

# ADEFIN XL

## *Nifedipine 30mg and 60mg extended release tablets*

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### What is in this leaflet

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This leaflet answers some common questions about ADEFIN XL. 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 taking ADEFIN XL against the benefits they expect it will have for you.

As ADEFIN XL is a prescription medicine, it should only be used under medical supervision.

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

Keep this leaflet with your medicine. You may need to read it again.

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### What ADEFIN XL is used for

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ADEFIN XL is used either to treat high blood pressure or to prevent chronic stable angina, one of a number of types of angina.

**Please note ADEFIN XL is not used for the relief of a sudden attack of angina.**

ADEFIN XL contains the active substance nifedipine which 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.

Your doctor, however, may prescribe ADEFIN XL for another purpose. Ask your doctor if you have any questions about why ADEFIN XL has been prescribed for you.

ADEFIN XL is specially designed to allow the slow release of the active substance from the tablet after it is taken. It is composed of a strong outer shell which does not dissolve in the body and is excreted in the faeces. It is normal to find these "ghost-tablets" in the faeces. The active substance contained in them has been absorbed by the body before excretion.

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### Before you take ADEFIN XL

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#### ***When you must not take it***

**Do not take ADEFIN XL if you are allergic to medicines containing nifedipine, other calcium channel blockers (such as amlodipine, felodipine and isradipine) or any of the ingredients listed at the end of this leaflet.**

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

**Do not take ADEFIN XL if you are pregnant or breastfeeding. Tell your doctor if you become pregnant while you are taking ADEFIN XL.**

**Do not take ADEFIN XL if you have or have had:**

- a heart attack in the last 8 days

- cardiogenic shock (very low blood pressure due to a failing heart).
- Kock Pouch or ileostomy.

**Do not take ADEFIN XL if you are taking another medicine containing the active substance rifampicin.**

Do not take ADEFIN XL after the expiry date which appears after the words "EXP" or "EXPIRY" printed on the pack.

Do not start taking ADEFIN XL if, when you start a new pack, the packaging is torn or shows signs of tampering.

Do not take tablets that show visible signs of deterioration (e.g. are broken or discoloured).

Do not use ADEFIN XL to treat any other medical conditions unless your doctor says so.

### ***Before you start to take ADEFIN XL***

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

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

- heart failure
- other heart or blood vessel disorders
- low blood pressure
- liver disease
- diabetes
- blockage of your oesophagus or intestine
- prolonged diarrhoea
- surgical operations carried out on your bowel.

You should discuss these medical conditions with your doctor to check whether ADEFIN XL is suitable for you.

**Tell your doctor if you experience symptoms of bowel blockage.**

The undissolved shell of the ADEFIN XL tablet or "ghost-tablets" may not be excreted in your faeces and may collect in your stomach. Surgical intervention may be necessary to remove the shells.

### ***Taking other medicines***

**Tell your doctor or pharmacist 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 XL or may affect how well it works. These include:

- cimetidine and cisapride, medicines used to treat reflux and/or ulcers
- erythromycin, an antibiotic used to treat infections caused by bacteria
- warfarin, a medicine used to treat and prevent blood clots
- digoxin, a medicine for controlling the rate and rhythm of heartbeats in atrial fibrillation or heart failure
- medicines used to treat irregular heartbeats such as quinidine and some beta-blockers
- quinupristin and dalfopristin, antibiotics for specific infections
- rifampicin, a medicine used to treat tuberculosis and certain types of infection
- medicines used to treat epilepsy such as phenytoin, carbamazepine and phenobarbitone

- medicines used to treat HIV such as amprenavir, indinavir, nelfinavir, ritonavir or saquinavir
- oral medicines used to treat fungal infections such as ketoconazole, itraconazole, fluconazole
- other medicines used to treat high blood pressure, angina, or other heart conditions, such as diltiazem, betablockers and nitrates
- tacrolimus, an immunosuppressant

You may need to take different amounts of your medicine or you may need to take different medicines. Your doctor or pharmacist has a more complete list of medicines to avoid while taking ADEFIN XL.

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

**If you have not told your doctor or pharmacist about any of the above, tell them before you start taking ADEFIN XL.**

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## **How to take ADEFIN XL**

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### ***How much to take***

The correct dose to take of ADEFIN XL has been decided by your doctor. Make sure you follow the instructions given to you by your doctor. The usual starting dose of ADEFIN XL is 30 mg each day. Your doctor may increase the dose slowly over a period of time, depending on how you respond to this medicine.

### ***How to take it***

The tablets must not be chewed or broken up. They are to be swallowed whole with a glass of water. They can be taken either with or without a meal. Do not halve the tablets.

### ***When to take it***

Take the tablets at about the same time each day. This will help you to remember to take it.

### ***How long to take it***

Your doctor will determine how long you should take ADEFIN XL tablets. Do not stop taking the tablets unless you are told to do so by your doctor or you do not feel well while you are taking them (see SIDE EFFECTS at the end of this leaflet).

### ***If you forgot to take it***

If you forgot to take your daily dose of ADEFIN XL at the right time and remember in less than 12 hours, take it straight away, then continue as normal the next day. Otherwise, skip that day's dose but be sure to take the next day's dose when it is due.

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

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

### ***If you take too much (overdose)***

**Immediately telephone your doctor or Poisons Information Centre for advice (0800 POISON or 0800 764 766), or go to the Accident or Emergency department at your nearest hospital, if you think that you or anyone else may have taken too many ADEFIN**

**XL tablets. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

Keep the telephone number of these places handy.

Some of the symptoms of an overdose may include feeling dizzy and fainting due to drop in blood pressure, irregular or rapid heart beats, shortness of breath and even loss of consciousness.

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## **While you are taking ADEFIN XL**

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### ***Things you must do***

**Take ADEFIN XL exactly as told by your doctor.** If you do not follow your doctor's instruction, 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 XL.**

Tell all doctors, dentists and pharmacists who are treating you that you are taking ADEFIN XL.

Tell your doctor if you become pregnant while taking ADEFIN XL.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed. Otherwise your doctor may think that it is not working and change your treatment unnecessarily.

### ***Things you must not do***

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

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

### ***Things to be careful of***

**Be careful driving or operating machinery until you know how ADEFIN XL affects you.** ADEFIN XL may cause dizziness or fainting in some patients who have low blood pressure, especially when they first start taking the medicine, change dose, or drink alcohol.

**Make sure you know how you react to ADEFIN XL before driving a car, operating machinery, or do anything else that could be dangerous if this happens to you.**

If you have angina, be careful not to overdo physical activities when you first start taking ADEFIN XL. You may feel better when you start taking it, but you will need time to improve your physical fitness.

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## **Side effects**

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**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ADEFIN XL.** Like other medicines ADEFIN XL can cause some side effects. Sometimes they are serious, most of the time they are not. In serious cases, you may need medical attention.

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

- headache

- constipation
- feeling dizzy,
- feeling sick (nausea),
- flushing
- loss of energy, unusual tiredness or weakness
- numbness in the hands and feet
- swelling of the ankles or legs

These are the more common side effects of ADEFIN XL. They are usually mild and go away with time.

Bleeding, tender or swollen gums may occur some time after starting ADEFIN XL. Muscle pain, trembling, visual disturbances and an increase in the need to pass water may also occur.

Occasionally, the treatment of high blood pressure may lead to slight breast swelling in older men. This side effect goes away when treatment is stopped.

**Tell your doctor immediately if any of the following happen to you:**

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

These side effects are rare but can be serious. You may need medical attention.

**If any of the following happen after taking ADEFIN XL, stop taking it and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- chest pain
- signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue, or other parts of the body, shortness of breath, wheezing, or trouble breathing
- signs of liver problems such as yellowing of the skin and/or eyes (jaundice).

These side effects are rare but very serious. 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 that some people develop a rash or blistering of the skin when they are exposed to sunlight.

In very rare cases, the undissolved shell of the ADEFIN XL tablet or "ghost-tablets" may not be excreted in the faeces and may collect in the stomach. Tell your doctor if you experience symptoms of bowel blockage. Surgical intervention may be necessary to remove these shells.

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 XL 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.

This is not a complete list of all possible side effects. Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything else that is making you feel unwell.

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

Ask your doctor or pharmacist any questions you may have.

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## After taking ADEFIN XL

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### ***Storage***

Keep ADEFIN XL tablets where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Keep ADEFIN XL tablets in a cool, dry place away from sunlight where the temperature stays below 25°C.

Do not leave ADEFIN XL tablets in the car or on window sills.

Do not store ADEFIN XL tablets or other medicines in the bathroom or near a sink.

Keep ADEFIN XL tablets in their blister pack until it is time to take them. Contact with moisture can cause the release of the active ingredient from the tablet. To prevent this, the tablets must be kept in their original packaging until immediately before use. Do not take a tablet if the blister-foil seal has been broken.

### ***Disposal***

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

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## Product description

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### ***What it looks like***

ADEFIN XL 30 mg tablets are round, biconvex, pink, film-coated tablets marked with "30" on one side.

ADEFIN XL 60 mg tablets are round, biconvex, pink, film-coated tablets marked with "60" on one side.

### ***Ingredients***

The active ingredient in ADEFIN XL is nifedipine.

Each ADEFIN XL 30 tablet contains 30 mg of nifedipine.

Each ADEFIN XL 60 tablet contains 60 mg of nifedipine.

The tablets also contain:

- polyethylene oxide
- magnesium stearate
- sodium chloride
- hypromellose
- iron oxide red (E172 / CI 77491)
- hydroxypropylcellulose
- cellulose acetate
- macrogol 3350
- titanium dioxide (E171 / CI77891)
- propylene glycol.

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## If you want to know more

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Should you have any questions regarding this product, please contact your doctor or pharmacist.

***Who supplies this medicine***

Distributed in New Zealand by:

Mylan New Zealand Ltd  
P O Box 11183  
Ellerslie  
AUCKLAND

Telephone: (09) 579 2792

***Date of information***

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