

CELESTONE® CHRONODOSE® INJECTION

Betamethasone sodium phosphate/betamethasone acetate

Consumer Medicine Information

What is in this leaflet?

This leaflet answers some common questions about Celestone Chronodose. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Celestone Chronodose against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine or in a safe place.

You may want to read it again.

What Celestone Chronodose is used for

Celestone Chronodose contains betamethasone as the active ingredient. Betamethasone is a glucocorticoid and belongs to a group of medicines called corticosteroids.

Celestone Chronodose is used to treat symptoms associated with inflammatory processes and/or allergic reactions, which may include:

- swelling
- redness
- itching.

It may be used as part of the treatment for a number of different diseases such as severe allergies, skin problems, asthma or arthritis. Although Celestone Chronodose may relieve the symptoms of these diseases, it will not cure them.

Celestone Chronodose can also be used to prevent respiratory distress syndrome in premature infants.

Your doctor may have prescribed Celestone Chronodose for another reason.

Ask your doctor if you have any questions about why Celestone Chronodose has been prescribed for you.

Before you start Celestone Chronodose

When you must not receive it:

Celestone Chronodose should not be used if:

1. you have an allergy to:

- Celestone Chronodose, or betamethasone
- any of the ingredients listed at the end of this leaflet
- any other cortisone-like medicines. Some of the symptoms of an allergic reaction may include:
 - shortness of breath, wheezing, difficulty breathing or a tight feeling in your chest
 - swelling of the face, lips, tongue or other parts of the body
 - rash, itching, hives or flushed, red skin.

2. you have a fungal infection within your body or any other serious or long-term infections

Cortisone-like medicines such as Celestone Chronodose may decrease your resistance and make infections spread.

3. you have recently been vaccinated against smallpox.

Cortisone-like medicines such as Celestone Chronodose must not be injected into unstable joints, infected areas, intervertebral spaces or by the epidural route.

Celestone Chronodose must not be used if the packaging is torn or shows signs of tampering.

Celestone Chronodose must not be used after the expiry date (EXP) has passed.

If you are not sure whether you should start Celestone Chronodose, talk to your doctor.

Before you start to receive it

Tell your doctor if:

- **you are allergic to:**
 - any other medicines including other cortisone-like medicines
 - any other substances such as foods, dyes or preservatives.
- **you are pregnant or intend to become pregnant**

If it is necessary for you to start Celestone Chronodose, your doctor will discuss the benefits and risks of using it during pregnancy.
- **you are breast-feeding or plan to breast-feed**

The active ingredients in Celestone Chronodose pass into breast milk and may affect your baby. If there is a need to use Celestone Chronodose, your doctor will discuss the benefits and risks of using it while breast-feeding.
- **you need any type of vaccination**

Cortisone-like medicines such as Celestone Chronodose may lower your body's immune response and result in nervous system complications if used with a vaccine.
- **you have any of the following:**
 - osteoporosis
 - emotional or mental health problems
 - stomach or intestinal problems, including ulcers
 - tuberculosis
 - Herpes infection of the eye
 - any other infections, including recent measles or chicken pox
 - kidney or liver problems
 - high blood pressure or heart problems
 - diabetes
 - myasthenia gravis
 - glaucoma
 - Cushing's syndrome
 - thyroid problems
 - seizures
 - bruising or bleeding problems.

Children

Cortisone-like medicines such as Celestone Chronodose can cause infections such as chicken pox or measles to be more serious in children. These medicines can also slow or stop growth in children or growing teenagers if used for a long time.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines and Celestone Chronodose may interfere with each other. These include:

- aspirin, salicylates, anti-inflammatory medicines
- barbiturate sedatives
- phenytoin, a medicine used to treat epilepsy
- certain antibiotics such as rifampicin, clarithromycin and amphotericin
- some cough and cold medicines
- tablets or injections used to treat diabetes
- hormone-type medicines including hormone replacement therapy and oral contraceptives
- certain diuretics, also called fluid or water tablets
- certain medicines used to treat heart failure
- medicines used to stop blood clots
- growth hormone
- vaccines
- certain antifungals such as ketoconazole and itraconazole
- some medicines used to treat HIV infection such as ritonavir and cobicistat - containing products

You may need to take different amounts of your medicines or you may need to take different medicines.

How Celestone Chronodose is used

How it is given

Celestone Chronodose is usually given by a doctor or nurse. How it is given and the amount depends on the condition being treated.

Into a muscle (e.g. allergic, skin and rheumatic conditions, bursitis)

- 1 mL, repeated weekly or more often if necessary
- 2 mL if the illness is severe

Into soft tissue (e.g. bursitis, fibrositis)

- 1 mL at intervals of 1 to 2 weeks

Into joints (e.g., rheumatoid arthritis, osteoarthritis, pain relief)

- 0.25 to 2 mL

Into the skin (eg skin lesions, psoriasis)

- not more than 1 mL at weekly intervals

How long it is given

Your doctor will decide how long you need to have this medicine. If you have been receiving it for some time, the dose will be reduced gradually before stopping.

If too much is given (overdose)

A single overdose of Celestone Chronodose is unlikely to cause serious side effects.

Repeated use of high doses may result in more severe side effects, as listed under Side Effects below.

Contact the Poisons Information Centre on 131126 if you think you or someone else may have been given too much Celestone Chronodose.

While you are using Celestone Chronodose

Things you must do

If you become pregnant while being treated with Celestone Chronodose, tell your doctor immediately.

If you are having emotional or physical stress such as serious infection, surgery or injury, tell your doctor.

This may affect the dose of Celestone Chronodose you need.

Check with your doctor about drinking alcohol.

If you drink alcohol while receiving Celestone Chronodose, the risk of ulcers is increased.

Tell all doctors, dentists and pharmacists who are treating you that you are being treated with Celestone Chronodose.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with Celestone Chronodose.

Things you must not do

While you are being treated with Celestone Chronodose, and even after you stop it, do not have any vaccinations without your doctor's approval.

Things to be careful of

If Celestone Chronodose is injected into one of your joints, you should be careful not to put too much stress or strain on that joint for a while, even if it begins to feel better. Make sure your doctor has told you how much you are allowed to move this joint while it is healing.

If redness or swelling occurs at the place of injection, and continues or gets worse, check with your doctor.

Always check with your doctor as soon as possible if you notice any signs of a possible infection, such as sore throat, fever, sneezing or coughing.

Celestone Chronodose may lower your resistance and make any infection you do get harder to treat.

If you are having any laboratory tests, tell your doctor.

Celestone Chronodose may give false results in skin tests.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Celestone Chronodose.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

When this medicine is used for short periods of time, side effects are usually rare.

Ask your doctor or pharmacist any questions you may have.

Older patients are more likely to develop high blood pressure or bone disease from cortisone-like medicines. Women are especially at risk of developing bone disease.

Tell your doctor immediately if any of the following occur:

- swelling of the face, lips or tongue that may cause difficulty in swallowing or breathing
- asthma, wheezing, shortness of breath
- sudden or severe itching, skin rash, hives
- fainting, seizures or fits
- vomiting blood or material that looks like coffee grounds
- bleeding from the back passage (rectum), black sticky bowel motions (stools) or bloody diarrhoea
- severe pain in the food pipe (oesophagus) or stomach
- irregular heart rhythm.

These are serious reactions. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

- unusual weight gain, puffiness, swelling of the ankles or legs
- muscle weakness with chronic fatigue, muscle loss, pain or cramps
- tendon pain
- joint pain
- slow wound healing, thinning and breakdown of skin, bruising or reddish or purplish spots under the skin, red face, increased sweating
- headache or dizziness
- menstrual irregularities
- swelling of the face (moon face), acne
- thirst or passing large amounts of urine
- feeling 'high', mood swings, depression and strange thoughts, personality changes, difficulty sleeping
- visual disturbances or blurred vision
- changes to your vision or pain in the eyes.

Very rarely, cortisone-like medicines given by injection may cause blindness if given around the head and neck. Skin darkening or loss of pigment, skin breakdown, abscess or redness, and joint damage caused by the injection, may also rarely occur.

Other side effects not listed above may also occur in some patients. If you notice any other side effects, check with your doctor.

After using Celestone Chronodose

Storage

Celestone Chronodose is usually stored in the doctor's surgery or clinic, or at the pharmacy.

It should be protected from light and kept at temperatures below 25°C.

Product description

What it looks like

Celestone Chronodose is a clear, colourless, suspension. It is available in 1mL glass ampoules in packs of 2 and 5.

Ingredients

Active ingredient:

- betamethasone sodium phosphate
- betamethasone acetate

Inactive ingredients:

- Benzalkonium chloride
- Disodium edetate
- Dibasic sodium phosphate

- Monobasic sodium phosphate monohydrate
- Nitrogen
- Water for Injections.

Sponsor

In Australia:

Merck Sharp & Dohme (Australia) Pty Limited
Level 1 Building A, 26 Talavera Road, Macquarie Park, NSW 2113 Australia

In New Zealand:

Merck Sharp & Dohme (New Zealand) Ltd
P O Box 99 851
Newmarket
Auckland 1149
New Zealand

Australian Registration Number

AUST R 18777

Date of Preparation

8 October 2018