications like antihistamines with opioid analgesics may result in increased CNS depressant and hypotensive effects; caution is recommended and dosage of one or both agents should be reduced.

SIDE EFFECTS:
Drowsiness may be experienced by some patients, especially on high dosage, although this effect frequently is not undesirable in some conditions for which dimenhydrinate is used. However, patients should be cautioned against operating automobiles or dangerous machinery while taking dimenhydrinate because of the possible drowsiness associated with the drug.
Dizziness may also occur. Symptoms of dry mouth, lassitude, excitement, nausea, fixed drug eruption, occasionally blurred vision and rarely convulsive disorders.

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SYMPTOMS AND TREATMENT OF OVERDOSE:
Symptoms. Drowsiness is the usual clinical side effect. Convulsions may occur with massive overdosage.
Anticholinergic effects: Clumsiness or unsteadiness, severe drowsiness, severe dryness of mouth, nose or throat, flushing or redness of face, shortness of breath or troubled breathing.
Treatment: Since there is no specific antidote for overdose with antihistamines treatment is symptomatic and supportive.
Stimulants may be administered (caffeine or amphetamine) to counteract sedation. Short acting barbiturates may be administered intramuscularly or intravenously, if convulsions occur, however, such treatment should be exercised with caution as sedatives may enhance the CNS depression produced by Dimenhydrinate.

PACKING/PACK SIZES:
Injection: Pack of 10 glass vials x 10ml, 25 glass vials x 10 ml, 50 glass vials x 10 ml and 100 glass vials x 10 ml
Not all pack sizes may be available locally

STORAGE CONDITION:
Store below 30°C. Protect from light.
KEEP OUT OF REACH OF CHILDREN. *JAUHKAN DARIPADA KANAK-KANAK.*
Chemical and physical in use stability has been demonstrated for 28 days at below 30°C. From a microbiological point of view, once opened, the product may be stored for a maximum of 28 days at below 30°C. Other in-use storage times and conditions are the responsibility of the user

SHELF LIFE:
Please refer to outer package.

PRODUCT REGISTRATION HOLDER (Malaysia)& MANUFACTURER:
DUOPHARMA (M) SDN BHD (42491 M)
Lot 2599 Jalan Seruling 59 Kawasan 3
Taman Klang Jaya, 41200 Klang, Selangor, Malaysia

PRODUCT REGISTRATION HOLDER (Singapore):
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