

Amoxiclav Juno

*Amoxicillin and clavulanic acid
Powder for injection*

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Amoxiclav Juno 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. In deciding to give you Amoxiclav Juno, your doctor has weighed the risks of you taking Amoxiclav Juno against the benefits it will have for you.

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

Keep this leaflet with this medicine.

You may need to read it again.

What Amoxiclav Juno is used for

This product contains two active ingredients. One of these is a penicillin called amoxicillin and the other is clavulanic acid.

Amoxiclav injection belongs to the penicillin group of antibiotics.

This product is used to treat a wide range of infections caused by bacteria. These infections may affect the respiratory tract (bronchitis, pneumonia, tonsillitis, sinusitis), genito-urinary tract (cystitis, urethritis, pyelonephritis, gonorrhoea), gastrointestinal tract (peritonitis, intra-abdominal sepsis) the ears (otitis media) and the skin. This product can also be used to

prevent infections in major surgical procedures.

Amoxicillin clavulanic acid injection works by killing the bacteria that cause these infections. This medicine will not work against infections caused by viruses such as colds or the flu.

Your doctor may have prescribed this medicine for another reason.

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

Before you take it

When you must not use Amoxiclav Juno

1. **Do not use Amoxiclav Juno if you are allergic to penicillins and cephalosporins or clavulanic acid.**
2. **Do not use Amoxiclav Juno if you have a previous history of amoxicillin / clavulanic acid associated jaundice / hepatic dysfunction.**
3. **You have had an allergic reaction to cephalosporin antibiotics. You may have an increased chance of being allergic to Amoxiclav Juno if you are allergic to cephalosporins.**
4. **The packaging is torn or shows signs of tampering.**
5. **The expiry date (EXP) printed on the pack has passed. If you use this medicine after the expiry date has passed, it may not work as well.**

Talk to your doctor if you are unsure whether you have any of the conditions listed above.

Do not use Amoxiclav Juno if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaint unless your doctor says it is safe. Do not give this medicine to anyone else.

Before you are given Amoxiclav Juno

You must tell your doctor if:

1. **You have any type of allergic reaction to penicillin, amoxicillin or cephalosporin antibiotics. You may have an increased chance of being allergic to Amoxiclav Juno if you are allergic to cephalosporins.**
2. **You have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**
3. **You have any other medical conditions, including:**
 - asthma, hayfever or hives
 - kidney problems
 - glandular fever (infectious mononucleosis)
4. **Tell your doctor if you are pregnant or intend to become pregnant. Your doctor will discuss the possible risks and benefits of using Amoxiclav Juno during pregnancy.**
5. **You are breast-feeding or plan to breast-feed. Your doctor will discuss the possible risks and benefits of taking / using Amoxiclav Juno while breast-feeding.**

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

- Reduced kidney function
- On controlled potassium intake

If you have not told your doctor about any of the above, tell them before you use this medicine.

Taking other medicines

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

Some medicines may interfere with Amoxiclav Juno. These include:

- allopurinol and probenecid, drugs used to treat high levels of uric acid in the blood such as gout and stone formations
- The contraceptive pill. As with other antibiotics, you may need to use extra birth control methods e.g. condoms.
- Other antibiotics such as tetracyclines, erythromycin, chloramphenicol and gentamicin.
- Anticoagulants (used to prevent blood clots) such as warfarin.
- Due to risk of disulfiram (Antabuse) like reaction in some patients treated with beta-lactam antibiotics, the ingestion of alcohol should be avoided during and for several days after treatment with AMOXYCLAV JUNO.

These medicines may be affected by Amoxiclav Juno, or they may affect how well it works. You may need different medicines. Your doctor will advise you.

Your doctor may have more information on medicines to be careful with or to avoid while taking Amoxiclav Juno.

You need to tell your doctor if you are using any other medicines.

If you are unsure whether you are taking one of the drugs that may

interact with Amoxiclav Juno, ask your doctor or pharmacist.

Your doctor or pharmacist can tell you what to do if you are taking any of such medicines.

If you have not told your doctor about any of these things, tell them before you take Amoxiclav Juno.

How Amoxiclav Juno is given

How Amoxiclav Juno is given

It must only be given by a doctor or nurse. Your doctor will decide what dose and how long you will receive it. This depends on your infection and other factors, such as your weight.

Amoxicillin / clavulanic acid may be administered either by slow intravenous injection over a period of 3 to 4 min directly into a vein or via a drip tube or by infusion over 30 to 40 min. This medicine is not suitable for intramuscular administration.

Children aged less than 3 months should be administered Amoxicillin / clavulanic acid by infusion only.

Amoxiclav Juno injection should be reconstituted with water for injection before use.

Treatment with amoxicillin / clavulanic acid may be initiated by the use of an intravenous preparation and completed with an appropriate oral presentation as will be considered appropriate for you.

While you are using Amoxiclav Juno

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.

If you develop itching with swelling or skin rash or difficulty breathing while you are receiving Amoxiclav Juno, do not have any more and tell your doctor immediately.

If you get severe diarrhoea, tell your doctor, pharmacist or nurse immediately. Do this even if it occurs several weeks after Amoxiclav Juno has been stopped.

If you become pregnant while you are receiving Amoxiclav Juno, tell your doctor.

If you are about to start taking any new medicine, tell your doctor and pharmacist that you are receiving Amoxiclav Juno.

If you have to have any blood or urine tests, tell your doctor you are being given Amoxiclav. It may affect the results of some blood and urine tests.

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

Avoid alcohol during and for several days after treatment.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while using Amoxiclav Juno.

All medicines can have side effects.

Check with your doctor as soon as possible if you have any problems while being treated with Amoxiclav Juno, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, Amoxiclav Juno can cause some side effects. If they occur, most are likely to be minor and temporary. However, some may be serious and need medical attention.

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

- Headache
- Nausea
- Vomiting
- Diarrhoea
- Indigestion
- Dizziness
- Soreness of the mouth or tongue
- Overgrowth of yeast infections (thrush).

Tell your doctor immediately if you notice any of the following:

- Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be symptoms of an allergic reaction.
- pain around the site of injection
- unusual bleeding or bruising
- yellowing of the skin or eyes
- dark urine or pale stools
- Difficulty or pain on passing urine.
- Severe diarrhoea.

Some people may get other side effects while being treated with Amoxiclav Juno.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

These are rare but serious side effects. You may have a rare but serious condition affecting your bowel which may need urgent medical attention.

Do not take any diarrhoea medicine without first checking with your doctor.

How is Amoxiclav Juno stored

Amoxiclav Juno should be stored below 25°C.

It should be used immediately after reconstitution.

If storage is required, it may be stored at 5°C.

- 3 hours at 20-25°C: Ringers Solution, Hartmann's Solution; Ringer-Lactate Solution, Potassium Chloride and Sodium Intravenous Infusion B.P
- 4 hours at 20-25°C: Sodium Lactate Intravenous Infusion, Sodium Chloride Intravenous Infusion B.P. 0.9% (w/v), Water sterile for injection
- 8 hours at 2-8°C: Water sterile for injection, Sodium Chloride Intravenous Infusion B.P. 0.9% (w/v)

Amoxiclav Juno 2000/200 Powder for Injection: sterile white to off-white powder providing amoxicillin sodium equivalent to 2 g amoxicillin and potassium clavulanate equivalent to 200 mg clavulanic acid.

Ingredients

Active Ingredient:

Amoxicillin sodium
Potassium clavulanate

Manufacturer

Amoxiclav Juno is supplied in Australia by:

Juno Pharmaceuticals Pty Ltd
42 Kelso Street,
Cremorne, VIC – 3121
Australia

This leaflet was prepared in September 2020.

AUST R 269158

AUST R 269159

AUST R 269162

Doc ID: 78.JU.M.1.2

Product description

What it looks like

Amoxiclav Juno 500/100 Powder for Injection: sterile white to off-white powder providing amoxicillin sodium equivalent to 500 mg amoxicillin and potassium clavulanate equivalent to 100 mg clavulanic acid.

Amoxiclav Juno 1000/200 Powder for Injection: sterile white to off-white powder providing amoxicillin sodium equivalent to 1 g amoxicillin and potassium clavulanate equivalent to 200 mg clavulanic acid.

After using Amoxiclav Juno

Tell your doctor immediately if you notice any of the following side effects, particularly if they occur several weeks after stopping treatment with Amoxiclav Juno:

- severe stomach cramps or abdominal cramps
- watery and severe diarrhoea, which may also be bloody
- fever, in combination with one or both of the above.