PACKAGE LEAFLET : INFORMATION FOR THE PATIENT

Cidomycin® 80mg/2ml Solution for Injection

Gentamicin

Is this leaflet hard to see or read? Phone +44 (0) 208 588 9131 for help

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Cidomycin is and what it is used for

The name of this medicine is Cidomycin 80mg/2ml Solution for Injection (called Cidomycin throughout this leaflet). It contains a medicine called gentamicin. This belongs to a group of antibiotics called 'aminoglycosides'.

Cidomycin 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 abdomen (including your gut)
- Your brain and spinal cord
- Your blood – this is sometimes called 'bacteraemia' or 'septicaemia'
- Newborn babies

2. What you need to know before you have Cidomycin

Do not have Cidomycin if:

X You are allergic (hypersensitive) to gentamicin, any other antibiotics or to any of the other ingredients of this medicine (see section 6).
Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat and tongue.

X You have myasthenia gravis. This is a disease that causes muscle weakness.

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

Warnings and precautions

Talk to your doctor or nurse before having Cidomycin if:
- You are pregnant, think you may be pregnant or are planning to have a baby.
- You are breast-feeding or are planning to breast-feed.
- You have any muscle weakness problems.
- You experience severe diarrhoea.
- You develop severe skin reactions such as Stevens-Johnson Syndrome (SJS) or toxic epidermal necrolysis (TEN) as described in section 4 "Possible side effects". If you have symptoms of a severe skin reaction, contact your doctor or nurse immediately.
- if you have, or have a maternal history of mitochondrial mutation disease (a genetic condition) or loss of hearing due to antibiotic medicines, you are advised to inform your doctor or pharmacist before you take an aminoglycoside; certain mitochondrial mutations may increase your risk of hearing loss with this product. Your doctor may recommend genetic testing before administration of Cidomycin.
- You are extremely overweight (obese).
- You have kidney problems.
- You have cystic fibrosis.
- You are elderly (over 65 years of age) or the patient is less than 1 year old.

Your doctor will need to monitor you before, during and shortly after your treatment. Your doctor may check your hearing, balance, how your kidneys are working and the amount of gentamicin in your blood. This is to prevent damage to your ears and/or kidneys and is particularly important if you have kidney problems, are obese, suffer from cystic fibrosis or are over 65 years of age, or the patient is less than 1 year old.

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

Other medicines and Cidomycin
Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines you buy 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 – used to treat bacterial infections.
- 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. If you are unsure about any of the above, consult your doctor or nurse.

Pregnancy and breast-feeding
Cidomycin is not recommended during pregnancy or breast-feeding.
Ask your doctor or nurse for advice before having this medicine if:
- You are pregnant, think you may be pregnant or are planning to have a baby.
- You are breast-feeding or are planning to breast-feed.

Cidomycin contains sodium
This medicine contains less than 1mmol sodium (23mg) per 2ml vial or ampoule, that is to say essentially 'sodium-free'.

3. How to have Cidomycin

Cidomycin is always given to you by a doctor or nurse. This is because it needs to be given as an injection.

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, in particular diseases of the kidney.

Tests
Blood samples will be taken by your doctor or nurse to check the dose is right for you. You should not receive Cidomycin if these blood tests cannot be performed. You may also need tests to check your hearing and balance.

Elderly or obese people, newborns, people with impaired kidney function and those with cystic fibrosis should be particularly closely monitored when having this medicine.

How much Cidomycin is given
Adults
- The usual daily dose in adults is 3-5mg for each kg of body weight.
- This is given either as one single dose (preferred) or split into two or three daily doses.
- This dose may be increased or decreased by your doctor depending on your illness and the results of your blood tests.
- If you have kidney problems your doctor may give you a lower dose or may prolong the interval between doses.

Use in children and adolescents
Children (aged 1 year and above)
- The usual daily dose is 3-6mg for each kg of body weight.
- This is given either as one single dose (preferred) or split into two separate doses.

Babies (aged 4 weeks to 1 year)
- The usual daily dose is 4.5-7.5mg for each kg of body weight.
- This is given either as one single dose (preferred) or split into two separate doses.

Premature babies or new born babies (up to 4 weeks)
- The usual daily dose is 4-7mg for each kg of body weight.
- This is given in one single dose.

If you have more Cidomycin than prescribed
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

Your doctor or nurse have instructions about when to give you your medicine. 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, this medicine can cause side effects, although not everybody gets them.

Tell your doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

Not known (frequency cannot be estimated from available data)
- Allergic reactions (including serious allergic reactions such as anaphylaxis), which may include:
  - An itchy, lumpy rash (hives) or nettle rash (urticaria)
  - Swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing
  - Fainting, dizziness, feeling lightheaded (low blood pressure)
- Severe allergic reaction of the skin and mucous membranes accompanied by blistering, peeling, bleeding and reddening of any part of the skin (including the lips, eyes, mouth, nose, genitals, hands or feet) with or without a rash. You may also have flu-like symptoms such as fever, chills or aching muscles. In very severe cases this might affect inner organs and might be life-threatening (Stevens-Johnson syndrome, toxic epidermal necrosis).

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

Very rare side effects (may affect less than 1 in 10,000 people)
- Acute kidney failure, which may cause you to pass less urine than is normal for you, fluid retention, breathlessness or fatigue/tiredness

Not known (frequency cannot be estimated from available data)
- Temporary or irreversible hearing loss or deafness
- Unusual difficulty in moving which has not happened before
- Numbness, weakness and pain in the arms and legs (peripheral neuropathy)
- Blood in the urine
- Diarrhoea, with or without blood and/or stomach cramps
- Infection with other gentamicin-resistant germs

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

Very common side effects (may affect more than 1 in 10 people)
- Feeling sick (vomiting)

Not known (frequency cannot be estimated from available data)
- Feeling sick (nausea)
- Mouth ulcers

- Rash, itching or a purplish or reddish-brown skin colouring
- Depression
- Seeing or hearing things that are not real (hallucinations)
- Feeling confused, tired or weak
- Fits

Other possible side effects:

Very rare side effects (may affect less than 1 in 10,000 people)
- High levels of phosphate and amino acids (so-called Fanconi-like syndrome, associated with high doses given over a long time)

Not known (frequency cannot be estimated from available data)
- Changes in the number of blood cells (including anaemia) – shown up in the results of blood tests
- Changes in the amount of liver enzymes – shown up in the results of blood tests
- A decrease in the level of magnesium in the blood, associated with prolonged therapy

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cidomycin

This medicine will be kept by your doctor or nurse in a safe place out of the sight and reach of children.
Do not have this medicine after the expiry date. This is stated in month and year on the carton and on the label after "EXP". The expiry date refers to the last day of that month. If you are not sure when this is, check with your doctor or nurse.
Do not store this medicine above 25°C. It should not be kept in a fridge or freezer. You will not be asked to store your medicine. It will be brought to you ready to be given straight away.
Do not throw away any medicines via wastewater. These measures will help protect the environment.

6. Contents of the pack and other information

What Cidomycin contains
- The active substance is gentamicin sulphate equivalent to 80mg of gentamicin.
- The other ingredients are sulphuric acid and sodium hydroxide (for pH adjustment), sodium chloride and water for injections.

What Cidomycin looks like and contents of the pack
The medicine is a clear, colourless solution for injection in 2ml ampoules or vials. Cidomycin is available in packs of 5 glass ampoules with an OPC (one point cut) break system and red and green rings or in packs of 5 glass vials closed with a chlorobutyl rubber stopper sealed with an aluminium capsule type flip-off.
Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:
Marketing Authorisation Holder
Mercury Pharmaceuticals Ltd,
Dashwood House,
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Manufacturer
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2 Rue Louis Pasteur,
Herouville St Clair,
14200, France

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or nurse.

This leaflet was last revised in **03/2024**

The following information is intended for healthcare professionals only: Practical information on preparation and administration of Cidomycin 80mg/2ml Solution for Injection (see also Section 3).

POSOLOGY AND METHOD OF ADMINISTRATION

Adults:

The recommended dose in adults with normal renal function is 3-5mg/kg/day, depending on the severity of infection, administered as one single dose (preferred) or in two divided doses. The dose should be adjusted according to clinical response and serum concentration levels. Dose calculations should be based on ideal body weight. A dosing frequency of more than twice daily may be adopted for some specific pathogens or some sites of infection as recommended in national and local guidance.

Once daily dosing is not recommended in cases of endocarditis, depending on the responsible pathogens. National and local guidance on treatment with gentamicin and serum level monitoring in endocarditis should be followed.

In patients with normal renal function, 160mg once daily may be used for the treatment of urinary tract infections.

Paediatric population:

The daily dose recommended in children (aged 1 year and above) and adolescents with normal renal function, is 3-6mg/kg/day as one single dose (preferred) or two divided doses.

The daily dose in infants after the first month of life is 4.5-7.5mg/kg/day as one single dose (preferred) or two divided doses.

The daily dose in neonates and pre-term infants (aged 0-4 weeks old) is 4-7mg/kg/day. Due to the longer half-life, newborns are given the required daily dose in one single dose.

Elderly:

There is some evidence that elderly patients may be more susceptible to aminoglycoside toxicity whether secondary to previous auditory/vestibular impairment or borderline renal dysfunction. Accordingly, therapy should be closely monitored by frequent determination of gentamicin serum levels, assessment of renal function and signs of ototoxicity.

Renal impairment:

In impaired renal function, the recommended daily dose has to be decreased and adjusted to the renal function. This can be achieved by reducing the dose and/or increasing the dose interval.

In all patients with renal impairment, serum gentamicin peak and trough concentration and renal function must be monitored frequently.

Nomograms are available for the calculation of dose, which depends on the patient's age, weight and renal function. Local guidance should be followed where available.
No clear recommendation can be made for once daily dosing; dosing should be guided by plasma concentration levels. In patients with moderate renal impairment, in whom once daily dosing would be considered appropriate if their renal function were normal, the dose interval should be at least 24 hours and extended according to the degree of renal impairment and the results of serum gentamicin monitoring. Limited data are available in patients with severe renal impairment (creatinine clearance <30ml/min) after once daily dose administration.

The following table may be useful when treating adults on multiple dose regimens:

Blood Urea		Creatinine clearance (GFR)	Dose & frequency of administration
(mg/100ml)	(mmol/L)		
<40	6-7	> 70	80mg* 8 hourly
40-100	6-17	30-70	80mg* 12 hourly
100-200	17-34	10-30	80mg* daily
>200	>34	5-10	80mg* every 48 hours
Twice weekly intermittent haemodialysis		<5	80mg* after dialysis

**60mg if body weight <60kg.*

Monitoring advice:
Regular serum concentration monitoring of gentamicin is recommended for all patients, and especially in the elderly, newborns, obesity and in patients with impaired renal function, as well as patients with cystic fibrosis. Gentamicin should not be prescribed if serum concentrations cannot be monitored.
There are no universally accepted guidelines for therapeutic drug monitoring of gentamicin. Local monitoring and dose adjustment guidelines should be followed where available.
Pre-dose ("trough level") monitoring is recommended to ensure that the interval between doses is correct. Trough levels are measured at the end of a dosing interval and should not exceed 1mg/L for once daily dosing or 2mg/L for multiple daily dosing. Levels in excess of these indicate the need to extend the interval between doses, not reduction of the dose.
Post-dose ("peak level") monitoring is recommended to check the adequacy of a dose or to ensure that it is not excessive and likely to cause toxicity. Peak levels should be measured one hour after an intravenous bolus or intramuscular bolus dose, or 30 minutes after the end of an infusion. A plasma concentration <4mg/L indicates that the dose is likely to be inadequate and a dose increase should be considered; plasma concentrations >10mg/L indicate an increased risk for toxicity, particularly ototoxicity, and a dose reduction should be considered.
Any change in dose should be re-assessed with pre- and post-dose levels to confirm the adequacy of the new dose and the appropriateness of the dose interval.

Method of administration:
The recommended dose and precautions for intramuscular and intravenous administration are identical. Gentamicin when given intravenously should be injected directly into a vein or into the drip set tubing over no less than three minutes. If administered by infusion, this should be over 20-30 minutes and in no greater volume of fluid than 100ml. Longer infusion times of up to 60 minutes may be used, in particular for a once daily dosing regimen. Once daily dosing should only be administered through the intravenous route.

OVERDOSE
Haemodialysis and peritoneal dialysis will aid the removal from blood, but the former is probably more efficient. Calcium salts given intravenously have been used to counter the neuromuscular blockade caused by gentamicin.

INCOMPATIBILITIES
In general, gentamicin injection should not be mixed.

In particular the following are incompatible in mixed solution with gentamicin injection: penicillins, cephalosporins, erythromycin, heparins, sodium bicarbonate.
*Dilution in the body will obviate the danger of physical and chemical incompatibility and enable gentamicin to be given concurrently with the drugs listed above either as a bolus injection into the drip tubing, with adequate flushing, or at separate sites. In the case of carbenicillin, administration should only be at a separate site.
*Carbon dioxide may be liberated on addition of the two solutions. Normally this will dissolve in the solution but under some circumstances small bubbles may form.

SHELF LIFE
3 years

SPECIAL PRECAUTIONS FOR STORAGE
Do not store above 25°C. Do not refrigerate or freeze.