NEW ZEALAND DATA SHEET

Unisom SleepGels 50mg capsules

Diphenhydramine hydrochloride

1 PRODUCT NAME

Unisom SleepGels 50mg capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Liquid filled, blue soft gelatine capsules imprinted with the word UNISOM

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Dose and method of 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.

4.3 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.

4.4 Special warnings and precautions for use

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

Unisom should be used with caution in subjects with a history of hyper thyroidism, cardiovascular and/or renal disease, hypertension and diabetes.

Use with caution in elderly patients who experience confusion at nighttime

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.

4.5 Interaction with other medicines and other forms of interaction

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.

Unisom (diphenhydramine hydrochloride) produces additive central nervous system effects when taken concomitantly with alcohol, hypnotics, anxiolytics, narcotic analgesics and neuroleptic drugs. Similarly significant interactions may occur if the drug is taken concomitantly with anticholinergic agents or tricyclic antidepressants.

4.6 Fertility, pregnancy and lactation

Pregnancy

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.)

Breastfeeding

Diphenhydramine has been detected in breast milk. See **Section 4.3**

Fertility

No fertility information available.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

The most frequently reported adverse reactions are dizziness, dryness of mouth, nose or throat, nausea and nervousness.

Other less frequently reported effects are vertigo, palpitation, blurring of vision, headache, restlessness, insomnia and thickening of bronchial secretions. The following effects may also occur: lassitude, excitement, diplopia, difficulty in urination, constipation, nasal stuffiness, vomiting, drug rash, urticaria, hypotension, photosensitivity, epigastric distress, tightness of the chest and wheezing, excessive perspiration, chills, confusion, restlessness, irritability, diarrhoea or constipation. Rarely prolonged therapy with antihistamines can produce blood dyscrasias.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/ .

4.9 Overdose

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.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antihistamines for systemic use

ATC code: R06AA02

Diphenhydramine is an ethanolamine antihistamine with anticholinergic and sedative effects.

The primary action of diphenhydramine is the antagonism of certain effect of histamine such as broncho-constriction and capillary dilation.

The most frequently encountered secondary effects of diphenhydramine are related to central nervous system depression. The effects vary from slight drowsiness to deep sleep and have been reported to include the inability to concentrate, lassitude, dizziness, muscular weakness and incoordination. However, the sedative action of diphenhydramine has been found to be of some value for occasional use in the relief of nighttime sleeplessness. The sedative action may last up to 6 hours but often diminishes after a few days as tolerance to this effect develops.
Other actions of diphenhydramine include an antiemetic effect and some anticholinergic activity which can produce blurred vision, dry mouth, and gastroinstestinal disturbances (e.g. nausea, vomiting, epigastric pain, diarrhoea).

5.2 Pharmacokinetic properties

Absorption

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.

Distribution

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.

Elimination

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.

5.3 Preclinical safety data

Mutagenicity and Carcinogenicity

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unisom SleepGels have a three year shelf-life.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Blister pack of 10 capsules

6.6 Special precautions for disposal

No special requirements for disposal.

7 MEDICINE SCHEDULE

Restricted medicine (Pharmacist Only).

8 SPONSOR

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9 DATE OF FIRST APPROVAL

12/2/1996

10 DATE OF REVISION OF THE TEXT

30 Nov 2018

[Prescribing Information v 3.0, 22 April 2009]

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All	Reformatted to new SPC format
4.4 and 4.5	Addition of safety information to align with the Prescribing Information v 3.0
4.8	Update to this section to align with the Prescribing Information v 3.0