PRESCRIBING INFORMATION

UNISOM®

(Diphenhydramine Hydrochloride)

50 mg

Sleep-Aid

Paladin Labs Inc.
6111 Royalmount Avenue, Suite 102
Montreal, QC
H4P 2T4

Date of revision:
April 22, 2009
Version : 3.0

Control No. : 129311 & 129312

ACTIONS: 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).

INDICATIONS: Unisom (diphenhydramine hydrochloride) is indicated for the relief of occasional sleeplessness. The use of Unisom for more than a few consecutive nights at a time is not recommended and more appropriate therapy should be considered in cases of severe and/or chronic insomnia. If pain or other factors appear to be the cause of sleeplessness, sleep-aids should not be considered as primary therapeutic agents.

CONTRAINDICATIONS: Unisom (diphenhydramine hydrochloride) is contraindicated in patients who are hypersensitive to the drug and in those with the following conditions: asthmatic attack, narrow angle glaucoma, prostatic hypertrophy, stenosing peptic ulcer, pyloroduodenal obstruction, bladder-neck obstruction. Patients receiving monoamine oxidase inhibitors should not be given diphenhydramine.

WARNINGS:

- Do not exceed recommended dose except on the advise of a physician

- If sleeplessness persists continuously for more than 2 weeks, consult your physician. Insomnia may be a symptom of serious underlying medical illness.

- Do not take this product if you have glaucoma, chronic lung disease, difficulty in urination due to an enlargement of the prostate gland, or if you are pregnant or breastfeeding, unless directed by a physician.

- Avoid alcoholic beverages while taking this product.

- If you are presently taking a prescription drug or other medication, do not take this product without first consulting your physician or pharmacists.

- Not to be used by elderly patients who experience confusion at nighttime. These drugs may produce excitation rather than sedation in the elderly. Therefore they should be avoided in this age group.

PRECAUTION: 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. Unisom should be used with caution in subjects with a history of bronchial asthma, increased ocular pressure, hyper thyroidism, cardiovascular and/or renal disease, hypertension and diabetes.

ADVERSE REACTIONS: 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.

DOSAGE: The recommended dose is 50 mg taken 30 minutes before retiring. It should be taken once daily or as directed by a physician and is not for children under 12 years of age.

AVAILABILITY: Unisom (diphenhydramine hydrochloride) is available in pale blue oval score tablets and a liquid filled soft gelatine capsule containing 50 mg of diphenhydramine hydrochloride supplied in boxes of 20 tablets or capsules, packaged in blister pack cards.

INFORMATION FOR THE CONSUMER:

INDICATION: For the relief of occasional nighttime insomnia when due to overwork, tiredness or fatigue.

DIRECTIONS: Adult and children 12 years of age and older: taken ONE tablet or softgel capsule at bedtime if needed or as directed by a physician. In some persons, persisting drowsiness may be experienced.

WARNINGS:

- Do not exceed recommended dose except on the advice of a physician.

- If sleeplessness persists continuously for more than 2 weeks, consult your physician. Insomnia may be a symptom of serious underlying medical illness.

- Do not take this product if you have glaucoma, chronic lung disease, difficulty in urination due to an enlargement of the prostate gland, or if you are pregnant or breastfeeding, unless directed by a physician.

- Avoid alcoholic beverages while taking this product.

- If you are presently taking a prescription drug or other medication, do not take this product without first consulting your physician or pharmacist.

- Not to be used by elderly patients who experience confusion at nighttime. These drugs may produce excitation rather than sedation in the elderly. Therefore they should be avoided in this age group.

CAUTION: **Keep safely out of reach of children.** Do not use if blister or backing is damaged.

Store between 15°C and 30°C.

UNISOM 50 MG TABLETS NONMEDICINAL INGREDIENTS: Dibasic Calcium Phosphate Dihydrate, FD&C Blue No. 1 Lake, Magnesium Stearate, Microcrystalline Cellulose, Opadry YS-1-7006, Purified Water and Sodium Starch Glycolate.

UNISOM 50 MG CAPSULES NONMEDICINAL INGREDIENTS: FD&C Blue No. 1, Gelatin, Glycerin, Opacode WB (Ammonium Hydrochloride, Ethanol, Isopropyl Alcohol, Polyvinyl Acetate Phthalate, Propylene Glycol, Titanium dioxide), Polyethylene Glycol 400, Purified Water, and Sorbitol.