

Adefin 10

Adefin 20

nifedipine tablets

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Adefin 10 and Adefin 20 tablets (described below as Adefin tablets).

It does not take the place of talking to your doctor or pharmacist.

This leaflet is for Adefin tablets. It is different from the leaflet for another form of Adefin known as Adefin XL. It is not to be used in relation to any other product, which may also contain the same active ingredient.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Adefin against the benefits expected for you.

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

Keep this leaflet with your medicine.

You may need to read it again.

What Adefin is used for

Adefin tablets are used either to treat high blood pressure or to prevent chronic stable angina (chest pain).

Adefin tablets are not used for the relief of a sudden attack of angina or to manage unstable angina.

Adefin tablets contain the active substance nifedipine that belongs to a group of medicines called calcium channel blockers. They work by opening up blood vessels in the body

to lower blood pressure and improve the supply of blood and oxygen to the heart.

Ask your doctor if you have any questions about why Adefin have been prescribed for you.

Your doctor may have prescribed Adefin for another reason.

Adefin is available only with a doctor's prescription.

Before you take Adefin

When you must not take it

Do not take Adefin if you are allergic to:

- medicines containing nifedipine (eg. in Adalat, Adefin XL)
- medicines similar to nifedipine such as amlodipine (Norvasc), felodipine (eg. Plendil, Felodur), lercanidipine (Zanidip), nimodipine (Nimotop)
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- Skin rash, itching or hives
- Swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- Wheezing or shortness of breath.

Do not take Adefin if you are in cardiogenic shock (very low blood pressure due to a failing heart).

Tell your doctor if you have had a heart attack in the last week or so.

Do not take Adefin if you are taking another medicine containing rifampicin (Rifadin, Rimycin), an antibiotic used to treat tuberculosis and other serious infections.

Do not take Adefin if you are pregnant or plan to become pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not take Adefin if you are breastfeeding or plan to breastfeed.

Adefin passes into breast milk and may affect your baby.

Do not take Adefin within eight days after a heart attack.

Do not take Adefin after the expiry date (EXP) printed on the pack has passed.

If you take this medicine after the expiry date, it may not work as well.

Do not take Adefin if the packaging shows signs of tampering or if the tablets do not look quite right.

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

Before you start to take it

Tell your doctor if you are allergic to any other medicines, foods, dyes or preservatives.

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

- heart failure
- other heart or blood vessel disorders
- low blood pressure
- stroke
- narrowing of the aorta
- mini-stroke (also known as TIA or transient ischaemic attack)
- liver disease
- diabetes

Tell your doctor if you plan to have surgery.

If you have not told your doctor about any of the above, tell him/her before you start taking Adefin.

Adefin contains lactose.

If you have been told by your doctor that you have intolerance to some sugars, tell your doctor before taking it.

Tell your doctor if you eat grapefruit or drink grapefruit juice regularly, including in the last 3 days before starting Adefin.

You should not eat grapefruit or drink grapefruit juice while you are taking Adefin because this can cause unwanted changes in the blood pressure lowering effect of the tablets.

Taking other medicines

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

Some medicines may be affected by Adefin or may affect how well it works. These include:

- medicines used to treat heart failure, such as digoxin, beta-blockers
- Other medicines used to treat high blood pressure or angina (chest pain), such as diltiazem, nitrates
- medicines used to treat arrhythmia (fast or irregular heartbeats), such as quinidine

- Other medicines used to treat heart disease, eg. digoxin
- medicines used to treat stomach ulcers and heartburn, such as cimetidine cisapride
- medicines used to treat tuberculosis, such as rifampicin
- medicines used to treat bacterial infections, such as quinupristin and dalbapristin
- medicines used to treat fungal infections, e.g. ketoconazole
- medicines used to treat HIV, e.g. ritonavir
- medicines used to treat epilepsy, such as phenytoin, carbamazepine, valproic acid, phenobarbitone
- anti-depressants, e.g. fluoxetine, nefazodone
- tacrolimus, used to prevent rejection after organ transplant
- medicines used to treat asthma, such as theophylline

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Adefin.

How to take Adefin

Follow all directions given to you by your doctor and pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the pack, ask your doctor or pharmacist.

How much to take

The dose of Adefin may vary from person to person.

Your doctor will decide the right dose for you. This may depend on your condition, other medicines you

are taking and how you respond to Adefin.

The usual dosage is 10 mg to 20 mg twice daily.

If required, your doctor may increase the dose up to 40 mg twice daily. The maximum dose of Adefin is 80 mg (daily).

How to take it

The tablets are to be swallowed with some liquid, with or without food.

When to take it

The tablets are usually taken every 12 hours.

The tablets should generally be taken first thing in the morning, followed by the second dose before going to bed.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take it for

Keep taking Adefin for as long as your doctor recommends.

Your doctor will determine how long you should take Adefin tablets.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

If you forget to take Adefin

If you have missed a dose by more than 6 hours, skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you have missed several doses, consult your doctor.

If you are not sure what to do or have any questions, ask your doctor or pharmacist.

If you take too much Adefin (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think you or anyone else may have taken too much Adefin.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Signs of an overdose include feeling dizzy and fainting due to drop in blood pressure, irregular or rapid heartbeats, shortness of breath and even loss of consciousness.

While you are taking Adefin

Things you must do

Take Adefin tablets exactly as prescribed by your doctor.

If you do not follow your doctor's instructions, you may not get control of your blood pressure or relief from your angina.

Tell your doctor if you continue to have angina attacks or if they become more frequent while you are taking Adefin tablets.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Adefin.

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

The use of Adefin may affect the results of certain laboratory tests or x-rays. If you are about to have any tests or x-rays, tell your doctor that you are taking this medicine.

If you become pregnant while taking Adefin, tell your doctor immediately.

Things you must not do

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects.

Do not use Adefin to treat any other conditions unless your doctor tells you to.

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

Do not eat grapefruit or drink grapefruit juice while you are taking this medicine.

Grapefruit can cause unwanted changes in the blood pressure lowering effect of Adefin.

Things to be careful of

Make sure you know how Adefin affects you before you drive a car, operate machinery, or do anything else that could be dangerous.

Adefin tablets may cause dizziness or fainting in some people who have low blood pressure, especially when they first start taking the medicine, change dose or drink alcohol.

If you have angina, be careful not to overdo physical activities when you first start taking Adefin tablets.

You may feel better when you start taking it, but you will need time to improve your physical fitness.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while taking Adefin.

Adefin helps most people with high blood pressure or chronic stable angina. However, like other

medicines, they may have unwanted effects in some people.

All medicines have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of these side effects.

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

You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- headache
- feeling dizzy
- fast or irregular heartbeats
- feeling sick (nausea)
- flushing
- constipation
- generally feeling unwell
- unusual tiredness or weakness
- general swelling and/or swelling of the arm, ankles or legs.

The above list includes the more common and mild side effects.

Your doctor may need to monitor your liver function, as Adefin can increase your liver enzymes. You may not experience any specific symptoms.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- chest pain
- signs of an allergic reaction such as skin rash, itching or hives; swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing; wheezing or shortness of breath
- signs of liver problems such as yellowing of the skin and/or eyes (jaundice)

- signs of frequent infections such as fever, severe chills, sore throat or mouth ulcers.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Very rarely, some people experience a purple/brown discolouration of the skin or redness, flaking and itching of the skin. Also, it has been reported for some people to develop a rash or blistering of the skin when they are exposed to sunlight. Tell your doctor if you experience any of these symptoms.

In a small number of cases of in vitro fertilisation, medicines like nifedipine appeared to have interfered with the normal function of sperm. This effect went away after the medicine was stopped. In those men who are taking Adefin tablets and are repeatedly unsuccessful in fathering a child by in vitro fertilisation, the medicine should be considered as one of the possible causes if no other explanation can be found.

Tell your doctor if you notice anything that is making you feel unwell.

This is not a complete list of all possible side effects.

Other side effects not listed above may also occur in some people.

After taking Adefin

Storage

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

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

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Adefin or any other medicine in the bathroom or near a sink.

Do not leave Adefin in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Adefin where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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

Product description

What it looks like

Adefin tablets are available in two strengths:

- Adefin 10 - round, film-coated pink-grey tablets marked with "A 10" on one side.
- Adefin 20 - round, film-coated pink-grey tablets marked with "1 U" on one side and the Bayer cross on the other.

Each pack contains 60 tablets.

Ingredients

The active ingredient in Adefin is nifedipine.

Each Adefin 10 tablet contains 10 mg of nifedipine.

Each Adefin 20 tablet contains 20 mg of nifedipine.

Adefin 10 and Adefin 20 tablets also contain the following inactive ingredients:

- cellulose
- maize starch
- lactose monohydrate
- polysorbate 80
- hypromellose
- macrogol 4000
- magnesium stearate
- iron oxide red (CI77491)
- titanium dioxide.

Adefin tablets also contain sulfites.

Supplier

Adefin is supplied by:

Alphapharm Pty Limited

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

Adefin 10 - AUST R 92999

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