

# Unisom SleepGels

## Diphenhydramine hydrochloride

### **Presentation**

Each liquid-filled blue, soft gelatine capsule is imprinted UNISOM and contains 50 mg of diphenhydramine hydrochloride.

### **Uses**

#### **Actions**

Diphenhydramine is an ethanolamine antihistamine with anticholinergic and sedative effects.

#### **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 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 quantitated. 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.

#### **Indications**

A night time sleep aid for the short-term management of insomnia.

### **Dosage and Administration**

Adults and children over 12 years of age. The dose is one softgel (50 mg) at bedtime if needed. Should sleeplessness persist for more than 7 to 10 nights further medical advice should be sought.

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

### **Contraindications**

Premature or newborn infants. Hypersensitivity to the drug. Asthma attack, narrow angle glaucoma, prostatic hypertrophy, stenosing peptic ulcer, pyloroduodenal obstructions, bladder neck obstruction, patients receiving antidepressant therapy.

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 increase the risk of worsening/contributing to gastrointestinal obstruction.

### **Warnings and Precautions**

Diphenhydramine has an atropine-like action, which should be considered. Use with caution in those with a history of asthma.

May have an additive effect when taken with alcohol and other CNS depressants. Avoid alcohol and do not drive a motor vehicle.

Should not be taken in conjunction with other antihistamines, sedatives or tranquilisers except on medical advice.

Do not take with any other product containing diphenhydramine including those applied topically. The terminal half-life may be prolonged in cirrhotic patients.

### **Use in pregnancy and lactation**

Category A. (Drugs which have been taken by a large number of pregnant women and women of child bearing age without increase in the frequency of malformations or other direct harmful effects on the foetus having been observed.)

Diphenhydramine has been detected in breast milk. See **Contraindications**.

### **Adverse Effects**

The most common side effect is slight drowsiness to deep sleep and including lassitude, dizziness, incoordination. Other effects are nausea, vomiting, diarrhoea, blurred vision, dry mouth, urinary retention, dysuria, tightness of the chest, hypotension, muscular weakness, tinnitus, euphoria and occasionally headache.

### **Interactions**

Antidepressants, particularly of the tricyclic and monoamine oxidase inhibitor types may interact with diphenhydramine. MAO inhibitors prolong and intensify the anticholinergic effects of antihistamines. The CNS effect is increased by alcohol and other CNS depressant drugs.

### **Mutagenicity and Carcinogenicity**

Long-term animal studies to determine the mutagenic and carcinogenic potential of diphenhydramine have not been performed to date.

### **Overdosage**

Antihistamine overdosage reactions 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. Administration of activated charcoal should be considered. Empty stomach by aspiration and lavage. Emetics may be tried if the patient is alert.

### **Pharmaceutical Precautions**

Store below 25°C.

Unisom SleepGels have a three year shelf-life.

### **Medicine Classification**

Restricted medicine (Pharmacist Only).

### **Package Quantities**

Blister pack of 10 capsules

### **Further Information**

Liquid filled, blue soft gelatine capsules imprinted with the word UNISOM. Each capsule contains diphenhydramine hydrochloride USP 50 mg with Macrogol 400, glycerol, gelatin, sorbitol, brilliant blue FCF, polyvinyl acetate phthalate, shellac, titanium dioxide, propylene glycol and purified water.

### **Name and Address**

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### **Date of Preparation**

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