

NORDIPINE TABLET 5MG & 10MG

Amlodipine Besylate 5mg & 10mg

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about NORDIPINE. 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 NORDIPINE against the benefits it is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What NORDIPINE is used for

NORDIPINE 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.

NORDIPINE is also used to 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.

NORDIPINE is not for the relief of a sudden attack of angina. Your

doctor will give you other medication to treat this.

How Nordipine Works

NORDIPINE 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.

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

Your doctor may have prescribed it for another reason.

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

Use in Children

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

Before you take NORDIPINE

When you must not take it

Do not take NORDIPINE if you have an allergy to:

- NORDIPINE, or any other medicine containing amlodipine
- other calcium channel blockers such as those listed below: felodipine, nifedipine, or lercanidipine. Check with your doctor or pharmacist if you are unsure.

• any of the ingredients listed at the end of this leaflet. Some of the 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 breast-feed if you are taking this medicine. It is not known if the active ingredient in NORDIPINE passes into breast milk or if your baby may be affected.

Do not take this medicine after the expiry date printed on the pack or if the packaging 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.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

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

- heart disease such as heart failure
- liver problems

Tell your doctor if you are pregnant or plan 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.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including:

- all prescription medicines
- all medicines, vitamins, herbal supplements or natural therapies you buy without a prescription from a pharmacy, supermarket, naturopath or health food shop.

Some medicines may be affected by NORDIPINE or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- Cimetidine
- grapefruit or grapefruit juice
- Aluminium/ Magnesium
- Sildenafil
- Atorvastatin
- Digoxin
- Ethanol (alcohol)
- Warfarin

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

How to take NORDIPINE

Take NORDIPINE 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 NORDIPINE is 5 mg each day. Your doctor may increase this to 10 mg each day.

Your doctor may prescribe another dose of NORDIPINE depending on your condition and how you respond to this medicine.

How to take it

Swallow the tablet whole with a full glass of water.

When to take it

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. NORDIPINE can be taken with or without food.

How long to take it

You must take NORDIPINE 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 it

If 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 that 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 (overdose)

Immediately telephone your doctor for advice or go to Accident and Emergency (Casualty) at your nearest hospital if you think that you or anyone else may have taken too much NORDIPINE.

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.

While you are taking NORDIPINE

Things you must do

Tell any other doctors, dentists and pharmacists who are treating you that you are taking NORDIPINE.

If you are about to start any new medicine, tell your doctor or pharmacist that you are taking NORDIPINE.

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

Things you must not do

Do not take NORDIPINE 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

Be careful driving or operating

machinery until you know how NORDIPINE affects you.

NORDIPINE 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.

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.

Side effects

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

NORDIPINE helps most people but it may have some unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

It can be difficult to tell whether side effects are the result of taking NORDIPINE, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

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

Tell your doctor or pharmacist if you experience any of the following and they worry you:

- swelling of the ankles, feet, face or hands
- headache
- dizziness
- flushing
- palpitations
- tiredness
- drowsiness or sleepiness
- stomach pain or nausea

These are the more common side effects of NORDIPINE.

Tell your doctor or pharmacist if you experience any of the following:

- indigestion
- unusual tiredness or weakness
- muscle cramps or aches
- sexual problems

These may or may not be due to NORDIPINE but you should tell your doctor if they worry you.

Tell your doctor immediately if you notice any of the following:

- changes in heart beat either fast or slow
- chest pain
- dizziness or lightheadedness on standing up from a sitting or lying position
- shortness of breath
- symptoms of allergy such as skin rash and/or itching
- symptoms of liver disease such as itching, yellowing of the skin and eyes, and dark colored urine

These may be serious side effects that may need urgent medical attention. Serious side effects are rare.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

If you notice any other symptoms that worry you, tell your doctor or pharmacist.

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

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)]

After taking NORDIPINE

Storage

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 30°

Do not store NORDIPINE or any other medicine in the bathroom or near a sink. Do not leave your medicines on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep NORDIPINE where children cannot reach it.

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

Disposal

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

Product description

What it looks like

NORDIPINE tablets are available in two strengths:

- NORDIPINE Tablet 5mg:
White to off white, shield shape, marked with 'COV' on one side and scored on the other
- NORDIPINE Tablet 10mg:
White to off white, shield shape, marked with 'COV' on one side and marked '10' with scoring on the other side

A trade pack of NORDIPINE contains 30 (3 x10's in blister) & 100 tablets (10 x10's in blister)

Ingredients

Active ingredients

- Each NORDIPINE 5mg tablet contain amlodipine besylate equivalent to amlodipine 5mg.

- Each NORDIPINE 10mg tablet contain amlodipine besylate equivalent to amlodipine 10mg.

Inactive ingredients

- Dibasic calcium Phosphate Anhydrous
- Microcrystalline Cellulose 112
- Sodium starch Glycolate
- Magensium Stearate

Manufacturer / Distributor

NORDIPINE is contract
Manufactured by:

Duopharma Manufacturing (Bangi) Sdn.Bhd.

Lot 2&4, Jalan P/7, Section 13,
Bangi Industrial Estate,
43650 Bandar Baru Bangi,
Selangor Darul Ehsan, Malaysia.

Marketing Authorization Holder

DUOPHARMA (M) SDN. BHD.

Lot. 2599, Jalan Seruling 59,
Kawasan 3, Taman Klang Jaya,
41200 Klang, Selangor Darul
Ehsan, Malaysia.

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