

### 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 The format of this leaflet was determined by the Ministry of Health and its content was checked and approved by it in 09/2010

<b>PREDNISONE</b>
1 mg
Tablets

# PREDNISONE **Tablets**

# PREDNISONE Tablets

Composition:

Each tablet contains: Fach tablet contains: Prednisone 1 mg Prednisone 5 mg

Fach tablet contains: Prednisone 20 mg

Inactive ingredients:

Prednisone 1 mg; Lactose, Starch, Gelatin, Talc, Powdered Cellulose, Stearic Acid. Sunset Yellow #6.

Prednisone 5 mg: Starch, Lactose, Microcrystalline Cellulose, Talc, Ac-di-sol, Magnesium stearate, Aerosil.

Prednisone 20 mg: Starch, Lactose, Microcrystalline Cellulose, Talc, Ac-di-sol, Magnesium stearate, Color Red FDC No 3 Lake 30%, Aerosil.

Therapeutic group: Anti-inflammatory from the corticosteroids group.

Indication: Anti-inflammatory preparation for treatment of inflammations responding to corticosteroids, such as severe allergies and arthritis.

#### When should the preparation not be used?

Do not use this medicine if there is a known sensitivity to any of its ingredients. Do not use this medicine if you are about to receive any vaccination.

Do not use this medicine if you have a fungal infection.

### 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 (e.g. hypertention), the eyes (e.g. glaucoma), the liver, the kidney/urinary tract, the digestive system (peptic ulcer), the thyroid gland, from ocular herpes, bone diseases (osteoporosis), tuberculosis or any other infections in the body (e.g. chickenpox or measles), serious injury, diabetes, emotional instability (psychoses), myasthenia gravis.

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 prolonged period, without consulting a doctor. If you are sensitive to any type of food or medicine, in particular to adrenocorticoids, inform your doctor before commencing treatment with this medicine. Inform your doctor (including the dentist) if you are about to undergo any dermal test or operation. Prolonged use of this medicine may slow growth in children and adolescents, therefore the doctor's instructions should be followed strictly. The preparation contains lactose and may cause an allergic reaction in certain people. During use, there is susceptibility to infections, therefore avoid contact with sick people (mainly with chickenpox or measles).

**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: aspirin and salicylates, drugs affecting the central nervous system (e.g. sedatives, hypnotics, drugs for parkinsonism, epilepsy, barbiturates, phenytoin), rifampin, diuretics, medicines that provide potassium, oral contraceptives (containing estrogen) or estrogen medications, antacids, amphotericin B, oral antidiabetic agents or insulin. digitalis glycosides, ritodrine, bupropion, some vaccines, anticoagulants, sodiumcontaining medications. Ketoconazole, Klaritromycin, antihypertensive drugs.

Side Effects: In addition to the desired effect of the medicine, adverse reactions may occur during the course of taking this medicine, for example: increased appetite, indigestion, nervousness or restlessness, insomnia, dryness of the mouth, nausea, rash, skin inflammations, confusion, mood changes, hypertension, Some of these side effects usually disappear within a short time following the period of adaptation to the medicine.

Side Effects that require special attention: Cataract, Glaucoma; stop treatment and contact your doctor. Blurred vision, frequent urination, increased thirst (rare); continue treatment and contact your doctor as soon as possible. Bloody or black stools (rare); contact your doctor immediately. Depression, euphoria. muscle weakness (rare): continue treatment and contact your doctor as soon as possible. Persistent abdominal, back, rib pain (rare): continue treatment and contact your doctor as soon as possible. Menstrual problems (rare): continue treatment and contact your doctor as soon as possible. Swelling of the face or hands, rash, weight gain (rare); contact your doctor immediately. Signs of infection: sore throat, fever, sneezing or cough; contact your doctor as soon as possible. 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. There is no information about crushing, dividing or chewing the tablets.

## 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 without consulting your doctor. If the doctor instructed you to discontinue use, stop treatment 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, neighbors 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 dark and dry place, below 25°C. The Prednisone 1 mg tablets product, can be used up to 2 months after the initial opening but not after the expiry date.

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. Should be stored in its original packaging.

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