Patient package insert according to Pharmacist's Regulations (Preparations)-1986
This medicine can be sold with a physician's prescription only

Prednisone Rekah 1, 5, 20 mg, Tablets

Composition:
Each tablet contains prednisone: 1, 5, or 20 mg, respectively.
Inactive ingredients and allergens in the medicine- see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of this medicine".
Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about the medicine. If you have any further questions, refer to the doctor or pharmacist.
This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. What is this medicine intended for?

The medicine **Prednisone Rekah** is indicated wherever corticosteroid therapy is indicated, such as: pemphigus vulgaris, allergic dermatitis, eczema, dermatitis accompanied by peeling of the skin (exfoliative dermatitis), dermatitis herpetiformis, drug- induced dermatitis (dermatitis medicamentosa), erythema multiforme; disseminated lupus erythematosus, dermatomyositis, polyarteritis nodosa; severe bronchial asthma and prolonged asthma attack (status asthmaticus), emphysema, pulmonary fibrosis (scarring of lung tissue); adrenal hyperplasia (adrenogenital syndrome); idiopathic thrombocytopenic purpura, acquired haemolytic anaemia, acute leukemia; nephrotic syndrome; iridochoroiditis; ulcerative colitis; rheumatoid arthritis; ankylosing spondylitis, rheumatic fever, gout, periarthritis of the shoulder ("frozen shoulder").
Pharmacotherapeutic group: Glucocorticoids.
Glucocorticoids are classified as steroids produced by the adrenal cortex (adrenocortical hormones), that cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli. Prednisone is a glucocorticoid, that is primarily used for its potent anti- inflammatory effects in disorders of various organ systems.

2. Before using this medicine:

Do not use this medicine if:

- You are hypersensitive (allergic) to the active ingredient (prednisone), or to any of the other ingredients this medicine contains (see section 6- "Additional information").
- You have a systemic fungal infection.
- You have recently received a smallpox vaccine or are planning to receive one during **Prednisone Rekah** treatment.

Special warnings regarding the use of this medicine
Before using Prednisone Rekah, tell the doctor if:

- You have or have had an uncontrolled infection caused by any pathogens, such as viral, bacterial, fungal or single- celled parasite (protozoan).
- You suffer from latent tuberculosis or have a reactive tuberculin skin test, reactivation of the disease may occur during treatment. Your doctor will monitor you closely, especially during prolonged treatment. In some cases, preventive treatment may be recommended to lower the risk of reactivation of tuberculosis.
- You have never had varicella or measles, or if you are not immune to these diseases- Treatment with corticosteroids, such as **Prednisone Rekah**, may lead to serious or even life-threatening course of these viral infections in non-immune individuals.
  In case of exposure to these diseases, your doctor may consider initiating preventive treatment.
- You are a carrier of hepatitis B virus (HBV) or have had it in the past, the virus may reactivate during treatment with **Prednisone Rekah**. In such cases, your doctor may refer you to a specialist for monitoring and consideration of preventive antiviral treatment.
- You have latent or active amebiasis, or you have spent time in a tropical country or have unexplained diarrhea. It is recommended to rule out amebiasis before starting treatment with **Prednisone Rekah**.
- You have or think you may have a strongyloides (threadworm) infestation. The use of corticosteroids, such as **Prednisone Rekah**, may worsen the infection and cause serious complications, such as a severe blood infection (sepsis/ septicemia).
- You have cerebral malaria.
- You have hypothyroidism or cirrhosis (liver disease), as these conditions may increase the effect of this medicine.
- You have or have had eye herpes (ocular herpes simplex), as this may increase the risk of corneal damage during treatment.
- You are taking aspirin and have low prothrombin in the blood (hypoprothrombinemia). In this case, aspirin should be used with caution when taken with this medicine.
- You have any of the following conditions:
  - Nonspecific ulcerative colitis, especially if there is a risk of perforation, abscess, or other infection
  - Diverticulitis
  - Recent intestinal surgery, involving a bowel reconnection (anastomosis)
  - Active or latent peptic ulcer
  - High blood pressure (hypertension)
  - Osteoporosis
  - Myasthenia gravis

  In these cases, this medicine should be used with caution.

Warnings and Precautions

- Suppression of immune system-
  - This medicine may suppress your immune system, decrease your resistance to infections and increase your risk of developing new infections.
  - Corticosteroid- associated infections can be mild but may also be severe and, in some cases, fatal. The rate of infectious complications increases with increasing corticosteroid dosages. Your doctor will monitor for the development of infection and consider **Prednisone Rekah** withdrawal or dosage reduction as needed.
  - Disseminated Infections- This medicine may increase the risk of disseminated infections.
  - Masking of infection- This medicine may mask signs of infection, which can make it difficult to diagnose an existing or developing infection.
  - Latent infections- This medicine may increase the risk of reactivation or exacerbation of latent infections.
- Vaccinations- Do not receive any vaccinations during treatment with **Prednisone Rekah**, especially high-dose treatment, unless approved by your doctor. Corticosteroid therapy may reduce the immune response to vaccines and increase the risk of neurological complications.
- Systemic fungal infections- **Prednisone Rekah** may worsen systemic fungal infections. If such an infection develops during long-term treatment, your doctor may consider stopping the treatment or reducing the dose.
- Kaposi's sarcoma- Treatment with corticosteroids, including **Prednisone Rekah**, has been associated with the development of Kaposi's sarcoma, particularly during chronic conditions. Your doctor will assess the need for continued treatment, as stopping corticosteroids may lead to clinical improvement of this condition.
- Unusual physical stress and treatment adjustment- Your doctor may temporarily increase the dosage before, during, and after a situation of unusual physical stress (such as surgery).
- Adrenal gland function and discontinuation of treatment- Gradual dose reduction is important to help prevent problems with the function of the adrenal glands. After stopping the treatment, your adrenal glands may not function properly for several months. During this period, in situations of unusual physical stress, your doctor may decide to temporarily restart the treatment. Additional treatment with salt and/ or appropriate hormonal therapy, such as administration of mineralocorticoids hormones, may be required.

- Fluid and electrolyte disturbances– Elevation of blood pressure, salt and water retention, and increased excretion of potassium and calcium may occur when used in large doses of this medicine. Potassium supplementation and dietary salt restriction may be necessary.
- Ophthalmic function- Prolonged use of this medicine may lead to eye complications, such as posterior subcapsular cataracts (a type of eye lens clouding), increased intraocular pressure (glaucoma) with possible damage to the optic nerves, and may enhance the risk of secondary eye infections caused by fungi or viruses. Contact your doctor if you notice any vision changes.
- Dosage adjustment- Your doctor will prescribe the lowest effective dose to control your condition. If it is necessary to reduce the dose, your doctor will do so gradually in order to minimize possible side effects.
- Mental and behavioral changes- Psychic disturbances may occur during treatment with corticosteroids, including **Prednisone Rekah**. These may include euphoria, insomnia, mood swings, personality changes, severe depression, or even marked psychotic symptoms. Also, existing emotional instability or psychotic tendencies may worsen during treatment with the medicine.
- Since the risk of complications from treatment with glucocorticoids depends on the dose and the duration of treatment, your doctor will carefully consider the risks and benefits for you individually. This includes deciding on the dose, the duration of treatment, and the treatment schedule that is most suitable for you.
- Tell your doctor if you are taking cyclosporin. Convulsions have been reported when this medicine was taken together with methylprednisolone (a similar corticosteroid). Using both medicines at the same time may increase the risk of side effects that can occur with either one of them.
- Renal insufficiency or liver failure- Caution and frequent monitoring by your doctor are necessary when using oral corticosteroids.

Children and adolescents
During prolonged corticosteroid therapy, close medical monitoring of growth and development in infants and children is required.
Use of this medicine and food
The tablets should be swallowed whole after food.
Pregnancy and breastfeeding:
If you are pregnant or breastfeeding, think you may be pregnant, or are planning to become pregnant, consult your doctor before using this medicine. Your doctor will prescribe treatment only after a careful benefit/ risk assessment. Infants born of mothers who have received high doses of corticosteroids during pregnancy, should be carefully observed by the doctor for signs of hypoadrenalism.
Important information about some of the ingredients of this medicine
- This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
- This medicine contains less than 1 mmol (23 mg) of sodium per tablet, that is to say essentially "sodium- free".
- **Prednisone Rekah 1 mg** contains Sunset Yellow (E 110), which may cause allergic reactions.

3. How to use this medicine?
Always use this medicine according to the doctor's instructions. Check with the doctor or pharmacist If you are not sure about the dosage and manner of treatment with the medicine.
The dosage and manner of treatment will be determined by the doctor only.
The dosage will depend on your medical condition and your response to the treatment.
Special dosing considerations
- For hepatic and renal impairment- see in section 2 "Warnings and Precautions".
- Your doctor may adjust your dose or monitor your treatment closely in certain cases- see in section 2- "Before using this medicine".

Do not exceed the recommended dose.
Method of administration
Swallow the tablets whole after food.
There is no information regarding the crushing, splitting, or chewing of the tablets.
If you have accidentally taken a higher dose
If you have taken an overdose, or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.
If you forgot to take the medicine
If you forgot to take to take this medicine at the designated time, take a dose as soon as you remember, but if it is almost time to take the next dose, skip the missing dose. Do not take a double dose to make up for a forgotten dose.
Adhere to the treatment as recommended by your doctor.
If you stop taking the medicine
Do not stop treatment with **Prednisone Rekah** abruptly. When a dosage reduction is necessary, it should be done gradually and according to your doctor's instructions, to minimize the risk of side effects.
Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.
If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects:
As with any medicine, the use of **Prednisone Rekah** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
Fluid and Electrolyte Disturbances
- Sodium retention
- Fluid retention
- Congestive heart failure in susceptible patients
- Potassium loss
- Decreased potassium levels in the blood (hypokalemia) and decreased acidity of the blood and body fluid (alkalosis)
- Hypertension

Musculoskeletal disorders
- Muscle weakness
- Muscle disease due to steroid treatment (steroid myopathy)
- Loss of muscle mass
- Osteoporosis
- Tendon rupture, particularly of the Achilles tendon
- Vertebral compression fractures
- Aseptic necrosis of femoral and humeral heads
- Pathologic fracture of long bones

Gastrointestinal disorders
- Peptic ulcer with possible perforation and hemorrhage
- Pancreatitis
- Abdominal distention
- Ulcerative esophagitis

Skin disorders
- Impaired wound healing
- Thin fragile skin
- Subcutaneous hemorrhages (petechiae and ecchymosis)
- Facial erythema

- Increased sweating
- May suppress reactions to skin tests

Metabolic disorders
- Negative nitrogen balance due to protein catabolism

Neurological disorders
- Increased intracranial pressure with papilledema (pseudotumor cerebri), usually after treatment
- Convulsions
- Vertigo
- Headache

Endocrine disorders
- Menstrual irregularities
- Development of Cushingoid state
- Secondary adrenocortical and pituitary unresponsiveness, particularly in situations of unusual physical stress
- Suppression of growth in children
- Decreased carbohydrate tolerance
- Manifestations of latent diabetes mellitus
- Increased requirements for insulin or oral hypoglycemic agents in diabetics

Eye disorders
- Posterior subcapsular cataracts
- Increased intraocular pressure
- Glaucoma
- Exophthalmos

Additional Reactions
- Urticaria and other allergic, anaphylactic or hypersensitivity reactions

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report adverse effects problems associated with medication and drugs" on the Ministry of Health homepage (www.health.gov.il), which links to an online form for reporting side effects, or by following the link: https://sideeffects.health.gov.il

5. How to store the medicine?

• Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/ or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
• Do not use the medicine after the expiry date (exp. Date) that appears on the package. The expiry date refers to the last day of that month.
• **Storage conditions:** Store in a dry and dark place, below 25°C.
• **Prednisone Rekah 1 mg:** Can be used for up to 2 months after the securitainer is first opened, and not later than the expiry date, that appears on the package.
• Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Further information:

In addition to the active ingredient, the medicine also contains:

Prednisone Rekah 1 mg: Lactose, Starch, Talc, Gelatine, Powdered Cellulose (Elcema), Stearic Acid, Sunset Yellow (E 110).
Prednisone Rekah 5 mg: Starch, Lactose, Microcrystalline Cellulose (Avicel PH 102), Microcrystalline Cellulose (Avicel PH 101), Talc, Croscarmellose Sodium (Ac- Di- Sol), Magnesium Stearate, Colloidal Silicon Dioxide (Aerosil 200).
Prednisone Rekah 20 mg: Starch, Lactose, Microcrystalline Cellulose (Avicel PH 102), Talc, Croscarmellose Sodium (Ac- Di- Sol), Magnesium Stearate, Color Red FDC No. 3 Lake 30%, Colloidal Silicon Dioxide (Aerosil 200).

What does the medicine look like and what is the content of the package:

Prednisone Rekah 1 mg: An orange tablet, "REKAH" engraved on one side and plain on the other.
Prednisone Rekah 5 mg: A white tablet, with "R" engraved on one side and plain on the other.
Prednisone Rekah 20 mg: A pink tablet, with "R" engraved on one side and plain on the other.

Approved package sizes:

Prednisone Rekah 1 mg: 100 tablets.
Prednisone Rekah 5 mg: 30, 250, and 1,000 tablets.
Prednisone Rekah 20 mg: 30 and 250 tablets.
Not all package size may be marketed.

Manufacturer and registration Holder: Rekah Pharmaceutical Industry Ltd., 30 Hamelacha St. Holon, 5881904, Israel.

Revised in August 2025 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:
Prednisone Rekah 1 mg: 118-06-26041-00
Prednisone Rekah 5 mg: 038-70-22458-01
Prednisone Rekah 20 mg: 113-33-22170-00