PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS - 1986

This medicine is dispensed with a physician's prescription only

Danalone
Syrup

Active ingredient and its concentration:
Each 1 ml contains: Prednisolone 3 mg
Inactive ingredients in this medicine - see section 6 "Additional information". See also "Important information about some of the medicine's ingredients" in section 2.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, consult your physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Danalone is a glucocorticoid with an anti-inflammatory effect.

Danalone is intended to treat inflammations that respond to glucocorticoids, for example: endocrine disorders, rheumatic disorders, hematologic disorders, collagen diseases, ophthalmic diseases, dermatologic diseases, respiratory diseases, neoplastic diseases, gastrointestinal diseases, allergic and edematous conditions.

Therapeutic group: Corticosteroids.

2. Before using the medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients contained in the medicine (see section 6). Symptoms of a severe allergic reaction may include a red and lumpy skin rash, difficulty breathing, swelling of the face, mouth, lips or eyelids, unexplained high temperature, and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to a hospital straight away.**
- You have an infection that affects your entire body (unless you are receiving treatment for the infection).
- You have recently had a "live" vaccination.

Special warnings regarding the use of the medicine:

Before treatment with Danalone, tell the physician if:

- You suffer, or have ever suffered, from severe depression or manic depression (bipolar disorder). This includes having had depression before or during the use of medicines that contain steroids, such as: Danalone.
- Any of your close family suffers, or has suffered in the past, from the above mental health problems.
- If you suffer from scleroderma (an autoimmune disease), because a daily dose of 15 mg or more may increase the risk of scleroderma renal crisis. Signs of scleroderma renal crisis are: increased blood pressure, decreased urine production. Your physician may recommend monitoring of your blood pressure and urine.

Contact your physician if you experience blurred vision or other visual disturbances.

- **Mental health problems while taking Danalone.** Mental health problems may occur while taking medicines that contain steroids, such as: Danalone.
  - These illnesses can be serious.
  - Mental health problems may start within a few days or weeks after starting the treatment.
  - Mental health problems are more likely at high doses.
  - Most of the mental health problems go away if the dose is lowered or the treatment is stopped. In any case, if they do occur, they must be treated.

  Tell your physician if you (or the patient who is taking this medicine) show signs of mental health problems, especially if you are depressed or thinking about suicide. In a small number of cases, mental health problems have occurred when the dose was lowered or the medicine was stopped.
- **Chickenpox, shingles or measles.**
  - Tell your physician if you have previously had chickenpox, shingles or measles, or if you have been vaccinated in the past against these infections.
  - While you are taking this medicine, avoid being in the vicinity of anybody who has chickenpox, shingles or measles, especially if you have not already had these diseases. If you have been with a person who has chickenpox, shingles or measles, **see your physician immediately**.
  - If you contract chickenpox, shingles or measles, **see your physician immediately**. Your physician will advise you on how to take this medicine. Your physician may change your dose of Danalone.
- You suffer, or have suffered in the past, from tuberculosis or septicemia (blood poisoning).
- You suffer from liver or kidney problems.
- You suffer from high blood pressure (or have a family history of high blood pressure), heart problems, or have recently had a heart attack.
- You suffer from or have a family history of:
  - diabetes.
  - osteoporosis.
  - glaucoma (increased intraocular pressure).
  - epilepsy (seizures).
- You have suffered in the past from muscle weakness while using prednisolone or other medicines containing steroids.
- You suffer, or have suffered in the past, from a stomach ulcer.
- You suffer from an underactive thyroid gland.

If you suffer from any of the above conditions, your physician may monitor you carefully while you are being treated with Danalone.

Additional warnings:

Drug interactions:

If you are taking or have recently taken any other medicines, including non-prescription medicines or nutritional supplements, tell your physician or pharmacist. Especially inform your physician or pharmacist if you are taking:

- **Some medicines may increase the effect of Danalone, and your physician may wish to monitor you carefully if you are taking these medicines (including medicines for HIV: ritonavir and cobicistat).**
- **Rifampicin and rifabutin** (antibiotics used to treat tuberculosis). Taking these medicines with prednisolone may stop prednisolone from working properly.
- **Carbamazepine, phenytoin, primidone, phenobarbitone** (for the treatment of epilepsy). Taking these medicines with prednisolone may stop prednisolone from working properly.
- **Ephedrine** (for the treatment of nasal congestion). Taking ephedrine with prednisolone may stop prednisolone from working properly.
- **Aminoglutethimide** (for the treatment of cancer). Taking this medicine with prednisolone may stop prednisolone from working properly.
- **Mifepristone** (for the termination of pregnancy). Taking mifepristone with prednisolone may stop prednisolone from working properly for several days.
- **Erythromycin** (an antibiotic for the treatment of infections). If this medicine is taken with prednisolone, your physician may change your dose of prednisolone, as you may otherwise experience more side effects.
- **Ketoconazole** (for the treatment of fungal infections). If this medicine is taken with prednisolone, your physician may change your dose of prednisolone, as you may otherwise experience more side effects.
- **Ciclosporin** (for the prevention of organ transplant rejection). If this medicine is taken with prednisolone, your physician may change your dose of prednisolone, as you may otherwise experience more side effects.
- **Estrogen hormones,** including **contraceptive pills.** You may experience more side effects. Your physician may change your dose of prednisolone.
- **Medicines for diabetes (such as: insulin)**. If taken with prednisolone, these medicines may not work properly.
- **Medicines for the treatment of high blood pressure** (such as: hydralazine). If taken with prednisolone, these medicines may not work properly.
- **Diuretics** (such as: bendroflumethiazide). If taken with prednisolone, these medicines may not work properly.
- **Somatotropin** (growth hormone). If taken with prednisolone, this medicine may not work properly.
- **Medicines for the treatment of myasthenia gravis** (muscle weakness), such as neostigmine. If taken with prednisolone, these medicines may not work properly.
- **Medicines taken for the purpose of an x-ray examination.** If taken with prednisolone, these medicines may not work properly.
- **Anticoagulants to thin the blood** (such as: warfarin and Coumadin). If taken with prednisolone, you are at increased risk of bleeding, so your physician will monitor your condition closely.
- **Aspirin and non-steroidal anti-inflammatory drugs** (such as: ibuprofen). If taken with prednisolone, you are at increased risk of developing ulcers or bleeding from the stomach.
- **Salicylates** (such as aspirin). You may experience more side effects of salicylates once you stop taking prednisolone.
- **Methotrexate** (anti-cancer treatment). If taken with prednisolone, you may experience more severe side effects.
- In addition, tell your physician or pharmacist if you are taking any of the following medicines, as taking these medicines with Danalone may cause you to have a lower level of potassium in your blood than normal (hypokalemia):
  - **Acetazolamide** (for the treatment of glaucoma and epilepsy).
  - **Diuretics,** such as: furosemide and bendroflumethiazide (for the treatment of high blood pressure).
  - **Carbenoxolone** (for the treatment of stomach ulcers).
  - **Medicines for the treatment of asthma (such as: theophylline, bambuterol, fenoterol, formoterol, ritodrine, salbutamol, salmeterol and terbutaline).**
  - **Amphotericin** (for the treatment of fungal infections).
- **Vaccinations.** If you have recently had or are planning to have any vaccinations, tell your physician before taking Danalone. This is because some injections or vaccinations should not be given to patients who are taking prednisolone.

Use of the medicine and food

Take this medicine with a meal or immediately after it.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you are pregnant or are planning to have a baby, ask your physician or pharmacist for advice before taking this medicine.

Important information about some of the medicine's ingredients

Each 1 ml of medicine contains:
- 0.86 mg sodium.
- 0.36 gram sucrose.

If your physician has told you that you/your child have intolerance to certain sugars, consult with your physician before taking/giving this medicine. Sugar could harm teeth.

- 1 mg benzoic acid.

Benzoic acid could increase jaundice in newborns.

- 0.23 gram propylene glycol.

For children under the age of 5, consult with your physician/pharmacist before giving the medicine, especially if the child is taking additional medicines that contain propylene glycol or alcohol.

If you are pregnant or nursing, consult with your physician before taking the medicine. Your physician may advise you to undergo additional tests while taking the medicine.

If you suffer from liver or kidney disease, consult with your physician. Your physician may advise you to undergo additional tests while taking the medicine.

- 36.1 mg ethanol.

Total ethanol content in this package: 2,166 mg.
This medicine contains 4.6% v/v ethanol (alcohol).

3. How should you use the medicine?

Your physician will decide on the most appropriate dose for you or your child.

Always use according to your physician's or pharmacist's instructions.

You should check with your physician or pharmacist if you are unsure about the dosage or treatment regimen for the preparation.

Attention:

With liquid medicines, use a syringe to measure the correct amount of medicine. Do not use an ordinary teaspoon to measure the amount of medicine. Ordinary teaspoons vary in size and you may not get the correct amount of medicine.

Child resistant caps have significantly reduced the number of poisoning cases caused by medicines every year. If you are having difficulty opening the package, you may ask the pharmacist for help.

If you accidentally took an overdose, consult immediately with a physician or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take this medicine at the scheduled time, take the dose as soon as possible. If it is almost time for the next dose, skip the forgotten dose and continue with the regular dose. **Do not** take a double dose.

Adhere to the treatment regimen as recommended by your physician.

If you stop taking Danalone:

Consult your physician before you stop taking Danalone.

- **Do not** stop treatment with this medicine suddenly. Your physician will instruct you how to reduce your dose slowly over a number of weeks or months in order to lower the risk of withdrawal symptoms.
- Stopping Danalone (particularly if stopped suddenly) can lead to **withdrawal symptoms**. The most common symptoms are:
  - high temperature.
  - muscle and joint pain.
  - runny nose.
  - weight loss.
  - itchy skin.
  - red, sore and sticky eyes (conjunctivitis).
  - headache.
  - nausea.
  - blurred vision.
  - low blood pressure.
- If you get severe withdrawal symptoms tell your physician **straight away.** Your physician may ask you to start taking your medicine again and then to start coming off it more slowly.

Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult your physician or pharmacist.

4. Side effects

As with any medicine, the use of Danalone syrup may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Consult your physician immediately if any of the following side effects occur:

- **Severe allergic reaction,** including a red and lumpy skin rash, difficulty breathing, swelling of the face, mouth, lips or eyelids. Unexplained high temperature and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to the hospital straight away.**
- **Serious mental health problems.** Steroids, including prednisolone, can cause serious mental health problems. These can occur in both adults and children. This effect can occur in 5 of every 100 people using prednisolone. The symptoms include:
  - feeling depressed, including thinking about suicide.
  - feeling euphoria (mania) or mood changes.
  - anxiety, problems sleeping, difficulty in thinking or being confused and losing your memory.
  - feeling, seeing or hearing things that do not exist. Strange or frightening thoughts, changes in behavior or loneliness.
- **You have epilepsy** and you suffer more fits than usual.

The following side effects may occur if prednisone is taken for a long period of time:

Frequency not known from the available data:

- if you have suffered from tuberculosis in the past, it may return.
- you may suffer more frequently from infections.
- a rare type of cancer that can affect both the skin and internal organs (Kaposi's sarcoma).
- raised level of white blood cells.
- facial puffiness and weight gain (Cushingoid).
- intolerance to carbohydrates which might result in a requirement for anti-diabetic treatment or you may develop a mild form of diabetes, but without any obvious symptoms.
- salt imbalances or water retention in the body.
- lowered levels of potassium in the blood, which may result in tiredness, confusion, muscle weakness or muscle cramps.
- increased appetite.
- loss of proteins, and calcium imbalance.
- dizziness.
- headache.
- increased pressure in the eye, swelling in the eye, cataract.
- detachment of the retina in the eye causing vision impairment.
- protrusion of the eyeballs.
- thinning of the eye membranes, worsening of existing eye infections.
- vertigo.
- tearing of the heart muscle tissue, particularly if you have recently had a heart attack.
- heart failure in susceptible people (to heart problems).
- high blood pressure.
- blocked blood vessel (embolism).
- hiccups or indigestion.
- nausea or vomiting.
- swollen abdomen or abdominal pain.
- diarrhea.
- ulcer in the esophagus (gullet).
- thrush.
- inflammation of the pancreas causing abdominal pain.
- stomach ulcer (which may bleed).
- thinning of the skin, marks or bruises on the skin.
- appearance of stretch marks.
- acne.
- visible swollen capillaries.
- increased sweating.
- rash, itching skin.
- excess body hair (particularly in women).
- muscle wasting, weakness or pain.
- thinning of the bones with an increased risk of fractures (osteoporosis).
- bone disease.
- irregular periods, or your periods may stop altogether.
- slow wound healing.
- feeling generally unwell.
- weight gain.
- torn tendon. Symptoms include hearing or feeling a tear, severe pain, immediate bruising, and an inability to either put weight on or use the affected area.
- blurred vision.
- scleroderma renal crisis - in patients who suffer from scleroderma (an autoimmune disorder). Signs of scleroderma renal crisis include increased blood pressure and decreased urine production.

Additional side effects in children and adolescents:

Prolonged use of this medicine in children and adolescents could cause slowed growth.

If you are the patient or the patient's carer and you are worried about the effects of this medicine, go back and consult with your physician.

Parents must inform their child's physician about any side effect, as well as about any additional medicine being given to the child. See above for details of side effects and specific drug interactions.

Elderly:

If you are elderly, your physician will monitor your condition closely while you are taking this medicine as you may experience more side effects.

Reporting side effects:

Side effects can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" on the homepage of the Ministry of Health website (www.health.gov.il), which will direct you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il/

5. How should the medicine be stored?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants, in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by your physician.
- Do not use this medicine after the expiry date (exp.date) which appears on the package/label. The expiry date refers to the last day of that month.
- Store below 25°C.
- Use within 6 months of first opening.
- In order to protect the medicine from light, keep it in the original package.
- Do not use the medicine if there are any clear signs of damage on the bottle. Return the medicine to the pharmacy.
- Do not throw away leftover medicines via wastewater or household waste. Ask your pharmacist how to throw away leftover medicines in order to protect the environment.

6. Additional information

- In addition to the active ingredient this medicine also contains the following inactive ingredients:
  Sucrose, propylene glycol, glycerin, alcohol 95%, saccharin sodium, apricot vanilla flavor, benzoic acid, citric acid anhydrous, disodium edetate, purified water.
- **What does the medicine look like and what are the contents of the package?**
  A clear colorless to yellowish solution with a vanilla-apricot odor.
  Each pack contains a 60 ml bottle of syrup and a 5 ml dosing syringe.
- **License Holder:** Megapharm Ltd., P.O.B. 519, Hod Hasharon, 4510501, Israel
- **Manufacturer:** Trima, Israeli Pharmaceutical Products Ma'abarot Ltd. Ma'abarot 4023000, Israel.
- Revised in August 2021 according to Ministry of Health guidelines
- **Registration number of the medicine in the National Drug Registry of the Ministry of Health:** 133.81.31155.00