

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

The dispersing of this medicine requires a doctor's prescription.
Read this package insert carefully in its entirety before using this medicine

The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by it in - 08/2011

Hydrocortisone 10 mg

Tablets

COMPOSITION: Each tablet contains: Hydrocortisone 10 mg
Inactive ingredients: Aerosil, Pregelatinized starch, Talc, Magnesium stearate, Lactose (each tablet contains 35.5mg of Lactose).

Therapeutic activity: A glucocorticosteroid preparation indicated for treatment and relief of inflammations, swelling, itching, severe allergies, skin problems, asthma and rheumatic diseases.

Therapeutic group: Glucocorticosteroid.

When should the preparation not be used?

Do not use this medicine if you are sensitive to any of its ingredients.
Do not use this medicine if you are about to receive any type of live attenuated vaccination.
Do not use this medicine if you are suffering from systemic fungal infections.
This medicine contains Lactose. Do not use this medicine if you are sensitive to lactose.

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

If you are pregnant or breastfeeding. If you are suffering, or have suffered in the past, from impaired function of the heart and/or vascular system (high blood pressure, clots in the veins), the eyes (e.g. glaucoma), the liver, the kidney/urinary tract, the digestive system (e.g. ulcer), the thyroid gland, ocular herpes, bone diseases (osteoporosis), tuberculosis, fungal infections or any other infections or serious injury, diabetes, AIDS, a recent operation, chickenpox, measles, hypercholesterolemia, myasthenia gravis, psychosis and lupus.

How will this medicine affect your daily life?

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

Warnings: Do not use this medicine frequently, or for a long period, without consulting a doctor. If you are sensitive to any type of food or medicine, inform your doctor before commencing treatment with this medicine. Patient should be monitored for blood pressure changes. Patient should be monitored for vision changes (blurred vision, cataract). Inform your doctor if you have to undergo a skin test or an operation. When used for a prolonged period this medicine may retard growth in children and adolescents, therefore, the doctor's instructions should be carefully followed. It is important for patients who has not already had these illnesses to avoid contact with someone who has chickenpox or measles. Diabetic patients- this medicine can affect blood glucose levels- if there is a change in glucose levels in the blood or urine, consult your doctor. Use of this medicine may cause oropharyngeal candidiasis. While using this medicine for a prolonged period with large doses- patient should undergo periodic urinary free cortisol test.

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, drug for parkinsonism, epilepsy), rifampin, diuretics/potassium supplements, antacids, amphotericin B, oral antidiabetic agents or insulin, digoxin, ritodrine, mitolane, live attenuated vaccines, anticoagulants, sodium containing medications, cyclosporine, ketoconazole, pyridostigmine, griseofulvin, clarithromycin, erythromycin, quinolone's antibiotics (Ciprofloxacin, Levofloxacin, Ofloxacin).

Side effects: In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, for example: impaired skin healing, depression, euphoria, increased appetite, gastrointestinal disturbances, nervousness or restlessness, insomnia, dry mouth, diarrhoea, nausea, weakness, rash. These side effects usually disappear within a short time following the period of adaptation to the medicine.

Effects that require special attention:

Blurred vision, frequent urination, increased thirst (rare): continue treatment and contact your doctor. Swelling of the legs or face (rare): stop treatment and contact your doctor. Menstrual problems (rare): stop treatment and contact your doctor. Dizziness, vomit with blood (rare): stop treatment and contact your doctor.

Signs of infection: sore throat, fever, sneezing or cough: contact your doctor as soon as possible. Muscle cramps, muscle weakness, reddish-purple strips on the skin, eye sensitivity to light, growth impairment in children, swollen legs, excessive hair growth, acne, osteoporosis, cataract, glaucoma, hyperglycemia, pulmonary tuberculosis, disturbed levels of water and/or salt content, contact the doctor.

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. 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: Take the medicine with a meal. Take antacids between meals.

The tablet can be halved or crushed.

How can you contribute to the success of the treatment?

Even if there is an improvement in your health, do not discontinue use of this medicine before consulting your doctor. If the doctor instructed you to discontinue use, it should be done gradually.

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 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.

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Manufacturer: Rekah Pharmaceutical Industry Ltd., 30 Hamelacha St., Holon, Israel.