AMOXYCLAV GH 500/125 AMOXYCLAV GH 875/125

amoxycillin and potassium clavulanate tablets

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you take AmoxyClav GH tablets.

This leaflet answers some common questions about AmoxyClav GH tablets.

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. Sometimes new risks are found even when a medicine has been used for many years. Your doctor has weighed the expected benefits of you taking AmoxyClav GH tablets against the risks this medicine could have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What is AmoxyClav GH tablets used for?

AmoxyClav GH tablets contain two active ingredients. One of these ingredients is a type of penicillin called amoxycillin and the other is potassium clavulanate.

AmoxyClav GH tablets are used for the short term treatment of 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 GH tablets work by killing the bacteria that cause these infections. AmoxyClav GH tablets will not work against infections caused by viruses such as colds or the flu.

Your doctor may prescribe AmoxyClav GH tablets for another use. If you want more information, ask your doctor.

There is no evidence that AmoxyClav GH tablets are addictive.

Before you take AmoxyClav GH tablets

Do not take AmoxyClav GH 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 GH 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 breathing and swelling of the face or tongue.
- You have previously experienced liver problems after taking AmoxyClav GH tablets 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.

If you are not sure whether you should start to take this medicine, talk to your doctor.

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 AmoxyClav GH tablets or any other medicines.
- You have glandular fever (mononucleosis) or leukaemia.
- You are pregnant or think you may be pregnant or are breastfeeding.
 Your doctor will discuss with you the possible risks and benefits of taking AmoxyClav GH tablets during pregnancy or while you are breastfeeding AmoxyClav GH tablets can pass to your baby from breast milk.
- You have any kidney or liver problems. The dosage of AmoxyClav GH 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 GH tablets may affect the results of these tests.
- Tell your doctor 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 or pharmacist if you are taking any of the following:
 - Warfarin or other medicines used to prevent blood clot
 - Mycophenolate
 - Medicine used to treat gout (eg. probenecid or allopurinol).
 - Other antibiotics. *These may interfere with the actions of AmoxyClav GH tablets.*
 - The contraceptive pill. As with other antibiotics, you may need to use extra birth control methods (e.g. condoms) while taking AmoxyClav GH tablets.
- Some medicines may affect the way other medicines work. Your doctor or pharmacist will be able to tell you what to do when taking AmoxyClav GH tablets with other medicines.

How to take AmoxyClav GH tablets

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

Please read the directions 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 GH is one tablet twice a day.

How to take it:

Swallow the AmoxyClav GH tablets with a full glass of water or other liquid.

AmoxyClav GH tablets should be taken immediately before or with the first mouthful of food.

AmoxyClav GH tablets work best when taken this way. It may also help to prevent stomach upset.

However, Amoxyclav GH tablets still work if they are taken without foods.

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

How long to take it:

Keep taking AmoxyClav GH tablets until the course is finished or for as long as your doctor tells you to.

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

Do not stop taking AmoxyClav GH tablets or change the dose, without 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 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 you missed.

Taking more than the prescribed dose can increase the chance of unwanted side effects.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice if you think you or anyone else has 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 GH pack.

While you are taking AmoxyClav GH tablets

Things you must do:

Take AmoxyClav GH 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 GH 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 GH tablets.

Things you must not do:

Do not use this medicine to treat any other complaint unless your doctor says to.

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

Things to be careful of:

Alcohol should be avoided during and for several days after treatment with AmoxyClav GH tablets. Some people who drink alcohol while taking antibiotics similar to AmoxyClav GH tablets have experienced adverse effects.

Be careful driving or operating machinery until you know how this medicine affects you. AmoxyClav GH tablets generally do not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, it may cause dizziness or tiredness in some people.

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

What are the side effects?

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

Like other medicines, Amoxyckav GH tablets can 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.

Tell your doctor about any effect which is troublesome or ongoing.

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 (vaginal thrush)
- headache, dizziness, tiredness, hot flushes
- · tooth discolouration
- unusually active (hyperactive)

MORE SERIOUS EFFECTS

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

- dark urine or pale stools
- · rash, itching
- 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 this AmoxyClav GH 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, difficult breathing, joint discomfort or swelling, swollen lymph glands, nausea and vomiting or fever.

These may be signs of an allergic reaction or other reaction to AmoxyClav GH tablets. Allergy to these antibiotics is rare.

• Fits/seizures.

Rare events that have been reported with AmoxyClav GH tablets include:

- inflammation of the bowel (colitis)
- inflammation of the liver (hepatitis)
- inflammation of the kidney (nephritis)
- · blood disorders
- crystal in the urine (crystalluria)

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 AmoxyClav GH tablets.

This is not a complete list of all possible side effects. Other may occur in some people and there may be some side effects not yet known.

Tell your doctor or pharmacist if you notice any side effects from your medicine which are not mentioned here.

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

How do I store AmoxyClav GH tablets?

Keep your medicine in the original pack until it is time to take them.

If you take the tablets out of the pack, they may not keep well.

Keep the pack in a cool dry place. Do not leave it in the car on a hot day. Do not store medicine in the bathroom or near a sink. *Heat and dampness can destroy AmoxyClav GH tablets*.

Store all medicines out of the reach of children, such as in a locked cupboard.

If your doctor tells you to stop taking AmoxyClav GH tablets, or if the expiry date has passed, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

AmoxyClav GH comes in two strengths:

- AmoxyClav GH 500/125*
 off white, oval, biconvex,
 film coated tablets scored on
 both sides.
- AmoxyClav GH 875/125 white to pale yellow, oblong, biconvex, film-coated tablets scored on both sides.

Available in strip and blister packs of 10 tablets.

Ingredients

Active Ingredients:

- AmoxyClav GH 500 mg/125 mg

 500 mg amoxycillin (as trihydrate) and 125 mg
 clavulanic acid (as potassium clavulanate).
- AmoxyClav GH 875 mg/125 mg

 875 mg amoxycillin (as trihydrate) and 125 mg
 clavulanic acid (as potassium clavulanate).

Inactive Ingredients:

- · magnesium stearate
- purified talc
- · povidone
- · croscarmellose sodium
- · microcrystalline cellulose
- · triethyl citrate
- ethylcellulose
- sodium lauryl sulfate
- · cetyl alcohol
- hypromellose
- titanium dioxide.

AmoxyClav GH 875/125 also contains silicon dioxide.

This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes.

* AmoxyClav GH 500/125 tablets are not marketed.

Supplier

AmoxyClav GH is supplied in Australia by:

Generic Health Pty Ltd Level 1, 1102 Toorak Rd Camberwell, VIC 3124 Tel: (03) 9809 7900

This leaflet was revised in March 2016.

Australian Register Number(s)

AmoxyClav GH 500/125 strip pack: AUST R 82833

AmoxyClav GH 875/125 strip pack: AUST R 82832

AUST K 02032

AmoxyClav GH 500/125 blister

pack: AUST R 198110

AmoxyClav GH 875/125 blister

pack: AUST R 198111