

Patient package insert in accordance with the Pharmacists' Regulations
(Preparations) - 1986

The dispensing of this medicine requires a doctor's prescription

STEROCORT 4 mg

Tablets

Active ingredient - Each tablet contains:
triamcinolone 4 mg

Inactive ingredients and allergens: See the section 'Important information about some of this medicine's ingredients' and Section 6 'Additional Information'.

Read the entire leaflet carefully before using this medicine. This leaflet contains concise information about this medicine. If you have further questions, refer to your doctor 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 illness is similar to yours.

1. What Sterocort 4 mg is and what it is used for?

Sterocort 4 mg tablets contain a corticosteroid with an anti-inflammatory and anti-rheumatic effect.

This corticosteroid provides relief to inflamed areas of the body, reduces swelling, redness, itching and allergic reactions.

Therapeutic group: anti-inflammatory corticosteroid.

2. Before using this medicine

☒ Do not use this medicine if:

- you are sensitive (allergic) to the active ingredient or any of the other ingredients that this medicine contains, listed in section 6.

! Special warnings regarding the use of the medicine

Before using Sterocort 4 mg, talk to your doctor or pharmacist

Treatment with glucocorticoids can lead to an underactive adrenal cortex (insufficient production of glucocorticoids by the body) which, depending on the dose and duration of treatment, may still persist for several months and, in isolated cases, for more than one year after discontinuation of glucocorticoids. If marked physical stress occurs during treatment with Sterocort 4 mg, such as feverish illness, accidents or surgery, your doctor must be informed or an emergency doctor told about the ongoing treatment with Sterocort 4 mg. It may become necessary to temporarily increase the daily dose of Sterocort 4 mg.

Glucocorticoid administration may also become necessary in physically stressful situations if underactivity of the adrenal cortex persists after the end of treatment with Sterocort 4 mg.

In order to avoid treatment-induced acute underactivity of the adrenal cortex, your doctor will work out a plan for reducing your dose when your treatment is scheduled to end, which you should follow exactly.

Treatment with Sterocort 4 mg tablets can lead to an increased risk of bacterial, viral, parasitic, opportunistic, and fungal infections due to suppression of the body's defenses. The signs and symptoms of an existing or developing infection may be masked and difficult to recognize. Latent infections can become reactivated.

Only start Sterocort 4 mg tablets for the treatment of the diseases listed below if your doctor thinks it is absolutely necessary in these conditions. You may also have to take medicines that target the pathogens (germs) of these diseases:

- acute viral infections (hepatitis B, chickenpox, shingles, herpes simplex infections, corneal inflammation caused by herpes viruses),
- acute and chronic bacterial infections,
- fungal disease affecting the internal organs,
- certain diseases caused by parasites (amoeba or worm infections). In patients with suspected or confirmed infection with threadworms (*Strongyloides*), Sterocort 4 mg tablets can lead to activation and mass proliferation of these parasites.
- inflamed lymph nodes after tuberculosis vaccination,
- if you have a history of tuberculosis, use only with protection from tuberculosis infection,
- HBsAg-positive chronic active hepatitis (hepatitis B virus antigen is present) (infectious inflammation of the liver),
- polio,
- approximately 8 weeks before and up to 2 weeks after preventive vaccinations with an attenuated pathogen (live vaccine).

Furthermore, only take Sterocort 4 mg tablets for the following diseases if your doctor thinks it absolutely necessary, and only if these diseases are being treated at the same time, as required in each individual case:

- gastrointestinal ulcers,
- bone loss (osteoporosis),
- severe heart failure (weak heart),
- difficult-to-control high blood pressure,
- difficult-to-control diabetes mellitus,
- mental disorders (including history of such disorders), including risk of suicide. In this case, neurological or psychiatric monitoring is recommended.
- increased pressure in the eye (narrow and open-angle glaucoma); monitoring by an eye specialist and accompanying therapy are recommended,
- wounds and ulcers in the cornea of the eye; monitoring by an eye specialist and accompanying therapy are recommended.

If you experience blurred vision or other disturbances of vision, consult your doctor.

Due to the risk of bowel-wall perforation as a result of peritonitis, you may only take Sterocort 4 mg, with appropriate monitoring, in the following cases, and only if there are compelling medical reasons:

- severe ulcerative colitis with a threat of perforation, with abscesses or purulent inflammation, possibly even without peritoneal irritation,
- diverticulitis (inflammation of pouches located on the bowel wall),

- after certain bowel operations such as: intestinal anastomosis immediately after surgery.

Signs of peritoneal irritation after perforation of a gastrointestinal ulcer may be absent in patients receiving high glucocorticoid doses.

In patients who also have diabetes, metabolism must be regularly checked; it may be necessary to increase the dose of medicines used to treat diabetes (insulin, oral antidiabetics).

Patients with severe high blood pressure and/or severe heart failure must be carefully monitored, as there is a risk of deterioration.

The pulse may become slower at high doses.

Severe anaphylactic reactions (overreaction of the immune system) may occur.

The risk of tendon problems, tendinitis and tendon ruptures is increased when fluoroquinolones (certain antibiotics) and Sterocort 4 mg tablets are administered together.

During treatment of a certain form of muscle paralysis (myasthenia gravis), symptoms may initially get worse.

If taken for an extended period of time, even low doses of triamcinolone increase the risk of infection, even by microorganisms which otherwise rarely cause infections (known as opportunistic infections). Sterocort 4 mg can mask signs of an infection which can make it difficult to identify an existing or developing infection.

Inoculation with inactivated vaccines is possible in principle. However, note that the immune response and consequently the success of the vaccine, may be compromised in patients receiving high doses of corticosteroids.

During long-term treatment with Sterocort 4 mg, regular medical check-ups (including eye checks) are required.

Particularly during long-term treatment with high doses of Sterocort 4 mg, you should ensure that your potassium intake is adequate (present in foods such as vegetables, bananas) and restrict your salt intake. Blood potassium levels should be monitored.

Depending on the dose and duration of treatment, an adverse effect on calcium metabolism must be expected. For this reason, it is advisable to receive treatment to prevent osteoporosis. This particularly applies if you already have existing risk factors, e.g. a family predisposition, advanced age, insufficient protein and calcium intake, heavy smoking, excessive alcohol consumption, menopause and lack of physical activity. Prevention consists of adequate calcium and vitamin D intake, as well as physical activity. In cases of existing osteoporosis, your doctor may additionally consider drug treatment.

The following risks should be taken into consideration when temporarily interrupting or, if necessary, ending long-term treatment with this medicine:

Flare-up or worsening of the existing disease, acute underactivity of the adrenal cortex, cortisone withdrawal syndrome.

Viral diseases (e.g. measles, chickenpox) may take a particularly severe course in patients treated with Sterocort 4 mg. At particular risk are patients with a weakened immune system who have never had measles or chickenpox. If during treatment with Sterocort 4 mg these patients

come into contact with people with measles or chickenpox, they should consult their doctor immediately, who will start preventive treatment as necessary.

Children

In children, due to the risk of stunted growth, Sterocort 4 mg should only be used if there are compelling medical reasons; height gain must be regularly checked during long-term treatment.

Elderly

In view of the increased risk of osteoporosis, the doctor should very carefully weigh the benefits against the risks.

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take Sterocort 4 mg.

Effects if misused for doping test purposes

Taking Sterocort 4 mg may lead to positive results in doping tests.

Other medicines and Sterocort 4 mg

If you are taking or have recently taken other medicines, including non-prescription medications and nutritional supplements, tell your doctor or pharmacist. Particularly if you are taking:

The following medicines may affect the way Sterocort 4 mg works:

- some medicines may amplify the effects of Sterocort 4 mg, so your doctor may need to monitor your condition closely if you are taking these medicines (this includes certain HIV medicines: ritonavir, cobicistat).
- medicines that speed up metabolism in the liver, such as certain sleeping pills (barbiturates), medicines for seizures (phenytoin, carbamazepine, primidone, barbiturates) and certain medicines for tuberculosis (rifampicin) can reduce the effect of Sterocort 4 mg.
- medicines that slow down metabolism in the liver, such as certain antifungal medicines (ketoconazole, itraconazole), can amplify the effect of Sterocort 4 mg.
- certain female sex hormones, such as those used in contraceptives (the Pill) can amplify the effect of Sterocort 4 mg.
- medicines for excessive stomach acid production (antacids): If magnesium hydroxide or aluminium hydroxide is given at the same time, glucocorticoid absorption may be reduced. This will make Sterocort 4 mg less effective. The glucocorticoid and antacid should therefore be taken separately, with an interval of 2 hours between them.
- medicines containing ephedrine to relieve swelling of the mucous membranes can reduce the effect of Sterocort 4 mg.

Sterocort 4 mg can affect the activity of the following medicines:

- increase the risk of developing changes in your blood count, if taken together with certain medicines used to lower blood pressure (ACE inhibitors).
- increase the effect of medicines used to treat heart rhythm disorders (cardiac glycosides), as a result of potassium deficiency.
- increase potassium excretion that is induced by water tablets (diuretics) and laxatives.
- reduce the blood sugar-lowering effect of oral antidiabetics and insulin.
- weaken the effect of medicines used to prevent blood clotting (oral anticoagulants, coumarins). Your doctor will decide whether it is necessary to adjust your anticoagulant dose.
- increase the risk of stomach ulcers and gastrointestinal bleeding, if used at the same time as medicines for inflammation and rheumatism (salicylates, indomethacin, and other non-steroidal anti-inflammatory drugs).

- prolong the muscle-relaxing effect of certain medicines (muscle relaxants that are not neuromuscular blockers).
- increase the effect of certain medicines that raise the pressure within the eye (atropine and other anticholinergics).
- reduce the effect of medicines for diseases caused by worms (praziquantel).
- increase the risk of muscle disease or heart muscle disease (myopathies, cardiomyopathies), if used at the same time as medicines for malaria or rheumatic disorders (chloroquine, hydroxychloroquine, mefloquine).
- particularly at high doses, reduce the effect of growth hormone (somatropin).
- reduce the increase in thyroid-stimulating hormone (TSH) after administration of protirelin (TRH, a hormone secreted by the hypothalamus in the brain).
- with medicines used to suppress the body's defence (immunosuppressants): make you more prone to infections and worsen not only pre-existing infections, but also potential ones that have not yet emerged.
- increase blood levels of cyclosporine (a medicine used to suppress the body's own immune defence), thereby increasing the risk of seizures.
- increase the risk of tendon ruptures if used at the same time as fluoroquinolone (a certain group of antibiotics).

Effect on lab tests:

Glucocorticoids can suppress skin reactions to allergy tests.

Using the medicine and food

Swallow the medicine with water, with or after a meal.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning a pregnancy, consult your doctor or pharmacist before taking this medicine.

Do not take triamcinolone in the first five months of pregnancy, as animal studies have revealed signs of congenital disorders (teratogenic effect). In long-term use, damage to the growth of the unborn child cannot be ruled out.

Treatment at the end of pregnancy exposes both unborn and newborn infants to the risk of shrinking (atrophy) of the adrenal cortex tissue.

Glucocorticoids, including triamcinolone are excreted in breastmilk. If high dose or long-term treatment is required, you should stop breast-feeding.

Driving and using machines

To date, there is no evidence that Sterocort 4 mg impairs the ability to drive or use machines. The same applies to working without a secure foothold.

Important information about some of this medicine's ingredients

Sterocort 4 mg contains lactose. If you know that you have an intolerance to some sugars, contact your doctor before taking Sterocort 4 mg.

3. How to use this medicine?

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine. Only your doctor will determine your dose and how you should take this medicine

Do not exceed the recommended dose.

Method of administration

Oral tablets.

You may split the tablets if you need to. There is no information about crushing or chewing. Take the medicine with or after food with sufficient fluids. The total daily dose should, if possible, be administered as a single dose in the morning. However, for disorders requiring high-dose therapy, multiple daily doses are often needed to achieve a maximum effect. Your doctor will check the possibility of alternate-day treatment (dosing on every other day) or intermittent treatment, depending on your symptoms and response to treatment.

Duration of treatment

Treatment duration is based on the existing disease and how the disease progresses. For this, your doctor will decide on a treatment schedule that you should follow exactly. As soon as a satisfactory treatment outcome is reached, your doctor will reduce the dose to a maintenance dose or stop the treatment. Treatment must be concluded gradually. Any dose reduction or discontinuation of treatment must always be done gradually.

In patients with an underactive thyroid or liver cirrhosis, lower doses may even be sufficient or a dose reduction may be required.

Talk to your doctor or pharmacist if you think that the effect of Sterocort 4 mg is too strong or too weak.

If you have accidentally taken a higher dose

In general, Sterocort 4 mg is tolerated without complications even when taken in large amounts over a short period. No specific measures are required. If you notice any enhanced or unusual side effects, you should ask your doctor for advice.

If a child has accidentally swallowed some medicine, go immediately to a hospital emergency room and bring the medicine package with you.

If you forget to take Sterocort 4 mg

You can make up for the missed dose during the day and continue taking the dose prescribed by your doctor as usual on the next day.

If you have missed several doses, the disease being treated may possibly flare up again or get worse. In such cases, you should consult your doctor, who will review the treatment and adjust it if necessary.

Persist with the treatment as recommended by the doctor.

If you stop taking Sterocort 4 mg

Always follow the dosage schedule prescribed by your doctor. Sterocort 4 mg must never be stopped without consulting a doctor, as prolonged treatment in particular can suppress glucocorticoid production by the body (underactive adrenal cortex). Situations of marked physical stress without sufficient glucocorticoid production may be life-threatening.

Do not take medicines in the dark! Check the label and dose each time you take the medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like all medicines, taking Sterocort 4 mg may cause side effects in some people. Do not be alarmed by this list of side effects. You may not experience any of them.

Depending on the dose and duration of treatment, the following side effects may occur:

Infections and infestations:

Masking of infections, onset, return and worsening of viral, fungal, bacterial and parasitic or opportunistic infections, activation of a threadworm infection.

Blood and lymphatic system disorders:

Blood count changes (increase in white blood cells or all blood cells, decrease in certain white blood cells).

Immune system disorders:

Hypersensitivity reactions (e.g. drug rash), severe anaphylactic reactions such as heart rhythm disorders, bronchospasms (spasms of the smooth bronchial muscle), blood pressure that is too high or too low, circulatory collapse, heart attack, weakened immune system.

Hormonal disorders:

Development of Cushing syndrome (typical signs are a large rounded face [“moon face”], obesity of the upper body and facial redness), underactive adrenal cortex, or atrophy (shrinkage) of the adrenal cortex.

Metabolism and nutrition disorders:

Weight gain, raised blood sugar levels, diabetes, increased blood lipid levels (cholesterol and triglycerides), raised sodium levels with tissue fluid accumulation (edema), potassium deficiency due to increased potassium excretion (may lead to heart rhythm disorders), increased appetite.

Psychiatric disorders:

Depression, irritability, euphoria, increased drives, psychosis, mania, hallucinations, mood swings, feeling anxious, sleep disorders, and risk of suicide.

Nervous system disorders:

Increased brain pressure, manifestation of previously undetected epilepsy, increased incidence of seizures in patients with known epilepsy.

Eye disorders:

Increase in pressure within the eye (glaucoma), clouded lens(cataract), worsening of corneal ulcers, greater likelihood of development or deterioration of viral, bacterial or fungal eye infections. With systemic corticosteroid treatment, there are reports of an increased risk of fluid accumulation beneath the retina, with a risk of retinal detachment (central serous retinopathy), blurred vision.

Blood vessel disorders:

High blood pressure, increased risk of arteriosclerosis and thrombosis, inflamed blood vessels (also as withdrawal syndrome after long-term treatment), increased vascular fragility.

Gastrointestinal disorders:

Gastrointestinal ulcers, gastrointestinal bleeding, pancreatitis, stomach complaints.

Skin and subcutaneous tissue disorders:

Stretch marks, thinning of the skin (“parchment skin”), dilated blood vessels of the skin, tendency to bruising, pinpoint or superficial bleeding under the skin, increased body hair, acne,

delayed wound healing, inflammatory changes in the skin of the face, particularly around the mouth, nose and eyes, changes in skin pigmentation, hypersensitivity reactions, such as rash.

Musculoskeletal and connective tissue disorders:

Muscle disorders, muscle weakness and wasting and bone loss (osteoporosis) occur depending on the dose and are possible even with short-term use; other forms of bone degeneration (osteonecrosis), tendon problems, tendinitis, tendon rupture, fatty deposits in the spine (epidural lipomatosis), growth inhibition in children.

Note: If the dose is reduced too rapidly after long-term treatment, withdrawal syndrome may occur together with other complaints, experienced as symptoms like painful muscles and joints.

Reproductive system and breast disorders:

Impaired sex hormone secretion (resulting in the development of irregular or absent periods (amenorrhoea), male body hair pattern in women (hirsutism), impotence).

General conditions and administration site conditions:

Delayed wound healing.

Special warnings

Talk to your doctor or pharmacist if you notice any of the side effects listed or any other undesirable effects during treatment with Sterocort 4 mg. Do not stop your treatment on your own initiative under any circumstances.

If you experience gastrointestinal complaints, pain in the back, shoulder or hip joint region, mental disorders, noticeable fluctuations in blood sugar levels (for patients with diabetes) or any other disorders, tell your doctor immediately.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health by clicking on the link: "Reporting side effects due to medical treatment" that is found on the homepage of the Ministry of Health website (www.health.gov.il) which refers to the online form for reporting side effects. You can also use this link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the carton. The expiry date refers to the last day of that month.
- **Storage conditions:**
Store below 25°C.

6. Additional information

In addition to the active ingredient this medicine also contains:

lactose monohydrate, corn starch, microcrystalline cellulose, gelatin, magnesium stearate.

What the medicine looks like and what are the contents of the package:

White, flat, bi-convex tablets with a score line on one side, packaged in a blister tray.

Each package contains 30 tablets.

Manufacturer and license holder: Taro Pharmaceutical Industry Ltd., 14 Hakitor St., Haifa Bay, 2624761

This leaflet was reviewed and approved by the Ministry of Health in November 2016, and revised in August 2019 in accordance with Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
024 58 21653 00