Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine can be sold with a doctor's prescription only

Celestone Chronodose
Suspension for injection

Each ampule contains:
3.945 mg betamethasone sodium phosphate
3 mg betamethasone acetate.

Inactive ingredients and allergens: see section 2 "Important information about some of ingredients of this medicine" and section 6 "Additional information".
Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness similar to yours.

1. What is this medicine intended for?
Celestone Chronodose is indicated in the management of conditions known to be responsive to corticosteroid therapy.
Therapeutic group: corticosteroids for systemic use, glucocorticoid.

Celestone Chronodose, suspension for injection (betamethasone) belongs to a group of medicines known as corticosteroids. These cortisone-type drugs help relieve parts of the body with an inflammation. They reduce swelling, redness, itching and allergic reactions, and are often part of the treatment of a number of diseases.

2. Before using this medicine
Do not use Celestone Chronodose if:

- you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6 "additional information").
- you are allergic to corticosteroids.
- you are suffering from infections caused by fungi or yeasts.

Special warnings regarding the use of Celestone Chronodose
Before using Celestone Chronodose, tell your doctor if you have:
- diabetes;
- a viral or bacterial infection;
- muscle weakness;
- thyroid problems;
- liver problems;
- eye problems;
- seizures;
- stomach or intestinal problems;
- kidney problems;
- heart or blood pressure problems;
- pheochromocytoma (a tumour of the adrenal gland);
- or if you have a history of psychiatric problems.

Serious neurologic events, some resulting in death, have been reported with epidural injection of corticosteroids. Specific events reported include, but are not limited to, spinal cord infarction, paraplegia, quadriplegia, cortical blindness, and stroke. These serious neurologic events have been reported with and without use of fluoroscopy. The safety and effectiveness of epidural administration of corticosteroids have not been established, and corticosteroids are not approved for this use.

- Inform your doctor if you need a vaccine of any kind.
- Patients, especially children, should avoid exposure to chickenpox or measles.
- Contact your doctor if you experience blurred vision or other visual disturbances.

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

Intestine or stomach disorders may occur when simultaneously taking cortisone-type drugs and certain anti-inflammatory drugs or alcoholic beverages.

Some medicines may increase the effects of Celestone Chronodose and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV: ritonavir, cobicistat).

Remember to inform your doctor that you are taking Celestone Chronodose if you have to undergo laboratory tests.

Using this medicine and alcohol consumption
Intestine or stomach disorders may occur when simultaneously taking cortisone-type drugs and alcoholic beverages.

Pregnancy, breastfeeding and fertility:
If you are pregnant, planning to become pregnant, think you may be pregnant or if you are breastfeeding, ask your doctor or pharmacist for advice before taking this medicine.

Given the lack of adequate studies in humans, glucocorticoids can only be administered during pregnancy, breastfeeding and in women of childbearing age, after having properly assessed the expected health benefits and the potential risks of these drugs for the mother, the embryo or the foetus.

Pregnancy
Published data shows that the prophylactic use of corticosteroids after the 32nd week of pregnancy remains controversial. Therefore, the doctor should weigh the benefits and potential risks to the mother and the foetus when using corticosteroids after the 32nd week of pregnancy.
Corticosteroids are not indicated for the treatment of hyaline membranes after birth.

In case of prophylactic treatment of hyaline membrane disease in premature infants, do not administer corticosteroids to pregnant women with seizures or who show signs of placental damage.

Newborn babies whose mothers received substantial doses of glucocorticoids during pregnancy should be carefully examined for possible signs of adrenocortical insufficiency.

Since corticosteroids readily cross the placenta, newborn babies and babies born to mothers who received corticosteroids during a greater part or during part of their pregnancy should be carefully assessed in order to detect a possible congenital cataract, although this is very rare.

Women who received corticosteroids during pregnancy should be monitored during and after contractions and during delivery in order to detect adrenocortical insufficiency due to stress caused by the delivery.

Newborn babies of mothers who received Celestone Chronodose near the end of pregnancy may have low blood sugar levels after birth.

Breastfeeding

Corticosteroids are excreted in breast milk.
Given that Celestone Chronodose is likely to induce adverse effects in breastfed infants, a decision on the termination of breastfeeding or discontinuation of the drug should be considered, while taking into account the importance of the drug to the mother.

Driving and using machines
Not applicable.

Important information about some of the ingredients of this medicine
Celestone Chronodose contains sodium and benzalkonium chloride
Celestone Chronodose contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially 'sodium-free'.
Celestone Chronodose contains 0.2 mg benzalkonium chloride in each 1 ml ampoule which is equivalent to 0.2 mg/ml.

3. How to use this medicine?
Always use the medicine according to the doctor's instructions. Check with the 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.

Shake before use.

Celestone Chronodose is a suspension for injection. The injection is usually administered by your doctor or a healthcare professional. Your doctor will determine the dose depending on your individual needs.

Celestone Chronodose is for intramuscular, intra-articular or intralesional administration.

Celestone Chronodose cannot be used for intrathecal administration.

Your doctor will evaluate your health regularly to make sure you get the correct dose.
Do not exceed the recommended dose.

If you have accidentally taken a higher dose of Celestone Chronodose
If you have taken an overdose, or if a child has accidentally swallowed this medicine, refer immediately to a hospital emergency room and bring the package of the medicine with you.

If you forget to use Celestone Chronodose
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 using Celestone Chronodose
After continuous use, the drug should not be stopped abruptly; the dose should be gradually reduced by your doctor.

Do not take medicines in the dark! Check the label and dose <u>each time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions on the use of this medicine, consult your doctor or pharmacist.

4. Side effects
Like with all medicines, using Celestone Chronodose may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not experience any of them.

The adverse effects observed with Celestone Chronodose, which are the same as those mentioned for other corticosteroids, are related to both the dose and the duration of treatment.

In general, the adverse effects of corticosteroids include the following:
Heart rhythm disorders - Fluid retention - Hypertension - Muscle weakness - Loss of calcium - Bruises - Redness of the face - Thin or delicate skin - Allergic reactions - Peptic ulcer - Hiccups - Disorders of the stomach or intestine - Seizures - Euphoria - Insomnia - Dizziness - Headache - Unstable mood - Eye problems (glaucoma) - Blurred vision - Swelling of the face - Acne - Irregular menstruation.

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

Side effects can be reported to the Ministry of Health by using the link "Report adverse effects and problems associated with medications and drugs" on the Ministry of Health home page (www.health.gov.il) which refers to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! this medicine and all other medicines, 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 a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the pack. The expiry date refers to the last day of that month.
  Storage conditions:
- Store at a temperature below 25°C.
- Do not freeze.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredients, this medicine also contains:
Disodium hydrogen phosphate dihydrate, sodium dihydrogen phosphate dihydrate, benzalkonium chloride, disodium edetate, water for injections.

What the medicine looks like and what is the content of the pack:
Celestone Chronodose is clear, colorless liquid containing easily re-suspendable white particles.
Celestone Chronodose is packed in a carton box containing 1 ampule of 1 ml.

License holder and address:
Organon Pharma Israel Ltd.,1 Atir Yeda, Kfar Saba

Manufacturer: Organon LLC, NJ USA

Revised in March 2024.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
131-43-23009