

Amoxyclav AN

[amoxicillin trihydrate and potassium clavulanate]

Consumer Medicine Information

Please read this leaflet carefully before you start Amoxyclav AN.

What is in this leaflet

This leaflet answers some common questions about this medicine.

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 you being given this medication against the benefits it is expected to have for you.

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

Keep this leaflet.

You may need to read it again.

What this medicine is used for

Amoxyclav AN tablets contain two active ingredients. One of these is from the penicillin group of antibiotics and is called amoxicillin (from amoxicillin trihydrate) and the other is clavulanic acid (from potassium clavulanate). Amoxyclav AN tablets are used to treat a wide range of infections caused by bacteria. These infections may affect the chest (bronchitis or pneumonia), bladder (cystitis), sinuses (sinusitis), the ears (otitis media) or the skin.

Amoxyclav AN tablets work by killing the bacteria that cause these infections. Amoxyclav AN tablets will not work against infections caused by viruses such as colds or the flu.

Your doctor may prescribe Amoxyclav AN tablets for another use. If you want more information ask your doctor.

There is no evidence that Amoxyclav AN tablets are addictive.

Before you take it

Do not take Amoxyclav AN tablets if:

- you have had an allergic reaction to penicillin or similar types of antibiotics (such as cephalosporins) or any of the ingredients contained in Amoxyclav AN tablets. The ingredients are listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include skin rash, itching, difficulty in breathing and swelling of the face or tongue.
- you have previously experienced liver problems after taking tablets containing amoxicillin and clavulanic acid or any other medicines.
- the expiry date printed on the pack has passed.
- the packaging is torn or shows signs of tampering.
- Do not give this medicine to anyone else; your doctor has prescribed it specifically for you and your condition.

Tell your doctor if:

- you have ever had an allergic reaction (such as a rash) to antibiotics or other substances in the past.
- you are allergic to foods, dyes, preservatives or any other medicines.
- you have experienced liver problems after taking tablets containing amoxicillin and clavulanic acid or any other medicines.
- you have glandular fever (mononucleosis) or leukaemia.

- you are pregnant or think you may be pregnant or are breast-feeding. Your doctor will discuss with you the possible risks and benefits of taking Amoxyclav AN tablets during pregnancy or while you are breast-feeding. The ingredients of Amoxyclav AN tablets can pass to your baby from breast milk.
- you have any kidney or liver problems. The dosage of Amoxyclav AN tablets may need to be changed or you may need to be given an alternative medicine.
- you have to test your urine for sugar. Amoxyclav AN tablets may affect the results of these tests.

Use in children

- Children weighing 40kg or more should be dosed in a manner similar to adults. Your doctor will advise you about suitable medicines for children under this weight.

Taking other medicines

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

In particular, tell your doctor and/or pharmacist if you are taking any of the following:

- medicines used to treat gout (eg probenecid or allopurinol).
- other antibiotics. These may interfere with the actions of Amoxyclav AN tablets.
- the contraceptive pill. As with other antibiotics, you may need to use extra birth control methods (eg condoms) while taking Amoxyclav AN tablets.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Amoxyclav AN.

How it should be used

Follow the directions given to you by your doctor and pharmacist. Their directions may differ from the information contained in this leaflet.

Please read the direction label carefully. If you have any concerns about how to take this medicine talk to your doctor or pharmacist.

How much to take

Take as directed by your doctor or pharmacist.

The usual dose of Amoxyclav AN is one tablet twice a day.

How to take it

Swallow the Amoxyclav AN tablet with a full glass of water or other liquid.

The tablet should be taken immediately before or may be taken with the first mouthful of food. Amoxyclav AN tablets work best when taken this way. It may also help to prevent stomach upsets. However, Amoxyclav AN tablets will still work if they are taken without food.

When to take it

Space the doses as evenly as possible throughout the day. If you are taking Amoxyclav AN tablets twice a day, take a dose about every twelve hours.

How long to take it

Keep taking Amoxyclav AN tablets until the course is finished or for as long as your doctor tells you.

Do not stop taking Amoxyclav AN tablets just because you feel better as the infection can return.

Do not stop taking, or change the dose without first checking with your doctor.

If you forget to take it

If your next dose is due within six hours, skip the dose you missed and take your next dose at the normal time. Otherwise, take the missed dose as soon as you remember and then go back to taking your tablets as directed by your doctor.

Do not take a double dose to make up for the dose that you have missed. Taking more than the prescribed dose can increase the chance of unwanted side effects.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much, even if there are no signs of discomfort or poisoning.

Symptoms of overdose include mild to severe nausea, vomiting, cramps and diarrhoea.

If you are not sure what to do, contact your doctor, pharmacist or nearest hospital. Be sure to show the doctor the Amoxyclav AN pack.

While you are taking it

Things you must do

Take Amoxyclav AN tablets exactly as your doctor has prescribed.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Tell your doctor, dentist or pharmacist you are taking Amoxyclav AN tablets before starting any other medicines. Some medicines may affect the way other medicines work.

Tell your doctor if the symptoms of your infection become worse, or do not improve within a few days of starting Amoxyclav AN tablets.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use to treat any other complaints unless your doctor says to.

Things to be careful of

Be careful drinking alcohol when you are taking Amoxyclav AN tablets. Drinking alcohol while taking these tablets does not usually cause any problems. However, some people who drink alcohol while taking antibiotics similar to Amoxyclav AN tablets have experienced adverse effects.

Be careful driving or operating machinery until you know how Amoxyclav AN tablets affect you. Generally, these tablets do not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Amoxyclav AN tablets may cause dizziness or tiredness in some people.

If you develop severe diarrhoea either when taking Amoxyclav AN tablets or within several weeks after treatment, tell your doctor as soon as possible. Do not take any medication to stop the diarrhoea (eg Lomotil or Imodium or other

medicines containing diphenoxylate of loperamide).

Side effects

All medicines can cause unwanted effects, and some side effects have been reported with medicines containing amoxicillin and clavulanic acid.

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Amoxyclav AN, even if the problem is not listed below.

Amoxyclav AN may cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

MILD EFFECTS

Tell your doctor if you notice any of the following that are troublesome or ongoing:

- diarrhoea (several loose bowel movements per day), indigestion, pain in the stomach, feeling sick or being sick
- white, furry, sore tongue and mouth (oral thrush), abnormal taste
- soreness or itching of the vagina or vaginal discharge (vaginal thrush)
- headache, dizziness, tiredness, hot flushes
- tooth discolouration

MORE SERIOUS EFFECTS

Tell your doctor immediately if you notice any of the following during or after taking Amoxiclav AN tablets:

- itching, rash
- dark urine or pale stools
- yellowing of the skin or eyes (jaundice)
- severe stomach cramps
- severe watery or bloody diarrhoea
- unusual bleeding or bruising

These may be symptoms of rare but serious side effects and require urgent medical attention.

Stop taking Amoxiclav AN tablets and immediately contact your doctor or go to the emergency department of your nearest hospital if any of the following happens:

- Wheezing, hives, severe skin reaction, fainting, swelling of limbs, face, lips, mouth or throat, difficulty swallowing or breathing. These are signs of a severe allergic reaction to Amoxyclav AN tablets. Allergy to these antibiotics is rare but serious.
- fitting

Rare events that have been reported with tablets containing amoxicillin and clavulanic acid include:

- inflammation of the bowel (colitis)
- inflammation of the liver (hepatitis)
- inflammation of the kidney (nephritis)
- blood disorders

Remember, you should tell your doctor or pharmacist as soon as possible if any of these, or any other unusual events or problems occur during or after treatment with Amoxiclav AN tablets.

This is not a complete listing. Occasionally, other side effects may be experienced.

If you experience any side-effects that have not been mentioned here, consult your doctor or pharmacist as soon as possible.

You should remember that all medicines carry some risks. It is possible that some risks might not yet have been detected despite many years of experience with the medicine.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

After taking it

Storage

- Keep Amoxyclav AN in a safe place, where children cannot reach them.
- Leave the tablets in the original pack until it is time to take them.
- Store in a cool, dry place, below 25°C. Do NOT store in the bathroom or near a sink.
- Keep away from direct sunlight.
- Do not use Amoxyclav AN after the use-by-date printed on the carton.

Disposal

If your doctor tells you to stop taking Amoxyclav AN, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets that are left over.

Product description

What it looks like

Amoxyclav AN 500/125 mg tablet – White, convex capsule shaped film coated tablet

Amoxiclav AN 875/125 mg tablet – White, convex capsule shaped film coated tablet

All tablets are contained in a blister pack with an extra layer of aluminium foil to help protect against moisture. The blister is contained within a carton.

Ingredients

Active ingredients:

- Amoxicillin trihydrate (which gives amoxicillin in the body)
- Potassium clavulanate (which gives clavulanic acid in the body)

Inactive ingredients:

- Microcrystalline cellulose
- Sodium starch glycollate
- Colloidal anhydrous silica
- Magnesium stearate
- Purified talc
- Titanium dioxide
- Methyl cellulose
- Diethyl phthalate
- Dimethicone 100
- Hypromellose
- Propylene glycol
- Macrogol 6000

Australian Registration Numbers

Amoxyclav AN 500/125:
AUST R 123968

Amoxiclav AN 875/125:
AUST R 123971

Sponsor

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