

Angitil® SR 90 mg, 120 mg & 180 mg Capsules

Angitil® XL 240 mg & 300 mg Capsules

Diltiazem hydrochloride

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 or pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- 1. What Angitil Capsules are and what they are used for**
- 2. What you need to know before you take Angitil Capsules**
- 3. How to take Angitil Capsules**
- 4. Possible side effects**
- 5. How to store Angitil Capsules**
- 6. Contents of the pack and other information**

1. What Angitil Capsules are and what they are used for

Angitil SR and XL Capsules contain diltiazem hydrochloride which belongs to a group of medicines called calcium-channel blockers that act on the cardiovascular system (the heart and blood vessels). Angitil Capsules has been prescribed by your doctor to treat your high blood pressure or to reduce the frequency of your anginal attacks. They are called prolonged-release capsules because they are manufactured in a way that allows the diltiazem hydrochloride to be released and slowly absorbed by your body over a period of several hours.

In high blood pressure, diltiazem hydrochloride works by widening the blood vessels. This creates less resistance to the blood flow, and results in lower blood pressure, which in turn reduces the strain on your heart.

In angina, diltiazem hydrochloride works by opening up the arteries supplying the heart muscle and this allows more blood and oxygen to reach the muscle, decreasing the chances of angina (chest pains) occurring when extra strain is placed upon the heart.

2. What you need to know before you take Angitil Capsules

Do not take Angitil Capsules if:

- You are allergic (hypersensitive) to diltiazem hydrochloride or any of the other ingredients in Angitil Capsules (listed in Section 6).
- Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You are breast-feeding or planning to breast-feed (see Section below: 'Pregnancy and breastfeeding').
- You are having a medicine called dantrolene used for severe muscle spasms or severe fever (see below: 'Other medicines and Angitil Capsules').
- You have a very slow heartbeat - less than 50 beats per minute.
- You are already taking a medicine containing ivabradine for the treatment of certain heart diseases.
- You have heart failure and problems with blood flow to your lungs. With these illnesses, you may feel out of breath and have swollen ankles.
- You have any other serious problems with your heart. This includes having an uneven heartbeat (unless you have a pacemaker).
- You are already taking a medicine containing lomitapide used for the treatment of high cholesterol levels (see section: 'Other medicines and Angitil Capsules').
- You are already taking a medicine containing asunaprevir used for the treatment of hepatitis C virus infection (see section: 'Other medicines and Angitil Capsules').

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Angitil Capsules.

Warnings and precautions

- Talk to your doctor or pharmacist or nurse before taking Angitil Capsules if:
- You have a history of heart failure, new shortness of breath, slow heartbeat or low blood pressure. As cases of kidney injury in patients with such conditions have been reported, your doctor may need to monitor your kidney function.
 - You have any other problem with your heart, apart from angina or those described in the previous section.
 - You are going to have an operation and/or an anaesthetic.
 - You are at risk of mood changes, including depression.
 - You are at risk of gut problems.
 - You are taking blood thinners such as direct acting oral anti-coagulants (example: dabigatran, rivaroxaban, apixaban) along with Angitil Capsules.
 - You suffer from porphyria, an inherited blood disorder that can cause increased sensitivity to light.

Your doctor will check you more closely particularly when you first start taking the capsules if:

- You are over 65 years old.
- You have liver or kidney problems.
- You have diabetes.
- You have or ever had asthma.
- You take any beta blocker medicines.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Angitil Capsules.

You may notice remains of the medication in your stool. However, this has no clinical relevance.

Other medicines and Angitil Capsules

Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because Angitil Capsules can affect the way some other medicines work. Also, some medicines can affect the way Angitil Capsules works.

If you have to go to a doctor, dentist or hospital for any reason, tell them that you are taking Angitil Capsules. This is especially important if you are likely to have an anaesthetic or an operation.

Angitil Capsules may lead to increase in level of colchicine (drug used to treat gout) when administered concomitantly.

Angitil Capsules may lead to increased risk of bleeding if taken along with blood thinners such as direct acting oral anti-coagulants (example: dabigatran, rivaroxaban, apixaban).

Angitil Capsules may lead to QT prolongation (ECG changes such as changes in heart rate, rhythm along with symptoms of dizziness), when administered along with drugs with the potential/known for prolonging the QT interval.

In particular, do not take this medicine and tell your doctor if you are taking:

- Dantrolene (an infusion) used for severe muscle spasms or severe fever (called 'malignant hyperthermia').
- Medicines containing ivabradine used for the treatment of certain heart diseases.
- Medicines containing lomitapide used for the treatment of high cholesterol levels. Diltiazem may increase the concentration of the lomitapide that may lead to an increase in the likelihood and severity of liver related side effects.
- Medicines containing asunaprevir used for the treatment of hepatitis C virus infection. Diltiazem may increase the concentration of the asunaprevir that may lead to an increase in the likelihood and severity of liver related side effects.

Angitil Capsules may increase the effect of the following medicines:

- Medicines for high blood pressure such as doxazosin, tamsulosin, atenolol, propranolol or acebutolol.
- Medicines used for an uneven heartbeat such as amiodarone and digoxin.
- Medicines used for angina, such as glyceryl trinitrate or isosorbide trinitrate.
- Medicines used for high levels of cholesterol such as simvastatin, fluvastatin and atorvastatin.
- Ciclosporin used for psoriasis or used to stop the rejection of organs after a transplant.
- Phenytoin and carbamazepine used for epilepsy.
- Antiplatelet medicines used to reduce the chance of blood clots forming, such as aspirin or clopidogrel.
- Iodinated contrast media (used for tests involving X-rays).
- Theophylline used for breathing problems.
- Lithium used for some types of mental illness (depression or a manic-depressive disorder).
- Medicines used for sleeplessness and anxiety, such as triazolam or midazolam.
- Methylprednisolone used for inflammation.
- Cilostazol used for intermittent cramp-like pain in your legs when you walk caused by insufficient blood supply in your legs.

Angitil Capsules may make the following medicine work less well:

- Rifampicin used for tuberculosis.

The following medicines can increase the effect of Angitil Capsules:

Medicines for stomach ulcers such as cimetidine and ranitidine.

Angitil Capsules with food, drink and alcohol

It is advisable to limit the amount of grapefruit juice you drink while taking Angitil Capsules as it can increase the blood levels of the active ingredient diltiazem and may increase your chance of getting side effects. If you are concerned you should stop drinking grapefruit juice and consult your doctor.

Do not take Angitil Capsules at the same time as an alcoholic drink.

Pregnancy and breast-feeding

You should **not** take Angitil Capsules if you are pregnant, might become pregnant or think you may be pregnant. This is because Angitil Capsules can cause problems for your baby. Talk to your doctor if you might be pregnant.

Do not breast-feed if you are taking Angitil Capsules. This is because small amounts may pass into mothers' milk. If you are breast-feeding or planning to breast-feed, talk to your doctor or pharmacist before taking any medicine.

Driving and using machines

You may feel dizzy while taking this medicine.

If this happens, **do not drive** or use any **tools or machines**.

Angitil Capsules contain sucrose

Angitil Capsules contain sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take Angitil Capsules

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Taking this medicine

- Take this medicine by mouth.
- Swallow your capsule whole with a glass of water.
- Do not break, crush or chew your capsules.
- Take your capsules at the same time each day.
- Angitil Capsules is formulated so that you only have to take your capsule once or twice a day.This depends on which strength capsule you are taking.

- If you are taking your capsule twice a day, it is important that the second dose is taken 12 hours after the first dose and that no more than 2 capsules are taken in any 24 hour period.
- If you feel the effect of your medicine is too weak or too strong, do not change the dose yourself, but ask your doctor.

How much to take

Adults:

- The usual starting dose is 90 mg twice a day.

Your doctor may decide to increase your dose to:

- 120 mg or 180 mg twice a day or
- 240 mg or 300 mg once a day.

Over 65 years or adults with liver or kidney problems:

Your doctor will prescribe a lower dose for you to take. Your doctor will also want to check your condition regularly and may gradually increase your dose.

Children and adolescents:

Angitil Capsules should not be given to children.

If you take more Angitil Capsules than you should

If you take more capsules than you should, tell a doctor or go to a hospital casualty department straight away. Take the medicine pack and any remaining capsules with you. This is so the doctor knows what you have taken.

The following effects may happen: feeling dizzy or weak, blurred vision, chest pain, shortness of breath, fainting, an unusually fast or slow heartbeat, slurred speech, confusion, decrease of kidney function, coma and sudden death.

If you take more Angitil Capsules than you should contact your doctor or nearest hospital straight away:

- Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

If, in an emergency situation, the patient is not treated quickly sudden death is not the only potential outcome.

If you forget to take Angitil Capsules

Do not worry. Simply leave out that dose completely and then take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Angitil Capsules

Keep taking Angitil Capsules until your doctor tells you to stop. Do not stop taking them just because you feel better. If you stop, your illness may get worse.

Tests

Your doctor may do regular tests while you are taking this medicine. These might include a check on your heart and blood tests to check on your liver and kidneys.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking and see a doctor or go to a hospital straight away if:

Frequency unknown (cannot be estimated from the available data)

- You have an allergic reaction. The signs may include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- You have a red or lumpy skin rash, swollen eyelids, face, lips, throat, or tongue, difficulty in swallowing.
- Your asthma gets worse.
- You have difficulty breathing, wheezing, tightness in the chest (called 'bronchospasm').
- You get blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu-like symptoms and fever. This could be an illness called 'Stevens-Johnson syndrome'.
- You get a severe blistering rash in which layers of the skin may peel off to leave large areas of raw exposed skin over the body. You may feel generally unwell and have a fever, chills and aching muscles. This could be an illness called 'Toxic Epidermal Necrolysis'.
- You have a skin rash or skin lesions with a pink/red ring and a pale centre which may be itchy, scaly, or filled with fluid. The rash may appear especially on the palms or soles of your feet. These could be signs of a serious allergy to the medicine called 'erythema multiforme'.

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

Common (affects less than 1 in 10 people)

- Slow or uneven heartbeat
- Very fast, uneven or forceful heartbeat (palpitations)

Frequency unknown (cannot be estimated from the available data)

- Skin rash caused by narrow or blocked blood vessels (called 'vasculitis')
- Being short of breath, feeling tired along with swollen ankles and legs. This could be signs of heart failure.
- Unusual movements of the tongue, muscle spasms in your face, rolling eyes and trembling
- High temperature, feeling tired, loss of appetite, stomach pain, feeling sick, yellowing of skin or eyes. These can be signs of inflammation of the liver (called 'hepatitis').
- Passing large amounts of urine, excessive thirst and having a dry mouth or skin. These may be signs of high blood sugar (hyperglycaemia).
- Get sunburnt easier, and which may be more severe than in someone not taking Angitil Capsules. You should use sun protection whilst taking this medicine.
- Breast enlargement in men

Tell your doctor as soon as possible if you have any of the following side-effects:

Very common (affects more than 1 in 10 people)

- Swelling of the lower legs

Common (affects less than 1 in 10 people)

- Indigestion, stomach pain, constipation

Uncommon (affects less than 1 in 100 people)

- Feeling dizzy, light-headed or faint when you stand or sit up quickly (low blood pressure)

Rare (affects less than 1 in 1000 people)

- Dry mouth
- Itchy, lumpy rash (called 'urticaria')

Frequency unknown (cannot be estimated from the available data)

- Swollen gums

Tell your doctor or pharmacist if any of the following side effects get serious or lasts longer than a few days:

Common (affects less than 1 in 10 people)

- Headache
- Flushing (feeling of warmth)
- Feeling sick (nausea)
- General feeling of being unwell
- Weakness or tiredness
- Feeling dizzy
- Skin redness

Uncommon (affects less than 1 in 100 people)

- Nervousness
- Difficulty sleeping
- Being sick (vomiting), diarrhoea

Frequency unknown (cannot be estimated from the available data)

- Mood changes, including depression
- Reduction in blood platelets, which increases risk of bleeding or bruising under the skin
- A condition in which the body's defence system attacks normal tissue causing symptoms such as swollen joints, tiredness and rashes (called 'lupus-like syndrome')
- Rash that may occur on the skin or sores in the mouth (Lichenoid drug eruption).

Blood tests

Angitil Capsules can change the levels of liver enzymes shown up in blood tests. This can mean that your liver is not working properly.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Angitil Capsules

- Keep this medicine out of the sight and reach of children.
- Do not store above 30°C. Store in the original packaging.
- Do not use this medicine after the expiry date which is stated on the blister and carton. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Angitil Capsules contain:

- The active substance in your capsules is diltiazem hydrochloride. Each capsule contains 90 mg, 120 mg, 180 mg, 240 mg or 300 mg of diltiazem hydrochloride.
- The other ingredients are sucrose, maize starch, povidone, ethylcellulose, talc, sodium lauryl sulfate, cetyl alcohol, dibutyl sebacate, gelatine, titanium dioxide (E171), red iron oxide (E172) [120mg and 180mg capsules only], yellow iron oxide (E172) [120mg, 180mg and 300mg capsules only], black iron oxide (E172), indigotine (E132) [120mg capsules only], shellac, propylene glycol, ammonium hydroxide and potassium hydroxide.

What Angitil Capsules look like and the contents of the pack:

Each strength of Angitil SR and XL Capsules can be identified by its colour and marking. 90 mg capsules are transparent and white marked with "90 mg" 120 mg capsules are transparent and brown marked with "120 mg" 180 mg capsules are transparent and pale brown marked with "180 mg" 240 mg capsules are white marked with "240 mg" 300 mg capsules are transparent and yellow marked with "300 mg" Angitil SR 90 mg, 120 mg and 180 mg Capsules are available in blister packs of 56 capsules. Angitil XL 240 mg and 300 mg Capsules are available in blister packs of 28 capsules.

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This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder: **United Kingdom:** Ethypharm UK Ltd - email: medinfo@ethypharm.com

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