

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The dispensing of this medicine requires a doctor's prescription.
Read this package insert carefully in its entirety before using this medicine
This leaflet has been imprinted and checked by health ministry of Israel. –11/ 2010

NORTYLIN 25mg Tablets

Composition: Each tablet contains: Nortriptyline hydrochloride 25 mg

Inactive ingredients: Lactose, Starch, Sodium starch glycolate, PVP K 30, Magnesium stearate, Acacia, Acetone, Alcohol, Carnauba wax, Cellulose acetate phthalate, Colloidal silicon dioxide, Color D&C yellow no. 10 lake 18-24%, Diethyl phthalate, Color FD&C yellow no. 6 aluminum lake 15-18%, Gelatin, Industrial methylated spirits, Isopropyl alcohol, Liquid glucose, Methylparaben, Monobasic Potassium phosphate, Povidone, Precipitated calcium carbonate, Polyethylene glycol, Propylparaben, Purified water, Sodium benzoate, Sucrose, Talc, Titanium dioxide.

Therapeutic group: Tricyclic antidepressant.

Therapeutic activity: For the treatment of depressive states.

When should the preparation not be used?

Do not use this medicine if you are pregnant or breastfeeding.
Do not use this medicine if you are sensitive to any of its ingredients or to another Tricyclic antidepressant.

Do not take this medicine without consulting a doctor before starting treatment:

If you are suffering, or have suffered in the past, from impaired function of: the respiratory system (e.g. asthma), the heart and/or vascular system (hypertension), the eyes (e.g. glaucoma), the liver, the kidney/urinary tract (urinary retention), the digestive system (gastrointestinal and bowel disturbances), the prostate gland, the thyroid gland, epilepsy, the nervous system- psychotic diseases such as schizophrenia or mania, Alcoholism.

How will this medicine affect your daily life?

Use of this medicine may impair alertness and therefore caution should be exercised when engaging in activities such as driving a car, operating dangerous machinery and in any other activity which requires alertness. Children should be cautioned against engaging in activities such as bicycle riding, playing near roads and the like.

Do not drink wine or alcoholic beverages while under treatment with this medicine.

This medicine may cause a special sensitivity when the patient is exposed to the sun, therefore, avoid exposure to the sun and take appropriate precautions (long clothes, a hat, protective creams, etc.).

Warnings: If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine.

Elderly patients are more sensitive to the effects of this medicine.

Inform your doctor that you are taking this medicine before using any other medication.

Caution should be exercised when getting up from sitting/lying position to a standing position because of possible dizziness.

The doctor should be informed that you are taking this medicine if you are about to undergo medical tests or surgery (including dental surgery).

This medicine is not intended for administration to children under 12 years.

Patients and their family members are advised to observe changes, such as: worsening of depression, suicidal thoughts, aggressiveness, etc. If such changes occur - refer to the doctor immediately. Extreme caution should be exercised in following this recommendation in young patients 18-24 years of age. In children, adolescents and young adults below 24 years of age who took antidepressants, an increase was observed in side effects such as suicide attempts, suicidal thoughts and hostility. Nevertheless, your doctor can prescribe this medicine, if he thinks it will benefit you.

If you do not understand this medicine to you and you are interested in discussing it with him, consult the doctor again. You must report to the doctor if some of the above side effects appear or get worse.

During treatment with this medicine, the following tests should be performed: periodical cardiac tests, kidney, liver, blood pressure, ECG and dental exams.

Drug interactions: If you are taking another drug concomitantly or if you have just finished treatment with another medicine, inform the attending doctor, in order to prevent hazards or lack of efficacy arising from drug interactions. This is especially important for medicines belonging to the following groups: drugs affecting the central nervous system (e.g. sedatives, hypnotics, drugs for parkinsonism/epilepsy), antidepressants, antihypertensives, drugs for the treatment of hyperthyroidism, cimetidine, cough and cold preparations, sympathomimetic drugs, MAO inhibitors, barbiturates, phenothiazines, clonidine, guanadrel, guanethidine, medicines causing extrapyramidal reactions. Use of these medicines should be discontinued 2 weeks before taking this medicine.

Side effects: In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, for example: dryness of the mouth, rash, nausea, drowsiness, dizziness, headache, mild tiredness or weakness, increased appetite followed by weight gain. These side effects usually disappear within a short time following the period of adaptation to the medicine.

Effects that require special attention: Blurred vision, confusion, hallucinations, fainting, fast heartbeat, difficult urination, muscle tremors (rare): stop treatment and refer to the doctor. Impairment of sexual function (rare): continue treatment and refer to the doctor immediately.

Pain in the eyes, Restlessness, difficulties speaking or swallowing, unbalance, stiffness of arms and legs- refer to the doctor immediately.

In the event that you experience side effects not mentioned in this leaflet, or if there is a change in your general health, consult your doctor immediately.

Dosage: Dosage is according to doctor's instructions only.

Do not exceed the recommended dosage or recommended period. If you forget to take this medicine at the specified time, take the dose as soon as you remember, but never take a double dose to compensate for a missed one!

Directions for use: Do not chew! Swallow the medicine with water. You may take this medicine with or after a meal.

Do not halve or crush the tablet.

How can you contribute to the success of the treatment?

Complete the full course of treatment as instructed by the doctor.

Even if there is an improvement in your health, do not discontinue use of this medicine without consulting your doctor.

Dosage should be reduced gradually. It takes time until the antidepressant effect is obtained (between 1 to 6 weeks).

Avoid poisoning! This medicine, and all other medicines, must be stored in a safe place out of the reach of children and/or infants, to avoid poisoning.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a hospital emergency room and bring the package of the medicine with you. **Do not induce vomiting** unless explicitly instructed to do so by a doctor! This medicine has been prescribed for the treatment of your ailment; in another patient it may cause harm. Do not give this medicine to your relatives, neighbours or acquaintances. **Do not take medicines in the dark!** Check the label and the dose each time you take your medicine. Wear glasses if you need them.

Storage: Store in a dry place and at a temperature below 25°C. Even if kept in their original container and stored as recommended, medicines may be kept for a limited period only. Please note the expiry date of the medicine! In case of doubt, consult the pharmacist who dispensed the medicine to you.

Do not store different medications in the same package.

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Manufacturer: Rekah Pharm. Prod. Ltd. .. 30 Hamelacha St., Holon.