

PRODUCT INFORMATION

Unisom[®] SleepGels[®]

Product description

Unisom[®] SleepGels[®] are liquid filled capsules containing 50 mg diphenhydramine hydrochloride.

Unisom[®] SleepGels[®] also contain gelatin, glycerol, macrogol 400, sorbitol, purified water, Brilliant Blue FCF and Opacode WB Monogramming Ink NSP-78-18022 White.

Pharmacology

Pharmacokinetics

Diphenhydramine is well absorbed following oral administration with the drug appearing in plasma within 15 minutes. High first-pass metabolism in the liver appears to affect systemic availability with only 40-60% of an oral dose reaching the systemic circulation as unchanged diphenhydramine. Peak plasma concentrations are achieved within 1-4 hours. The sedative effect appears to be maximal within 1-3 hours after administration of a single dose of diphenhydramine and appears to be positively correlated with plasma drug concentration, with marked drowsiness and/or sleep occurring at plasma concentrations of 70 ng/mL or greater.

Diphenhydramine is widely distributed throughout the body including the CNS. The drug crosses the placenta and has been detected in human milk although the extent has not been quantified. Diphenhydramine is approximately 80-85% protein bound *in-vitro*. Less extensive protein binding has been reported in healthy oriental adults and in adults with liver cirrhosis.

The terminal elimination half-life of diphenhydramine appears to range from 2.4 - 9.3 hours in healthy adults. It may be prolonged in adults with liver cirrhosis.

Diphenhydramine is rapidly and almost completely metabolised. Following oral administration of a single 100 mg dose in healthy adults, about 50-75% of the dose is excreted in urine within 4 days almost completely as metabolites. Most urinary excretion occurs within the first 24-48 hours and only about 1% of a single dose is excreted unchanged in the urine.

Pharmacodynamics/Mechanism of action

Diphenhydramine is an ethanolamine antihistamine with anticholinergic and sedative effects. It produces its sedative effect by depression of the CNS.

Diphenhydramine competes with histamine at central and peripheral histamine₁-receptor sites, preventing the histamine-receptor interaction and subsequent mediator release.

Indications

Unisom SleepGels are used as a temporary sleeping aid.

Contraindications

Diphenhydramine is contraindicated for use in patients with:

- a history of hypersensitivity to the substance, or substances of similar chemical structure, or any of the other ingredients in the product
- narrow-angle glaucoma
- symptomatic prostatic hypertrophy
- bladder neck obstruction
- pyloroduodenal obstruction and stenosing peptic ulcer. Both stenosing peptic ulcer and pyloroduodenal obstructions predispose the patient to an increased risk of gastrointestinal obstruction. Agents with anticholinergic properties such as diphenhydramine, reduce the tone and motility of the gastrointestinal tract and thus may contribute to worsening of gastrointestinal obstruction.

Diphenhydramine is contraindicated for use in:

- newborns or premature infants
- lactating women
- patients having an asthma attack
- patients receiving antidepressant therapy, especially monoamine oxidase inhibitors (MAOIs) and tricyclic antidepressants (TCAs)
- patients receiving any other product containing diphenhydramine.

Precautions

Diphenhydramine has an atropine-like action which should be considered. It should be used with caution in patients with a history of asthma.

Diphenhydramine may cause drowsiness and may have an additive effect when taken with alcohol and other CNS depressants. Avoid alcohol, do not drive a motor vehicle or operate machinery.

Diphenhydramine should not be taken in conjunction with other antihistamines, sedatives or tranquillisers except on medical advice.

The terminal half-life of diphenhydramine may be prolonged in cirrhotic patients.

Use in children and the elderly

Children and the elderly may experience paradoxical excitation with diphenhydramine. The elderly are more likely to have central nervous system (CNS) depressive side effects, including confusion.

Use in pregnancy

Category A: Diphenhydramine has been taken by a large number of pregnant women and women of childbearing age without any proven increase in the frequency of malformations or other direct or indirect harmful effects of on the foetus having been observed.

Use in lactation

Diphenhydramine has been detected in breast milk. Therefore it is not recommended for breastfeeding mothers unless the potential benefits to the patient are weighed against the possible risk to the infant.

Interactions with other drugs

The following interactions with diphenhydramine have been noted:

- CNS depressants (alcohol, barbiturates, anxiolytic sedatives, opioid analgesics, hypnotics and antipsychotics) – may cause an increase in sedation effects
- Antidepressants (particularly tricyclic antidepressants (TCAs) and monoamine oxidase inhibitors (MAOIs)) – may prolong and intensify the anticholinergic and CNS depressive effects.

Adverse reactions

The most common side effects are drowsiness, lassitude, dizziness and incoordination. Other effects are nausea, vomiting, constipation, diarrhoea, blurred vision, dry mouth, urinary retention, dysuria, tightness of the chest, hypotension, tachycardia, muscular weakness, tinnitus, euphoria and occasionally headache.

Dosage

Adults and children over 12 years of age: Take one capsule at bedtime, if needed.

Do not give to children under 12 years of age. Do not exceed the recommended dosage.

Should sleeplessness persist for more than 7 to 10 nights, further medical advice should be sought.

Overdosage

In case of overdose, immediately contact the Poisons Information Centre for advice. In Australia, call 13 11 26; in New Zealand call 0800 764 766.

Symptoms of antihistamine overdose may vary from central nervous system depression to stimulation. Stimulation is particularly likely in children. Atropine-like signs and symptoms such as dry mouth, fixed and dilated pupils, flushing, and gastrointestinal symptoms may also occur.

Presentation

Unisom SleepGels are clear, blue, oval, soft, liquid filled capsules with 'UNISOM' printed in white.

Unisom SleepGels are available in blister packs containing 10 capsules

(S3) Pharmacist Only Medicine

Store below 25°C.

AUST R 55323

Name and Address of Sponsor

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