

Amtrel 5mg/10mg Tablets

Amlodipine Besylate 5mg and Benazepril Hydrochloride 10mg

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What Amtrel is used for

Amtrel is used to treat high blood pressure. The combination medications should not be used as a first therapy. When using Amtrel, consideration should be given that Angiotensin-converting enzyme inhibitors (ACEI) have caused agranulocytosis, especially in patients with renal impairment or autoimmune disease.

How Amtrel works

Amtrel contains two prescription medicines that work together to lower blood pressure: amlodipine besylate, a calcium channel blocker, and benazepril hydrochloride, an Angiotensin-converting enzyme (ACE) inhibitor.

If you have any questions about how Amtrel works or why this medicine has been prescribed to you, ask your doctor.

Before you use Amtrel

- When you must not use it

Follow all instructions given to you by your doctor or pharmacist carefully, even if they differ from the general information contained in this leaflet.

Do not take Amtrel

- If you are allergic to any of the ingredients. There is a complete list at the end of this leaflet.

- If you are pregnant or plan to become pregnant.
- If you are breastfeeding.
- If you have a heart condition
- If you have liver problems
- If you have kidney problems
- If you are treated for hyperkalemia (too much potassium in the blood)
- If you are already taking a diuretic (a medicine to increase the amount of urine you produce)

If any of these apply to you, tell your doctor, and do not take Amtrel. If you are not sure, talk to your doctor or pharmacist before taking Amtrel.

- Pregnancy and breast-feeding

Do not take Amtrel if you are pregnant or think that you may be pregnant.

You should tell your doctor if you are breast-feeding. Amlodipine besylate and benazepril hydrochloride tablets may pass into your milk. Don't breastfeed while you are taking amlodipine besylate and benazepril hydrochloride tablets.

If the use of Amtrel is unavoidable, breast-feeding should be discontinued.

- Before you start to use it

Talk to your doctor or pharmacist before taking Amtrel if:

- If you have any allergies.
- If you have a heart condition
- If you have liver problems or a history of liver problems.
- If you have kidney problems.

You will need to look out for these while you are taking Amtrel. If you get a serious side effect, you need to stop taking Amtrel and talk to your doctor straight away.

- Taking other medicines

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

Also remember those not prescribed by a doctor.

It is particularly important to tell your doctor if you are taking any of the following medicines:

- Simvastatin (a medicine used to control elevated cholesterol)
- medicines for high blood pressure or heart failure
- water pills, extra potassium or a salt substitute
- Lithium (Eskalith®, Lithobid®)
- potassium-containing medicines, potassium supplements or salt substitutes containing potassium

How to use Amtrel

- How much to use

The recommended dose is amlodipine 5 mg/benazepril hydrochloride 10 mg orally once daily (1 tablet).

The initial recommended dose is amlodipine 2.5 mg/benazepril hydrochloride 5 mg (1/2 tablet), or amlodipine 5 mg/ benazepril hydrochloride 10 mg once daily.

If the initial recommended dose is amlodipine 2.5 mg/benazepril hydrochloride 5 mg, it could be increased to amlodipine 5 mg/ benazepril hydrochloride 10 mg once daily after 4 weeks treatment.

Amtrel tablets can be split into halves. Only split the tablet that you're about to take. Don't cut them all at once, as factors like heat, humidity, and moisture can affect split tablets that are stored.

Your doctor will tell you how many tablets of Amtrel you should take.

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Depending on how you respond to the treatment, your doctor may suggest a higher or lower dose.

Do not change the dose or stop treatment without talking to your doctor.

- When to use it

Use as directed by your doctor or pharmacist.

Take Amtrel tablets at the same time each day, with or without food.

- How long to use it

Continue taking Amtrel for as long as your doctor recommends.

- If you forget to use it

If you miss a dose, take it as soon as you remember. If it is more than 12 hours, just take your next dose at the regular time.

- If you use too much (overdose)

If you take too many Amtrel tablets, call your doctor, or go to the emergency room.

While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Amtrel.

Tell your doctor immediately if you become pregnant while taking Amtrel.

Stop taking Amtrel and see a doctor straight away if you get:

- swelling of your face, eyelids, lips, tongue, or throat
- have trouble swallowing
- asthma (wheezing) or other breathing problems

- Things you must not do

Do not stop taking Amtrel unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give Amtrel to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of driving and using machines

No studies on the effects of Amtrel on the ability to drive and use machines have been performed.

When driving vehicles or operating machines it should be taken into account that occasionally dizziness or weariness may occur.

Tell your doctor as soon as possible if you experience such effects.

Side effects

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

If you have any side effects, talk to your doctor or pharmacist.

Amlodipine besylate and benazepril hydrochloride tablets can cause serious side effects including:

- serious allergic reactions that can be life threatening.

These allergic reactions are rare but happen more times in people who are African American.

- Low blood pressure (hypotension). Low blood pressure is most likely to happen if you also take water pills, are on a low salt diet, get dialysis treatments, have heart problems or get sick with vomiting or diarrhea.

Lie down if you feel faint or dizzy.

- Liver problems. Call your doctor if:
 - you have nausea
 - you feel more tired or weaker than usual
 - you have itching
 - your skin or eyes look yellow
 - you have pain in your upper right stomach
 - you have flu-like symptoms
- Low white blood cells. Low white blood cells happen more in people who have kidney problems and collagen vascular diseases. Low white blood cells can give you a higher chance of getting infections. Call your doctor if you get a fever, sore throat, or other signs of infection that do not go away.
- Kidney problems. Kidney problems may get worse in people that already have kidney disease. Some people will have changes on blood tests for kidney function and need a lower dose of amlodipine besylate and benazepril hydrochloride tablets.

Call your doctor if you get swelling in your feet, ankles, or hands or unexplained weight gain.

More chest pain and heart attacks in people that already have severe heart problems. Get emergency help if you get worse chest pain or chest pain that does not go away.

The more common side effects of amlodipine besylate and benazepril hydrochloride tablets are:

- Cough
- Dizziness
- Headache
- Swelling of the feet, ankles, and hands

These are not all side effects of amlodipine besylate and benazepril hydrochloride tablets.

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For a complete list, ask your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my

[Consumers ➡ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Amtrel

- Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

- Disposal

Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use.

Product Description

- What it looks like

White round tablet with a cutting line through the middle. tsh and CVI are written on the surface.

- Ingredients

- Active ingredient:
Amlodipine Besylate and
Benazepril Hydrochloride

- Inactive ingredients:
Lactose Anhydrous, Croscarmellose
Sodium, Microcrystalline Cellulose,
Calcium Phosphate Dibasic
Dihydrate, Sodium Lauryl Sulfate,
Magnesium Stearate

- MAL number:

MAL24066004ARZ

Manufacturer and Product Registration Holder

- Manufactured for

TSH Biopharm Corporation Ltd
3F-1, No. 3-1, Yuanqu St.,
Nangang Dist., Taipei City 11503,
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- Manufactured by

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