

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking NORDIP?

NORDIP contains the active ingredient amlodipine besilate. NORDIP is used to lower high blood pressure and treat angina pectoris (chest pain due to the heart not getting enough oxygen).

For more information, see Section [1. Why am I taking NORDIP?](#) in the full CMI.

2. What should I know before I take NORDIP?

Do not take if you have ever had an allergic reaction to NORDIP or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I take NORDIP?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NORDIP and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I take NORDIP?

- The usual dose of NORDIP is 5 mg each day. Your doctor may increase this to 10 mg each day.
- You must take NORDIP every day. Continue taking it for as long as your doctor tells you.
- Swallow the tablet whole with a full glass of water.

More instructions can be found in Section [4. How do I take NORDIP?](#) in the full CMI.

5. What should I know while take NORDIP?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are taking NORDIP. • Keep all your doctor's appointments so that your progress can be checked. • Tell your doctor immediately if you become pregnant while taking NORDIP.
Things you should not do	• Do not take NORDIP to treat any other conditions unless your doctor tells you to. • Do not give this medicine to anyone else, even if they have the same condition as you.
Things to be careful of	• Avoid eating large quantities of grapefruit or drinking large quantities of grapefruit juice.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how NORDIP affects you. NORDIP may cause dizziness or drowsiness in some people.
Looking after your medicine	• Keep your tablets in the pack it is time to take them. • Keep NORDIP in a cool dry place, away from moisture, heat, or sunlight where the temperature stays below 25°C.

For more information, see Section [5. What should I know while taking NORDIP?](#) in the full CMI.

6. Are there any side effects?

Common side effects of NORDIP include headache, dizziness, flushing, tiredness, drowsiness or sleepiness, or stomach pain or nausea. Serious side effects may also occur while taking NORDIP. Serious side effects include fast or irregular heart beats; chest pain (which may or may not be associated with exertion (angina) that lasts longer, is more severe or occurs more often); shortness of breath; symptoms of allergy (such as skin rash and/or itching); and severe upper stomach pain, often with nausea and vomiting. This is not a complete list of all possible side effects. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Consumer Medicine Information (CMI)

This leaflet provides important information about taking NORDIP. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking NORDIP.**

Where to find information in this leaflet:

1. [Why am I taking NORDIP?](#)
2. [What should I know before I take NORDIP?](#)
3. [What if I am taking other medicines?](#)
4. [How do I take NORDIP?](#)
5. [What should I know while taking NORDIP?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I taking NORDIP?

NORDIP contains the active ingredient amlodipine besilate ingredient. NORDIP belongs to a group of medicines called calcium channel blockers or calcium ion antagonists. They work by widening your blood vessels, making it easier for your heart to pump blood around the body and help increase the supply of blood and oxygen to your heart. Calcium channel blockers do not change the amount of calcium in your blood or bones.

NORDIP is used to:

- **lower high blood pressure (hypertension).**

There are usually no symptoms of hypertension. The only way of knowing that you have hypertension is to have your blood pressure checked on a regular basis. If high blood pressure is not treated it can lead to serious health problems.

- **treat angina pectoris.**

Angina is a pain or uncomfortable feeling in the chest, often spreading to the arms or neck, and sometimes to the shoulders and back. The pain of angina is due to a shortage of oxygen to the heart.

NORDIP is NOT for the relief of a sudden attack of angina. Your doctor will give you other medication to treat this.

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

Your doctor may have prescribed it for another reason.

2. What should I know before I take NORDIP?

Warnings

Do not take NORDIP if:

- you are allergic to amlodipine, other calcium channel blockers (e.g. felodipine, nifedipine or lercanidipine),

or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- o shortness of breath
- o wheezing or difficulty breathing
- o swelling of the face, lips, tongue or other parts of the body
- o rash, itching or hives on the skin.

Always check the ingredients to make sure you can take this medicine. Check with your doctor or pharmacist if you are unsure.

- the expiry date on the pack has passed, or the package is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Check with your doctor if you:

- have or have had any of the following medical conditions:
 - o heart problems, including heart failure
 - o liver problems
- Take any medicines for any other condition.
- have allergies to any other medicines, or any other substances, such as foods, preservatives or dyes.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

This medicine may affect your developing baby if you take it during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Do not breast-feed if you are taking this medicine.

The active ingredient in NORDIP passes into breast milk. Your baby may be affected. Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

Use in children

There is not enough information to recommend the use of this medicine in children.

3. What if I am taking other medicines?

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

Some medicines may interfere with NORDIP and affect how it works. Tell your doctor or pharmacist if you are taking any of the following:

- other medicines used to treat angina, such as diltiazem
- some antibiotics, such as erythromycin, clarithromycin or rifampicin
- some antifungals such as ketoconazole or itraconazole
- anti-proteases, medicines used to treat HIV infection, such as ritonavir
- simvastatin, a medicine used to lower cholesterol
- ciclosporin, tacrolimus, sirolimus or everolimus, medicines used to suppress the immune system
- temsirolimus, a medicine used to treat kidney cancer
- St John's Wort

You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

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

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NORDIP.

4. How do I take NORDIP?

Take NORDIP exactly as your doctor has prescribed.

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

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box ask your doctor or pharmacist for help.

How much to take

- The usual dose of NORDIP is one 5 mg tablet each day. Your doctor may increase this to one 10 mg tablet each day.
- Your doctor may prescribe another dose of NORDIP depending on your condition and how you respond to this medicine.

When to take NORDIP

- Take your medicine at about the same time each day, either morning or evening.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.
- NORDIP can be taken with or without food.

How to take NORDIP

- Swallow the tablet whole with a full glass of water.

How long to take it

- You must take NORDIP every day. Continue taking your medicine for as long as your doctor tells you.
- 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 NORDIP

If you miss your dose at the usual time and it is less than 12 hours before your next dose, skip the dose you missed and take your 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 you missed.

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

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much NORDIP

If you think that you have taken too much NORDIP, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many tablets, you may feel dizzy, lightheaded or faint and have an irregular heartbeat.

5. What should I know while taking NORDIP?

Things you should do

- Tell any other doctors, dentists and pharmacists who are treating you that you are taking NORDIP.
- If you are about to start any new medicine, tell your doctor or pharmacist that you are taking NORDIP.
- Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Call your doctor straight away if you:

- become pregnant while taking NORDIP, tell your doctor immediately.

Remind any doctor, dentist or pharmacist you visit that you are taking NORDIP.

Things you should not do

- Do not take NORDIP to treat any other conditions unless your doctor tells you to.
- Do not give this medicine to anyone else, even if they have the same condition as you.

Things to be careful of

Avoid eating large quantities of grapefruit or drinking large quantities of grapefruit juice.

Grapefruit juice contains one or more components that alter the metabolism of some medicines, including NORDIP.

Drinking very large quantities (over 1.2 litres) of grapefruit juice each day while taking NORDIP may increase the effects of this medicine.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how NORDIP affects you.

NORDIP may cause dizziness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous if you are not alert.

Things that would be helpful for your high blood pressure or angina.

Some self-help measures suggested below may assist your condition.

Your doctor or pharmacist can give you more information about these measures.

- **Weight:** Your doctor may suggest losing some weight. Some people may need a dietician to plan a suitable diet to help with weight loss.
- **Exercise:** Regular exercise helps lower blood pressure and strengthen the heart. It is important not to overdo it. Before commencing regular exercise you should consult your doctor who will suggest the most suitable exercise for you. If you feel uncomfortable when exercising or experience symptoms such as unusual chest pain or breathlessness see your doctor.
- **Alcohol:** Your doctor may advise you to limit your alcohol intake.
- **Salt:** Your doctor may advise you to watch the amount of salt in your diet. To reduce your salt intake you should avoid using salt at the table or in cooking.
- **Smoking:** Your doctor may advise you to stop smoking or at least cut down.

Looking after your medicine

- Keep your tablets in the pack until it is time to take them. If you take your tablets out of the pack they may not keep as well.
- Keep your tablets in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
These are the more common side effects of NORDIP. • headache • dizziness • flushing • tiredness • drowsiness or sleepiness • stomach pain or nausea These may or may not be due to NORDIP, but you should tell your doctor. • indigestion • sexual problems	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
• changes in heart beat either fast or slow • swelling of the ankles, feet, face or hands • tingling or numbness of the hands or feet • dizziness or light-headedness on standing up from a sitting or lying position • unusual tiredness or weakness	Call your doctor straight away if you notice any of these serious side effects. These may be serious side effects that may need

Serious side effects	What to do
- muscle cramps or aches - joint pain - eye pain or change in vision - changes in mood, feeling anxious or nervous - symptoms of liver disease such as itching, yellowing of the skin and eyes, and dark coloured urine - unusual movements, including trembling and shaking of the hands and fingers, twisting movements of the body, shuffling walk and stiffness of the arms and legs	urgent medical attention.

Very Serious side effects

Very serious side effects	What to do
- fast or irregular heart beats - chest pain - chest pain associated with exertion (angina) that lasts longer, is more severe or occurs more often - shortness of breath - symptoms of allergy such as skin rash and/or itching - severe upper stomach pain, often with nausea and vomiting	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

If you are 65 years or older, you should be especially careful while taking NORDIP. Report any side effects promptly to your doctor.

Some people in this age group may be more likely to experience side effects such as swelling of the feet and ankles, muscle cramps and dizziness.

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What NORDIP contains

Active ingredient (main ingredient)	amlodipine besilate (equivalent to amlodipine) 5 mg or 10 mg per tablet
Other ingredients (inactive ingredients)	- microcrystalline cellulose - pregelatinised maize starch - sodium starch glycolate Type A - magnesium stearate
Potential allergens	sulfites

Do not take this medicine if you are allergic to any of these ingredients.

What NORDIP looks like

NORDIP 5 mg is a white to off-white, round tablet with "AB" over scoreline over "5" on one side and "G" on the other. (AUST R 133159).

NORDIP 10 mg is a white to off-white, round tablet with "AB" over scoreline over "10" on one side and "G" on the other (AUST R 133146).

Available in blister packs of 30 tablets.

Who distributes NORDIP

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com.au

Phone: 1800 274 276

This leaflet was prepared in October 2024.

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