

Chloromycetin® Succinate Injection

Chloramphenicol

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Chloromycetin Succinate injection. 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 treating you with Chloromycetin Succinate 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.

You may need to read it again.

What Chloromycetin Succinate is used for

Chloromycetin Succinate injection is used to treat serious infections including bacterial meningitis, typhoid fever, rickettsial infections and eye infections.

Chloromycetin Succinate belongs to a group of medicines called antibiotics.

It works by stopping the growth of bacteria causing your infection.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Chloromycetin Succinate is not addictive.

It is available only with a doctor's prescription.

Before you are given Chloromycetin Succinate

When you must not be given it

You must not be given Chloromycetin Succinate if you have an allergy to:

- chloramphenicol
- any of the ingredients listed at the end of this leaflet
- any other similar medicines

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Chloromycetin Succinate must not be given after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- anaemia, bleeding or any other blood related disorders
- reduced liver function
- reduced kidney function

Tell your doctor if you have been recently immunised.

Chloromycetin Succinate may interfere with the development of immunity if you have been recently immunised.

Tell your doctor if you are pregnant or plan to become pregnant.

It is not recommended that you be treated with Chloromycetin Succinate during the week before giving birth due to possible effects on the baby. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breastfeeding or plan to breastfeed.

Chloromycetin Succinate is not recommended during breastfeeding. The active ingredient passes into breast milk and there is a possibility that your baby may be affected. Your doctor can discuss with you the risks and benefits involved.

If you have not told your doctor about any of the above, tell him/her before you are treated with Chloromycetin Succinate injection.

Taking other medicines

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

Some medicines may interact with Chloromycetin Succinate or affect how well it works. These include:

- medicines that stop you from having fits or seizures, such as phenytoin or phenobarbitone
- medicines that affect blood clotting, such as warfarin
- medicines that affect the bone marrow or blood cells
- other antibiotics, such as erythromycin, clindamycin, lincomycin or rifampicin
- tolbutamide, a medicine used to treat diabetes
- oral contraceptives containing oestrogen ("the Pill")
- alfentanil, used in anaesthesia and to treat pain
- tacrolimus, used to prevent rejection after kidney or liver transplant
- vaccines

These medicines may be affected by Chloromycetin Succinate or may affect how well it works. You may need different amounts of your medicines, or you may need to use different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while being treated with Chloromycetin Succinate.

How Chloromycetin Succinate is given

How much is given

The dose of Chloromycetin Succinate will vary for different people and depends on your weight and type of infection.

Your doctor will work out how much of this medicine you need.

Adults: The usual dose is 50 mg of chloramphenicol per kilogram of body weight per day. In certain cases, a dose of up to 100 mg per kilogram may be given for a limited time.

Children: After the first two weeks of life, full-term infants can usually receive up to 50 mg per kilogram of body weight per day. Chloromycetin Succinate should only be given to newborns if it may be life-saving and there is no alternative. When given to newborns, the usual dose is reduced to 25 mg per kilogram of body weight per day.

How the injection is given

Chloromycetin Succinate is given by injection into a vein or muscle by your doctor or a trained nurse.

Chloromycetin Succinate is a powder that is diluted by your hospital pharmacist, doctor or trained nurse by mixing with Water for Injections, sodium chloride 0.9% injection or glucose 5% injection.

When it is given

You will be given four injections per day at intervals of six hours. It does not matter if this medicine is given before or after food.

How long it is given for

The length of time you are given Chloromycetin Succinate will depend on the sort of infection present.

Your doctor will treat you with Chloromycetin Succinate for the shortest duration necessary to effectively treat your condition.

Prolonged use may cause bleeding and increase the risk of other side effects.

Repeated courses of Chloromycetin Succinate should be avoided.

If a dose is missed

It is unlikely that a dose will be missed as Chloromycetin Succinate is given under close medical supervision. However, talk to your doctor or nurse if you have any concerns.

If too much is given (overdose)

Overdose is unlikely as treatment will be given by your doctor or other medical professional. However, tell your doctor or nurse if you do not feel well during or after an injection.

Immediately telephone the Poisons Information Centre (In Australia: 13 11 26, in New Zealand: 0800 POISON or 0800 764 766) for advice if you think that you or anyone else may have been given too much.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include:

- feeling sick, vomiting and diarrhoea
- effects on blood cells and blood clotting

While you are receiving Chloromycetin Succinate

Things you must do

If the symptoms of your infection do not improve within a few days, or if they become worse, tell your doctor.

Tell your doctor, pharmacist or nurse immediately if you get diarrhoea. Do this even if it occurs several weeks after stopping treatment.

Diarrhoea can be a sign that you have a serious condition affecting your bowel. You may need urgent medical care. Do not take any diarrhoea medicine without first checking with your doctor.

If you get a sore white mouth or tongue during a treatment course or after stopping Chloromycetin Succinate, tell your doctor. Also tell your doctor if you get vaginal itching or discharge.

This may mean you have a fungal infection called thrush. Treatment with Chloromycetin Succinate may result in an overgrowth of fungi which can cause thrush.

Tell any other doctors, dentists, and pharmacists who treat you that you are being given this medicine.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being given Chloromycetin Succinate.

If you are going to have surgery, tell the surgeon or anaesthetist that you are being given Chloromycetin Succinate.

It may affect other medicines used during surgery.

If you are about to have any blood tests, tell your doctor that you are being given Chloromycetin Succinate.

Chloromycetin Succinate may interfere with the results of some tests.

Your doctor may recommend that you have blood tests before, during or after treatment.

It is essential that you attend these appointments so your doctor can assess the effects Chloromycetin Succinate is having on you.

Things to be careful of

Be careful driving or operating machinery until you know how Chloromycetin Succinate affects you.

This medicine generally does not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Chloromycetin Succinate may cause tiredness in some people. If you are affected, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well during or after treatment with Chloromycetin Succinate.

This medicine helps most people with bacterial infections but it may have unwanted side effects in some people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not.

You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- soreness at the injection site

- fever
- skin rash, itching, swelling or hives
- worsening of your condition
- headache, depression or confusion
- nausea or vomiting

Tell your doctor as soon as possible if you notice any of the following:

- diarrhoea
- white, furry, sore tongue and mouth
- sore and itchy vagina and/or white discharge
- eye pain, numbness, blurred vision or blind spots
- unusual tiredness, weakness, bleeding or bruising more easily than normal

The above list includes serious side effects, which may require medical attention. Some of these effects can occur several weeks or months after stopping treatment. Serious side effects are rare.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- Allergic reactions including fever, rash, swelling of the face, lips, mouth or sore throat that may cause difficulty in swallowing or breathing, shortness of breath, swelling of the hands, feet or ankles.
- In newborn babies, vomiting, refusal to suck, fast irregular breathing, swelling of the stomach, blue discolouration of the skin or green coloured diarrhoea.

The above list includes very serious side effects which require urgent medical attention or hospitalisation. These side effects are very rare.

Other side effects not listed may also occur in some people.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell during or after treatment with Chloromycetin Succinate.

Some side effects (for example, blood disorders) can only be found when your doctor does tests from time to time to check your progress.

After being given Chloromycetin Succinate

Storage

Chloromycetin Succinate vials should be stored in a dry place where the temperature stays below 25°C.

Prepared Chloromycetin Succinate solution should be administered as soon as possible. If storage of prepared solution is necessary, store between 2°C to 8°C for not more than 24 hours.

Chloromycetin Succinate will be stored in the pharmacy or on the hospital ward, out of reach of children.

Disposal

Chloromycetin Succinate is for single use in one patient only. The hospital staff will dispose of any left over or expired Chloromycetin Succinate injection.

Product Description

What it looks like

Chloromycetin Succinate is a white or yellowish-white powder in a glass vial with a

rubber stopper and aluminium cap or flip-off cap.

After reconstitution, Chloromycetin Succinate solution should not be cloudy in appearance.

Ingredients

Each vial contains chloramphenicol sodium succinate equivalent to 1g of chloramphenicol. It also contains sodium hydroxide.

Supplier

Chloromycetin Succinate injection is supplied in Australia by:

Link Medical Products Pty Ltd
5 Apollo Street
Warriewood, NSW 2102,
Australia

Chloromycetin Succinate injection is supplied in New Zealand by:

Link Pharmaceuticals Ltd.
Level 31, Vero Centre
48 Shortland Street
Auckland 1140
New Zealand

Australian Registration Number:

AUST R 58794

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