**APPROVED**

**by the Order of the Ministry of Health of Ukraine**

**27.02.2020 No. 577**

**Marketing Authorization**

**No. UA/17957/01/01**

**PACKAGE LEAFLET**

**for medical use of a medicinal product**

Hypnos®

***Qualitative and quantitative composition:***

*active substance:* doxylamine;

1 film-coated tablet contains 15 mg of doxylamine succinate;

*List of excipients:* lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, Opadry F85 White.

**Pharmaceutical form.** Film-coated tablets.

*Main physical and chemical properties:* oval tablets, coated white or almost white, with a double-sided dividing line.

**Pharmacotherapeutic group.** Antihistamines for systemic use. Doxylamine. ATC code R06А А09.

Other hypnotics and sedatives. ATC code N05C M.

**Pharmacological properties*.***

*Pharmacodynamic properties.*

Hypnos® is a hypnosis medicinal product of the ethanolamine class from the group of histamine H1 receptor blockers, has a sedative and M-anticholinergic effect. Reduces the time to fall asleep, increases the duration and quality of sleep.

*Pharmacokinetic properties.*

Cmax in blood plasma concentration is achieved 2 hours after administration. The plasma half-life is on average 10 hours.

Doxylamine succinate undergoes biotransformation in the liver. Doxylamine succinate is partially metabolized in the liver by demethylation and N-acetylation. The half-life can be significantly increased in elderly patients or in patients with renal or hepatic insufficiency. The various metabolites formed during the breakdown of the molecule are not quantitatively significant, as 60% of the applied dose is found in the urine in the form of unchanged doxylamine.

**Clinical particulars.**

***Therapeutic indications.***

Periodic and transient insomnia in adults.

***Contraindications.***

Hypersensitivity to any components of the medicinal product or to other antihistamine medicinal products; angle-closure glaucoma in the patient's history or in the family history; difficult urination (diseases of the urethra and prostate).

***Interaction with other medicinal products and other forms of interaction.***

Alcohol enhances the sedative effect of most H1-antihistamines. Drinking alcoholic beverages and using medicines containing ethanol should be avoided.

The following combinations of Hypnos® should be considered:

- atropine and atropine-like medicinal products (imipramine antidepressants, anticholinergic antiparkinsonian medicinal products, atropine antispasmodics, disopyramide, phenothiazine neuroleptics) due to the occurrence of side effects such as urinary retention, constipation, dry mouth;

- other antidepressants that affect the central nervous system (morphine derivatives) (pain relievers used to treat cough and substitution therapy), neuroleptics, barbiturates, benzodiazepines, anxiolytics, except benzodiazepines, sedative antidepressants, (amitriptyline, doxepin, mianserin, mirtazapine, trimipramine) sedative H1-antihistamines; antihypertensive drugs of central action; others: baclofen, pizotifen, thalidomide, due to increased suppression.

***Special warnings and precautions for use.***

Insomnia can have a variety of causes that do not require medication, so it is recommended to consult a doctor before using the medicinal product.

Like all hypnotics or sedatives, doxylamine succinate can exacerbate sleep apnea syndrome (an increase in the number and duration of respiratory arrest).

H1-antihistamines should be used with caution in elderly patients due to the risk of dizziness, which may increase the risk of falls (e.g. when people get up at night) with consequences that are often serious for this category of patients.

To prevent drowsiness during the day, it must be remembered that the duration of sleep after using the medicinal product should be at least 7 hours.

Alcohol intake should be avoided when using the medicinal product.

*Important information about excipients.*

The medicinal product contains lactose, therefore patients with rare hereditary forms of galactose intolerance, lactase deficiency or glucose-galactose malabsorption syndrome cannot use it.

The medicinal product contains sodium, so patients on a sodium-controlled diet should be careful when using it.

*Fertility, pregnancy and lactation.*

The medicinal product is contraindicated during pregnancy or lactation.

*Effects on ability to drive and use machines.*

Hypnos® affects the speed of psychomotor reactions (the risk of daytime drowsiness), so you should refrain from driving or other mechanisms.

***Posology and method of administration.***

For oral administration. Apply 15-30 minutes before bedtime.

The recommended dose is 7.5–15 mg per day (½ – 1 tablet per day). If necessary, the dose can be increased to 30 mg per day (2 tablets per day).

Elderly patients and patients with renal or hepatic insufficiency are advised to reduce the dose.

The maximum duration of treatment is 2 -5-day.

If insomnia persists for more than 5 days, it is necessary to consult a doctor about the feasibility of further use of the medicinal product.

*Children.*

The medicinal product is not recommended for use in children under the age of 18 years.

***Overdose.***

*Symptoms.*

The first signs of acute poisoning are drowsiness and manifestations of anticholinergic effects: agitation, dilation of the pupils, accommodation paralysis, dry mouth, redness of the face and neck, hyperthermia, sinus tachycardia. Delirium, hallucinations and atheotic movements are more often observed in children, sometimes they are harbingers of seizures - rare complications of severe poisoning. Even if seizures do not occur, acute doxylamine poisoning sometimes causes rhabdomyolysis, which can be complicated by acute renal failure. This muscle disorder is common, requiring regular systematic screening by measuring creatine phosphokinase activity.

*Treatment.*

Activated charcoal intake (50 g for adults and 1 g/kg for children), if necessary, carry out symptomatic treatment. According to the indications, anticonvulsants and artificial lung ventilation are prescribed.

***Undesirable effects.***

In the morning after the evening intake of the medicinal product, there may be a slowdown in reactions and dizziness, therefore, to prevent falling, it is necessary to avoid sudden movements. Anticholinergic effects rarely develop: constipation, dry mouth, accommodation disorders, palpitations, urinary retention.

Daytime sleepiness: at development of such effect it is necessary to reduce a dose.

Allergic reactions are possible, including skin rashes, itching.

Reporting of suspected adverse reactions.

Reporting suspected adverse reactions after registration of a medicinal product is an important procedure. This allows for continued monitoring of the benefit/risk ratio for the respective drug. Healthcare providers should be informed of any suspected adverse reactions through the national alert system.

***Shelf life*** 1.5 years

**Special precautions for storage.**

Store in the original package at a temperature below 25°C. Keep out of the reach of children.

**Nature and contents of container.**

10 tablets in a blister container; 1 or 2 blister containers in a package.

**Category of release.**

film-coated tablets No. 10 (10x1) - non-prescription medicine.

film-coated tablets No. 20 (10x2) - prescription only medicine.

**Manufacturer.** PrJSC “Pharmaceutical firm “Darnitsa”.

**The manufacturer's location and address of the place of business.**

13, Boryspilska Street, Kyiv, 02093, Ukraine.

**Date of last revision.** 27.02.2020р.