1 NAME OF THE MEDICINAL PRODUCT

Diphenhydramine Hydrochloride 50 mg Tablets
Numark Night Time Sleep Aid 50 mg Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 50 mg of Diphenhydramine Hydrochloride.

Excipient(s) with known effect:

Each tablet contains 100.00 mg lactose monohydrate.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Tablet

White, circular, biconvex tablets with embossed ‘50’ on one side & plain on other side.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

An aid to the relief of temporary sleep disturbance.

4.2 Posology and method of administration

Dosage instructions:

Two tablets to be taken 20 minutes before going to bed, or as directed by a physician.

Do not exceed the stated dose or frequency of dosing.

Children: Do not use in children under 16 years.

This medicinal product should not be used continuously for longer than 2 weeks without consulting a doctor.

Method of administration

For oral administration.

4.3 Contraindications

Diphenhydramine is contraindicated for patients known to be hypersensitive to the drug or to any of the excipients listed in section 6.1.

Contraindicated for use in patients with the following conditions: stenosing peptic ulcer, pyloroduodenal obstruction.

4.4 Special warnings and precautions for use

Diphenhydramine should be used with caution in patients with myasthenia gravis, epilepsy or seizure disorders, prostatic hypertrophy, urinary retention, narrow-angle glaucoma, asthma, bronchitis and chronic obstructive pulmonary disease (COPD), moderate to severe hepatic impairment and moderate to severe renal impairment.

Tolerance may develop with continuous use. Seek medical advice if sleeplessness persists, as insomnia may be a symptom of a serious underlying medical illness.

This medicinal product should not be used continuously for longer than 2 weeks without consulting a doctor.

May increase the effects of alcohol, therefore alcohol should be avoided.

Avoid use of other antihistamine-containing preparations, including topical antihistamines and cough and cold medicines.

Use with caution in the elderly, who are more likely to experience side-effects.

Avoid use in elderly patients with confusion.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Diphenhydramine may potentiate the sedative effects of alcohol and other CNS depressants (e.g. tranquillizers, hypnotics and anxiolytics).

Monoamine oxidase inhibitors (MAOIs) prolong and intensify the anticholinergic effects of diphenhydramine. The product should be used with caution with MAOIs or within 2 weeks of stopping an MAOI.

As diphenhydramine has some antimuscarinic activity, the effects of some anticholinergic drugs (e.g. atropine, tricyclic antidepressants) may be potentiated therefore medical advice should be sought before taking diphenhydramine with such medicines.

Diphenhydramine is an inhibitor of the cytochrome p450 isoenzyme CYP2D6.

Therefore, there may be a potential for interaction with drugs which are primarily metabolised by CYP2D6, such as metoprolol and venlafaxine.

Diphenhydramine should not be used in patients receiving any of the above drugs unless directed by a doctor.

4.6 Fertility, pregnancy and lactation

Pregnancy

Diphenhydramine crosses the placenta. Because animal reproduction studies are not always predictive of human response and since there is inadequate experience with use of diphenhydramine in pregnant women, the potential risk for humans is unknown. Use of sedating antihistamines during the third trimester may result in reactions in the newborn or premature neonates. This drug is not recommended during pregnancy. Consult a doctor before use.

Breastfeeding

Diphenhydramine has been detected in breast milk, but the effect of this on breastfed infants is unknown. Diphenhydramine is not recommended for use during breastfeeding. Consult a doctor before use.

Fertility

There are no available data on the effect of diphenhydramine on fertility.

4.7 Effects on ability to drive and use machines

Diphenhydramine is a hypnotic and will produce drowsiness or sedation soon after the dose has been taken. It may also cause dizziness, blurred vision, cognitive and psychomotor impairment. These can seriously affect the patient's ability to drive and use machines. If affected, do not drive or operate machinery.

4.8 Undesirable effects

Specific estimation of the frequency of adverse events for OTC products is inherently difficult (particularly numerator data). Adverse reactions which have been observed in clinical trials and which are considered to be common (occurring in >1/100 to <1/10) or very common (occurring in >1/10) are listed below by MedDRA System Organ Class. The frequency of other adverse reactions identified during post-marketing use is unknown, but these reactions are likely to be uncommon (occurring in >1/1000 to <1/100), or rare (occurring in <1/1000).

Blood and lymphatic system disorders:

Unknown: agranulocytosis

Immune system disorders:

Unknown: hypersensitivity reactions including rash, urticaria, dyspnoea and angioedema

Psychiatric disorders:

Unknown: confusion, paradoxical excitation (e.g. increased energy, restlessness, nervousness), depression, sleep disturbances

* The elderly are more prone to confusion and paradoxical excitation.

Nervous system disorders:

Common: sedation, drowsiness, disturbance in attention, unsteadiness, dizziness

Unknown: convulsions, headache, paraesthesia, dyskinesias

Eye disorders:

Unknown: blurred vision

Cardiac disorders:

Unknown: tachycardia, palpitations, arrhythmias

Respiratory, thoracic and mediastinal disorders:

Unknown: thickening of bronchial secretions

Gastrointestinal disorders:

Common: dry mouth

Unknown: gastrointestinal disturbance including nausea, vomiting

Musculoskeletal and connective tissue disorders:

Unknown: muscle twitching

Renal and urinary disorders:

Unknown: urinary difficulty, urinary retention

General disorders and administration site conditions:

Common: fatigue

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdose is likely to result in effects similar to those listed under adverse reactions.

Additional symptoms may include mydriasis, fever, flushing, agitation, tremor, dystonic reactions, hallucinations and ECG changes. Large overdose may cause rhabdomyolysis, convulsions, delirium, toxic psychosis, arrhythmias, coma and cardiovascular collapse.

Treatment should be supportive and directed towards specific symptoms. Convulsions and marked CNS stimulation should be treated with parenteral diazepam.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic classification: Antihistamines for Systemic Use – aminoalkyl ethers
ATC code: R06AA02

Diphenhydramine is an ethanolamine-derivative antihistamine. It is an antihistamine with anticholinergic and marked sedative effects. It acts by inhibiting the effects on H1-receptors.

Diphenhydramine is effective in reducing sleep onset (i.e. time to fall asleep) and increasing the depth and quality of sleep.

5.2 Pharmacokinetic properties

Diphenhydramine hydrochloride is rapidly absorbed following oral administration.

Apparently it undergoes first-pass metabolism in the liver and only about 40-60% of an oral dose reaches systematic circulation as unchanged diphenhydramine.

It is rapidly distributed throughout the whole body. Peak plasma concentrations are attained within 1-4 hours. The sedative effect also appears to be maximal within 1-3 hours after administration of a single dose.

It is positively correlated with the plasma drug concentration.

Diphenhydramine is approx 80-85% bound to plasma proteins. Diphenhydramine is rapidly and almost completely metabolised. The drug is metabolised principally to diphenylmetoxyacetic acid and is also dealkylated.

The metabolites are conjugated with glycine and glutamine and excreted in urine.

Only about 1% of a single dose is excreted unchanged in urine.

The elimination half-life ranges from 2.4-9.3 hours in healthy adults. The terminal elimination half-life is prolonged in liver cirrhosis.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate

Maize Starch

Magnesium Stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Diphenhydramine Hydrochloride Tablets are available in cartons containing blister packs of Aluminium-PVC/PVDC foil of 12's, 16's and 20's along with a leaflet inside.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Any unused product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Flamingo Pharma UK Ltd.

Ist floor, Kirkland House,

11-15 Peterborough Road,

Harrow, Middlesex,

HA1 2AX, United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 43461/0066

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16/06/2025

10 DATE OF REVISION OF THE TEXT

29/08/2025