

[GlaxoSmithKline Logo]

Package Leaflet: Information for the User

Ampiclox[®] Injection

250mg ampicillin & 250mg cloxacillin

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

What is in this leaflet

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1 What Ampiclox is and what it is used for

What Ampiclox is

Ampiclox Injection (called Ampiclox in this leaflet) is an antibiotic and works by killing bacteria that cause infections. It contains two different medicines called ampicillin and cloxacillin. They both belong to a group of antibiotics called 'penicillins'.

What Ampiclox is used for

Ampiclox is used in adults and children to treat the following infections:

- infected wounds or lung infections following surgery
- respiratory tract infections
- fever associated with childbirth
- bacteraemia

2 What you need to know before you have Ampiclox

Do not have Ampiclox if you:

- are allergic (hypersensitive) to amoxicillin, cloxacillin or penicillin

- have ever had an allergic (hypersensitive) reaction to any antibiotic. This can include a skin rash or swelling of the face or neck.

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

Look out for important symptoms

Ampiclox can make some existing conditions worse, or cause serious side effects such as allergic reactions, bleeding and severe diarrhoea (pseudomembranous colitis). You must look out for certain symptoms while you are taking Ampiclox, to help reduce the risk of any problems. See section 4.

Take special care with Ampiclox

Check with your doctor, pharmacist or nurse before having this medicine if you:

- have ever had any reactions to antibiotics, including a skin rash or swelling of the face or neck when taking any antibiotic
- are being treated for kidney or liver problems
- have glandular fever and/or leukaemia as you may develop a rash if you have these conditions and take ampicillin
- are on a diet that restricts the amount of sodium you can eat.

If this medicine is being given to your baby, tell your doctor:

- if you (mother) are allergic to penicillin
- if your baby has jaundice (yellowing of the skin and/or eyes).

If you are not sure if any of the above apply to you, talk to your doctor, pharmacist or nurse before you have Ampiclox.

Other medicines and Ampiclox

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

- If you are taking allopurinol (used for gout) with Ampiclox, it may be more likely that you'll have an allergic skin reaction.
- If you are taking probenecid (used for gout), your doctor may decide to adjust your dose of Ampiclox.
- If you are taking methotrexate for conditions such as rheumatoid arthritis, psoriasis or cancer, your doctor may decide to adjust your dose of Ampiclox

Ampiclox may stop the contraceptive pill working. You will need to use extra contraceptive precautions, such as using a condom. If you need any advice, talk to your doctor, pharmacist or nurse.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Important information about one of the ingredients of Ampiclox

Each vial of Ampiclox contains 30 mg of sodium.

To be taken into consideration by patients on a controlled sodium diet.

3 How Ampiclox is given

You will never give yourself this medicine. A qualified person, like a doctor or a nurse, will give you this medicine.

- Ampiclox will be given as an injection or an infusion into a vein (intravenously) or muscle (intramuscularly).
- Your doctor will decide how much you need each day and how often the injections should be given.
- Make sure you drink plenty of fluids while having Ampiclox.

The usual doses are as follows.

Adults, elderly patients and children over 10 years of age

One to two vials every four to six hours

Children 2 – 10 years

Half adult dose. Dosage may be further increased where necessary.

Children up to 2 years

Quarter adult dose.

Kidney and liver problems

If you have kidney or liver problems the dose might be lower than the usual dose.

If more Ampiclox is given to you than recommended

It is unlikely you will be given too much, but if you think you have been given too much Ampiclox, tell your doctor, pharmacist or nurse immediately. Signs might be an upset stomach (feeling sick, being sick or diarrhoea) or neurotoxic symptoms (limb weakness or numbness, loss of memory, loss of vision, headache) in very high doses. You may also experience these signs if you have kidney problems.

If you think you have missed an injection of Ampiclox

Speak to your doctor, pharmacist or nurse.

How long will you need to take Ampiclox for?

Your doctor will tell you how long you will need to be given your medication.

If you have any further questions on the use of this medication, ask your doctor, pharmacist or nurse.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

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

The following are very rare (affects less than 1 in 10,000 people)

- allergic reactions, the signs may include: skin itching or rash, swelling of the face, lips, tongue, body or breathing difficulties.
- rash or pinpoint flat red round spots under the skin surface or bruising of the skin. This is due to inflammation of blood vessel walls due to an allergic reaction. It can be associated with joint pain (arthritis) and kidney problems
- a delayed allergic reaction can occur usually 7 to 12 days after having Ampiclox, some signs include: rashes, fever, joint pains and enlargement of the lymph nodes especially under the arms
- a skin reaction known as 'erythema multiforme' where you may develop: itchy reddish purple patches on the skin especially on the palms of the hands or soles of the feet, 'hive-like' raised swollen areas on the skin, tender areas on the surfaces of the mouth, eyes and private parts. You may have a fever and be very tired
- other severe skin reactions can include: changes in skin colour, bumps under the skin, blistering, pustules, peeling, redness, pain, itching, scaling. These may be associated with fever, headaches and body aches
- high temperature (fever), chills, a sore throat or other signs of an infection, or if you bruise easily. These may be signs of a problem with your blood cells
- inflammation of the large bowel (colon) with diarrhoea sometimes containing blood, pain and fever
- serious liver side effects may occur which are often reversible. You must tell your doctor or nurse urgently if you get:
 - severe diarrhoea with bleeding
 - blisters, redness or bruising of the skin
 - darker urine or paler stools
 - yellowing of the skin or the whites of the eyes (jaundice). See also anaemia below which might result in jaundice.

These can happen when having the medicine or for up to several weeks after.

If any of the above happen to you talk to your doctor or nurse straight away as your medicine should be stopped.

Sometimes you may get less severe skin reactions such as:

- a mildly itchy rash (round, pink-red patches), 'hive-like' swollen areas on forearms, legs, palms, hands or feet. This is uncommon (affects less than 1 in 100 people).

If you have any of these talk to your doctor or nurse as Ampiclox will need to be stopped.

The other possible side effects are:

Common (may affect up to 1 in 10 people)

- skin rash
- feeling sick (nausea)
- diarrhoea.

Uncommon (may affect up to 1 in 100 people)

- being sick (vomiting).

Very rare (may affect up to 1 in 10,000 people)

- kidney problems
- fits (convulsions), seen in patients on high doses or with kidney problems
- sudden, involuntary jerking or a muscle or group of muscles
- hyperactivity
- an excessive breakdown of red blood cells causing a form of anaemia. Signs include: tiredness, headaches, shortness of breath, dizziness, looking pale and yellowing of the skin and the whites of the eyes

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

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

5 How to store Ampiclox

Ampiclox is for use in hospital only and the expiry date and storage instructions stated on the vial label and carton are for the doctor, nurse or pharmacist's information. The doctor, pharmacist or nurse will make up your medicine.

6 Contents of the pack and other information

What Ampiclox contains

- Each 500 mg vial of Ampiclox Injection contains ampicillin 250 mg and cloxacillin 250 mg.

There are no other ingredients. However, for information about sodium in Ampiclox, please see section 2 **Important information about one of the ingredients of Ampiclox.**

- The doctor, nurse or pharmacist will make up the injection before use using an appropriate fluid (such as Water for Injections or an injection/infusion fluid).

What Ampiclox looks like and contents of the pack

Ampiclox is supplied as a clear glass vial of sterile powder for making up as an injection. The vials are packed in cartons of 10.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Beecham Group plc, 980 Great West Road, Brentford, Middlesex TW8 9GS

Manufacturer: SmithKline Beecham, Worthing, West Sussex BN14 8QH

Other formats

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name	Ampiclox Injection
Reference number	00038/5003R

This is a service provided by the Royal National Institute of Blind People.

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