

**PACKAGE LEAFLET:
INFORMATION FOR THE USER**

Cidomycin Paediatric 20mg/2ml Solution for Injection Gentamicin

SANOFI 

Is this leaflet hard to see or read? Phone 01 403 5600 for help

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again
- If you have any further questions, ask your doctor or pharmacist
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist

In this leaflet:

1. What Cidomycin Paediatric is and what it is used for
2. Before you use Cidomycin Paediatric
3. How to have Cidomycin Paediatric
4. Possible side effects
5. How to store Cidomycin Paediatric
6. Further information

1. What Cidomycin Paediatric is and what it is used for

The name of this medicine is Cidomycin Paediatric 20mg/2ml Solution for Injection (called Cidomycin in this leaflet). It contains a medicine called gentamicin sulphate. This belongs to a group of antibiotics called 'aminoglycosides'.

Gentamicin is used to treat infections caused by bacteria. This includes infections in:

- Your urinary tract (including your kidneys or bladder)
- Your chest (including your lungs)
- Your blood – this is sometimes called 'bacteraemia' or 'septicaemia'

2. Before you use Cidomycin Paediatric

Do not have this medicine if:

- You have Myasthenia Gravis. This is a disease that causes muscle weakness.
- You are allergic (hypersensitive) to Cidomycin or to any of the other ingredients of this medicine (see Section 6: Further Information). Signs of an allergic reaction include: a rash (hives), itching, swallowing or breathing problems, swelling of your lips, face, throat or tongue.

Cidomycin must not be given by injection to the brain (Intraventricular administration) to infants (under 1 year old)

Do not have this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before having Cidomycin.

Take special care with Cidomycin and check with your doctor or pharmacist before having your medicine if:

- You are pregnant, might become pregnant, or think you may be pregnant.
- You are breast-feeding (see 'Pregnancy and breast-feeding' section below)
- You have any muscle weakness problems
- You have kidney problems, are over 65 years of age or the patient is less than 1 year old. This is because your doctor will need to keep a careful eye on you during your treatment, to prevent damage to your ears. He may check your hearing, your balance, how your kidneys are working and the amount of Cidomycin in your blood.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before having Cidomycin.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, including herbal medicines. This is because Cidomycin can affect the way some other medicines work. Also, some medicines can affect the way Cidomycin works.

In particular tell your doctor if you are taking any of the following:

- Medicines used to thin the blood such as warfarin
- Water tablets or injections (diuretics) such as furosemide or etacrynic acid
- Amphotericin B (used to treat fungal infections)
- Cephalosporin antibiotics such as cephaloridine
- Ciclosporin (used in organ transplants or for severe skin problems)
- Neostigmine or pyridostigmine (used to treat Myasthenia Gravis)
- Muscle relaxants - sometimes used during operations which need an anaesthetic
- Indometacin (used to treat pain or swelling)
- Bisphosphonates (used to treat osteoporosis)
- Cisplatin (used to treat some cancers)
- Botulinum toxin – used to lower the activity of overactive muscles. This is also sometimes used in cosmetic procedures.

These medicines may increase the chances of getting certain side effects (see Section 4: Possible side effects). If you are unsure about any of the above, consult your doctor.

Pregnancy and breast-feeding

Talk to your doctor before having this medicine if:

- You are pregnant, think you may be pregnant or plan to get pregnant. Cidomycin should not normally be used during pregnancy.
- You are breast-feeding or planning to breast-feed

Important information about some of the ingredients of Cidomycin

Cidomycin contains very little sodium. It contains less than 1 mmol sodium (23 mg) per ampoule or vial.

3. How to have Cidomycin

Cidomycin is always given to you by a doctor or nurse.

Having this medicine

Your doctor will decide how much to give you, depending on your weight. The correct dose also depends on the type of infection and any other illnesses you may have. Blood samples will be taken by your doctor or nurse to check the dose is right for you.

How much Cidomycin is given:

Adults

- The recommended daily dose in children, adolescents and adults i.e. 3-6mg/kg body weight per day as 1 (preferred) up to 2 single doses.
- If you have kidney problems your daily dose will be reduced and adjusted appropriately.

Infants:

(Age: 28 days to 2 years):

- The recommended daily dose after the first month of life is 4.5-7.5mg/kg body weight per day as 1 (preferred) up to 2 single doses.
- In the case of renal impairment, the dose will be reduced and adjusted appropriately.

Neonates:

(Age: up to 1 month):

- The recommended daily dose is 4-7mg/kg body weight per day. This should be given in 1 single dose.
- In the case of renal impairment, the dose will be reduced and adjusted appropriately.

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If you have more Cidomycin than you should

It is most unlikely that you will be given too much medicine by the doctor or nurse. Your doctor or nurse will be checking your progress and checking the medicine that you are given. Ask if you are not sure why you are getting a dose of medicine.

If you miss a dose of Cidomycin

Cidomycin will be given to you by a doctor or nurse. It is most unlikely that you will not be given the medicine as it has been prescribed. If you think that you may have missed a dose then talk to your nurse or doctor.

If you stop having Cidomycin

It is important that the course of treatment your doctor has prescribed is finished. You may start to feel better but it is important to continue your treatment until the doctor advises. If you stop, your infection may get worse again.

4. Possible side effects

Like all medicines, Cidomycin can cause side effects, although not everybody gets them.

Tell your doctor or nurse as soon as possible if any of the following side effects happen:

- Acute kidney failure (frequency very rare).
- High urine levels of phosphate and amino acids (so called Fanconi-like syndrome, associated with high doses given over long time) (frequency very rare).
- Irreversible hearing loss, deafness (frequency unknown).
- It becomes difficult keeping your balance, you feel dizzy or your hearing becomes poor. Cidomycin can sometimes damage the ear. This is more likely to happen if your kidneys do not work very well.
- If you notice anything unusual when you pass water, such as any sign of blood in your water (urine) or you find you are passing less water than is normal for you. This may mean you have kidney problems.
- If you have unusual difficulty in moving which has not happened before, feel weak or unusually tired or have any breathing difficulties that have not happened before. This may mean you have nerve or muscle problems.
- Numbness, weakness and pain in the arms and legs (peripheral neuropathy)
- Cidomycin can cause serious allergic reactions (including anaphylaxis); symptoms may include:
 - breathing problems
 - swelling of the face, mouth, and tongue
 - fainting, dizziness, feeling lightheaded (low blood pressure)
 - hives
 - itching
 - skin rash

If you suspect a serious allergic reaction, get immediate medical attention.

- Dizziness, light headedness and fainting. This could be because of low blood pressure.

If you notice any of the above, talk to your doctor or nurse as soon as possible.

Tell your doctor or nurse if any of the following side effects gets serious or last longer than a few days. Also tell them if you notice any side effects not listed in this leaflet

- Headache
- Feeling tired
- Purplish or reddish-brown skin colouring
- Mouth ulcers
- Feeling or being sick (nausea or vomiting)
- Rash
- Bloody diarrhoea, possibly with stomach pain/cramps
- Fits or convulsions
- Feeling confused
- Depression
- Strange visions or sounds (hallucinations) and memory loss

Talk to your doctor or nurse if any of the side effects gets serious or lasts longer than a few days, or if you notice any side effects not listed in this leaflet

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cidomycin

- You will not be asked to store your medicine. It will be brought to you ready to be given straight away.
- Keep out of the sight and reach of children.
- Discoloured solution should not be used.
- Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.
- Do not store this medicine above 25°C. Do not keep this medicine in a fridge or freezer.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Cidomycin contains

The active substance is gentamicin sulphate, each vial contains the equivalent of 20mg of gentamicin. The other ingredients are sodium chloride, sulphuric acid and sodium hydroxide (for pH adjustment), and water for injections.

What Cidomycin looks like and content of the pack

The medicine is a clear, colourless solution for injection in 2ml vials. Cidomycin is available in packs of 5 vials.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

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