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

The dispensing of the medicine requires a doctor's prescription

**DEXAMETHASONE**  
**0.5mg**  
Tablets

**DEXAMETHASONE**  
**2mg**  
Tablets

#### Composition:

Each tablet contains:  
Dexamethasone 0.5 mg

Each tablet contains:  
Dexamethasone 2 mg

Inactive ingredient: see the chapter 6- further information.

**Read this package insert carefully in its entirety before using this medicine.** This leaflet contains essential information of this medicine. If you have any further questions, ask your doctor or pharmacist.

**Take this medicine regularly to get the maximum benefit from the treatment.**

**This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.**

### 1. For what is intended this medicine?

**For the treatment and relief in cases of inflammation, swelling, itching, severe allergies, skin conditions and joint inflammation.**

**Therapeutic group:** Potent synthetic glucocorticoid.

### 2. Before use this medicine:

#### Do not take this medicine

- If you are allergic (hypersensitive) to dexamethasone or any other ingredients in this medicine (listed in Section 6). The signs of an allergic reaction include a rash, itching or shortness of breath
- If you are about to receive any vaccination (especially attenuated live virus vaccine)
- If you are suffering from infection that affects whole body.

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

- Are suffering, or have suffered from severe depression or manic depression (bipolar disorder), or if any of you close family has had these illnesses.
- Are suffering, or have suffered in the past, from impaired function of: the heart and/or vascular system (e.g. high blood pressure), the liver, the kidney.
- Are suffering from diabetes or there is a family history of diabetes.
- Are suffering from thinning of the bones (osteoporosis), particularly if you are a female who has been through the menopause.
- Are suffering from muscle weakness with steroids administration in the past.
- Are suffering from an increased eye pressure (glaucoma) or there is a family history of glaucoma.
- Are suffering from stomach ulcers (ulcers)
- Use of this medicine may worsen your condition if you suffer or have suffered from mental disorders (psychosis due to steroid use)
- Are suffering from epilepsy.
- Are suffering from migraines.
- Have an underactive thyroid gland.
- Are suffering from infection with parasites.
- Are suffering from tuberculosis.
- Are suffering from growth disorder (delay)

#### Special warnings concerning the medicine use:

- 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.
- Inform your doctor (including your dentist) if you are about to undergo skin tests or a surgery.
- Inform your doctor, dentist or medical staff if you took or have taken in the past as a steroid like dexamethasone.
- Inform your doctor if you develop an infection during the treatment with this medicine.
- Prolonged use of this medicine may slow growth in children and adolescents. Therefore, the doctor's instructions must be strictly followed
- While using this medicine you are susceptible to infections; therefore avoid contact with sick people (mainly with chickenpox or measles).
- Patient should report signs/symptoms of increased blood sugar levels (hyperglycemia). Diabetic patients may need to closely monitor blood glucose.
- Patients should avoid sudden discontinuation of drug.
- **Mental health problems** may happen while taking steroids like Dexamethasone (see also Section 4: side effects):
  - These illnesses can be serious.
  - Usually they start within a few days or weeks of starting the medicine
  - They are more likely to happen at high doses
  - Most of these problems go away if the dose is lowered or the medicine is stopped. However, if problems do happen, they might need treatment
  - If you take or someone take this medicine, inform a doctor from any signs of mental problems. This is particularly important if you are depressed, or might be thinking about suicide. In a few cases, mental problems have happened when doses are being lowered or stopped.
- Do not use Dexamethasone for the treatment of Acute Respiratory Distress Syndrome (ARDS; a serious lung disease) if you have been diagnosed with this condition for over 2 weeks.

**If you are taking or have recently taken other medicines, including non-prescription medicines and dietary supplement, inform the doctor or the pharmacist.** Specially, refer to the doctor or pharmacist if you take medicines of the following:

- Medicines used to prevent blood clotting (such warfarin)
- High blood pressure medicine
- Water tablets (diuretics)
- Rifampicin and rifabutin (antibiotic to treat the tuberculosis)
- Medicines used to treat epilepsy, such as phenytoin, carbamazepine, phenobarbitone and primidone
- Medicines used to treat stomach problems, such as antacids
- Carbenoxolone, sometimes used for ulcers
- Medicines used to treat pain and inflammation, such as aspirin, ibuprofen or similar non-steroidal anti-inflammatories (NSAIDs)
- Medicines used to treat diabetes
- Medicines used to increase lower potassium levels
- Medicines used to treat myasthenia
- Ritonavir, indinavir or saquinavir used to treat HIV
- Oral contraceptives containing oestrogen and progesterone
- Anti-cancer treatments, such as aminoglutethimide
- Methotrexate used to treat cancer or inflammatory problems
- Ephedrine used to relieve symptoms of a stuffy nose (nasal congestion)
- Acetazolamide used for glaucoma

**Use of this medicine and food:** Take the medicine before the meal with glass of water

**Use of this medicine and alcohol:** Do not drink wine or alcoholic beverages while under treatment with this medicine.

**Pregnancy and breast-feeding:** Do not take this medicine during pregnancy, whilst breast-feeding, or you are planning to become pregnant unless advised by your doctor.

**Driving and using machines:** Dexamethasone tablet is not likely to affect you being able to drive.

### Important information on the Dexamethasone tablets

**composition:** Each Dexamethasone 0.5 mg tablets contains 47.7 mg of lactose and Each Dexamethasone 2 mg tablets contains 80 mg.

If you are allergic to lactose, consult your doctor before commencing the treatment.

### 3. How use this medicine?

Always take this medicine exactly as instructed by the attending doctor. **If you are unsure how to use this medicine, you should consult your doctor or your pharmacist.** Do not exceed the recommended dose.

This medicine is to be taken at specific time intervals as determined by the attending doctor.

Do not chew! Swallow the medicine with water. Take the medicine with a meal.

It is possible to crush or halve the tablet if necessary.

**If you forget to take this medicine,** take the dose as soon as you remember, but never take a double dose to compensate for a missed one! Take the next dose at the usual time and consult your doctor or pharmacist.

**If you have accidentally taken an overdose,** or if a child has accidentally swallowed the medicine, contact immediately the doctor or proceed immediately to a hospital emergency room and bring the package of the medicine with you. You may experience swelling in the throat, skin allergic reactions and breathing difficulties.

**Do not stop taking this medicine,** even if you are feeling well, unless your doctor tells you. This medicine may cause dependence; therefore you could get a withdrawal reaction [headache, problems with your vision (including pain or swelling in the eye), vomiting and nausea, fever, pain in your muscles and joints, swelling in the inside of nose, weight loss, itchy skin and conjunctivitis]. You must stop the treatment gradually according to your doctor's recommendation.

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.

**If you have any further questions on the use of this medicine, ask your doctor or pharmacist.**

### 4. Side Effects:

Like all medicine, Dexamethasone tablets use can cause side effects, although not everybody gets them.

Do not be alarmed by this list of possible events. You may not have any of them.

**Severe side effects:** Consult your doctor immediately:

Steroids including Dexamethasone can cause serious mental health problems in adults and children. **Consult your doctor immediately.**

They can affect about 5 in every 100 people taking medicines like Dexamethasone. These include:

- Feeling depressed, including thinking about suicide
- Feeling high (mania) or moods that go up and down
- Feeling anxious, having problems sleeping, difficulty in thinking or being confused and losing your memory
- Hallucination, feeling afraid.

**If you have an allergic reaction to Dexamethasone, consult your doctor immediately.** An allergic reaction may include:

- Any kind of skin rash or itching of the skin
- Difficulty in breathing or collapse

**If you get any of the following side effects see your doctor as soon as possible:**

- **Stomach and intestinal problems:** ulcers in the throat, stomach ulcers, which may perforate or bleed, indigestion, nausea vomiting, a swollen stomach, having more of an appetite than usual, hiccups, diarrhoea.
- **Inflamed pancreas:** this may cause severe pain in the back or tummy.
- **Problems with Electrolyte balance in your blood** such as increased level of sodium or low level potassium or calcium that may cause edema.
- **Heart and blood problems:** high blood pressure, blood clots, problems with heart after a recent heart attack.
- **Bone problems:** thinning of the bones (osteoporosis) with an increased risk of fractures, bone disease.
- **Recurring infections** like fungal infections or viral infection (chicken pox)
- **Skin problems:** wounds that heal more slowly, skin hemorrhages, acne.
- **Eye problems:** increased pressure in the eye including glaucoma, eye disorders such as cataracts, eye infections.
- **Hormone problems:** irregular or missing periods, stunted growth in children and teenagers, swelling of the face (called 'Cushingoid' or 'moon' face), it may affect your diabetes and you may notice you start needing higher doses of the medicine you take for diabetes, your body may not be able to respond normally to severe stress such as accidents, surgery or illness, growth of extra body hair (particularly in women), increased appetite or weight gain.
- **Nervous system problems:** fits or epilepsy may become worse, severe unusual headache with visual problems, being unable to sleep, depression, schizophrenia has become worse, pain or swelling in the eyes.
- **General problems:** may make you feel generally unwell or tired.

**If one of the side effects gets worse, or in the event that you experience side effects not mentioned in this leaflet, consult your doctor immediately**

### 5. How to store this medicine?

**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. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not take medicines in the dark! Do not use this medicine after the expiry date stated on the label/carton/bottle. The expiry date refers to the last day of that month.

Store below 25°C in a dark and a dry place.

Do not throw this medicine into dustbin. This medicine have to be returned to the pharmacy.

### 6. Further information:

**In addition of active ingredient (substance) this medicine contains also:**

**Dexamethasone 0.5 mg:** Starch, lactose, avicel, talc, PVP K-30, stearic acid, aerosil.

**Dexamethasone 2 mg:** Lactose, starch 1500, microcrystalline cellulose (Avicel PH 102), talc, stearic acid, colloidal silicone dioxide (Aerosil 200), croscarmellose sodium (Ac-Di-Sol)

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

**Dexamethasone 2 mg:** not coated white tablet with R engraved on one side, plain on the other. 50 tablets into white bottle.

**Dexamethasone 0.5 mg:** not coated white tablet with R engraved on one side, scored in half on other side. 30 tablets into white bottle.

**Manufacturer and Holder:** Rekah Pharmaceutical Prod. Ltd., 30 Hamelacha St., Holon, Israel

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**License number:** Dexamethasone 0.5 mg: 118-05-22579-00  
Dexamethasone 2 mg: 036-08-22562-00

For simplicity and easier to read, this leaflet is formulated male, however, the medicines is intended for members of both sex.