

PACKAGE LEAFLET: INFORMATION FOR THE USER
NIVADIL 8 mg / 16 mg
PROLONGED RELEASE CAPSULES
nilvadipine

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Nivadil is and what it is used for
2. Before you take Nivadil
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4. Possible side effects
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1. WHAT NIVADIL IS AND WHAT IT IS USED FOR

Nivadil contains nilvadipine as the active ingredient which is a calcium channel blocker and belongs to a group of medicines known as anti-hypertensives. Nilvadipine works by causing widening of the blood vessels (vasodilatation) which decreases the effort needed by your heart to push the blood around the body and in turn reduces your blood pressure.

Nivadil is indicated for the treatment of high blood pressure (essential hypertension).

2. BEFORE YOU TAKE NIVADIL

Do not take Nivadil if you:

- are allergic to nilvadipine or any other ingredient of this medicine please refer to section 6 of this leaflet
- are within 4 weeks of heart attack
- have unstable angina pectoris
- have kidney problems
- have a serious heart problem where your

- heart fails to pump effectively
(cardiovascular shock)
- have a restriction in your heart output (aortic stenosis)
 - are receiving a medicine known as dantrolene (medicine used to for malignant hyperthermia)
 - you are or might be pregnant or you are breast-feeding.

Nivadil is not recommended for use in children.

Take special care with Nivadil

Speak to your doctor before taking Nivadil if you have:

- liver problems
- heart problems
- first degree AV block
- mild bradycardia

Your doctor will monitor your blood pressure regularly during treatment with Nivadil.

Taking other medicines

If you are taking other medicines make sure your doctor is aware of them before you take Nivadil, particularly if they are any of the following:

- other anti-hypertensives such as beta blockers
- tricyclic antidepressants
- other medicines for the heart e.g. digoxin, amiodarone or quinidine
- medicine used to prevent organ rejection after a kidney, liver, or heart transplant e.g. cyclosporine
- medicine used to treat and prevent heartburn e.g. cimetidine, ranitidine, nizatidine or famotidine
- anticonvulsant medicines e.g. phenytoin, carbamazepine or phenobarbitone (phenobarbital)
- antiproteases
- ketoconazole
- itraconazole
- erythromycin
- clarithromycin
- verapamil

Please tell your doctor or pharmacist if you are

taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Nivadil with food and drink

Do not take Nivadil with grapefruit juice.

Pregnancy and breast-feeding

Do not take Nivadil if you are pregnant, may be pregnant or are breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

Nivadil may impair your ability to drive a vehicle or to operate machinery. This is particularly true at the start of treatment, or when the dosage is changed, or when alcohol is taken.

3. HOW TO TAKE NIVADIL

Always take Nivadil exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Nivadil should only be taken once a day, as the capsules release their contents gradually throughout the day.
- The dose should be taken each morning after breakfast as directed by your doctor.
- Nivadil capsules must be swallowed whole and not chewed, with a small amount of water.
- Do not take Nivadil on an empty stomach.
- Nivadil should not be taken with grapefruit juice.

Adults and the elderly:

Your doctor will normally start you on a dose of one 8 mg capsule a day, which may be increased after a few weeks to two 8 mg capsules or one 16 mg capsule each day.

Always take the dosage recommended by your doctor. Do not exceed the dose that is printed on the pharmacists label.

Kidney impairment: no dosage adjustment is required in mild to moderate kidney insufficiency, Nivadil should not however be used in patients with severe kidney insufficiency.

Liver impairment: In patients with cirrhosis of the liver a daily dose of 1 x 8 mg nilvadipine (equivalent to 1 Nivadil 8 mg prolonged release capsule).

Children:

Nivadil is not recommended for use in children.

If you take more Nivadil than you should

Contact a doctor immediately and take your medicine with you. If you take more than the recommended dose of Nivadil your blood pressure will become too low and the heart will beat irregularly. You may also notice flushing (redness) of the skin or have a headache, drowsiness, confusion and, rarely, convulsions, nausea and vomiting or high blood sugar levels.

If you forget to take Nivadil

Do not take a double dose to make up for a forgotten dose. If you forget to take your dose in the morning you should take it as soon as you remember that day. However, if you have missed a complete days dose, take only your normal daily dose the following morning.

If you stop taking Nivadil

You should not stop taking your medicine without talking to your doctor.

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

4. POSSIBLE SIDE EFFECTS

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

If you experience the following side effects, stop taking Nivadil and either tell your doctor immediately or go to your nearest hospital. You may be experiencing an allergic or other type of reaction to Nivadil:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing, skin rash or hives)

The frequency of the side effects listed below is defined using the following convention:

Very common ($\geq 1/10$);

Common ($\geq 1/100$ to $< 1/10$)

Uncommon ($\geq 1/1,000$ to $< 1/100$)

Rare ($\geq 1/10,000$ to $< 1/1,000$)

Very Rare ($< 1/10,000$)

Not Known (cannot be estimated from available data).

The following side effects have been reported:

Common: may affect up to 1 in 10 people

- headache
- dizziness
- flushing
- swelling of the hands, ankles or feet

Uncommon: may affect up to 1 in 100 people

- rapid heartbeat (tachycardia)
- slow or fast heart beats (palpitations)
- angina pectoris
- hypotension
- hypotensive crisis
- fatigue
- swelling of the lower legs, aches in the joints or muscles and heaviness of the arms and legs
- stomach upset
- feelings of fullness
- feeling sick (nausea) or stomach pressure
- constipation or diarrhoea
- transaminases increased (increase in certain liver enzymes), blood alkaline phosphatase increased
- hypersensitivity reactions, rash, pruritus (itching), erythema (redness of the skin)
- tremor, myalgia (muscle pain), arthralgia (joint pain)
- sensation of heaviness

Rare: may affect up to 1 in 1,000 people

- anaemia (reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- appetite disorder
- nervousness and lack of sleep
- allergic skin reactions
- being sick (vomiting)
- itchiness
- visual complaints
- increased weight
- decrease weight
- ringing in the ears or problems with breathing
- nose bleed
- dry mouth
- shortness of breath
- sensation of tingling, burning, pricking, or numbness of a person's skin
- neck pain, chest discomfort
- increase frequency of urine
- erectile dysfunction
- abnormally increased sweating

Very rare: may affect up to 1 in 10,000 people

- increased appetite
- weight gain
- sweating
- throat and nasal complaints
- hair loss
- leukopenia which is the decreased number of white blood cells in the blood, thrombocytopenia which is the decrease of platelets in the blood
- heart attack
- overgrowth of gums
- coldness of the extremities
- breast enlargement in men
- change in blood tests (reversible after discontinuation of Nivadil).

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NIVADIL**Keep out of the reach and sight of children.**

Nivadil does not require any special storage conditions.

Do not use Nivadil after the expiry date as stated on the label and carton. The expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION**What Nivadil contains**

The active substance is nilvadipine.

The other ingredients are maize starch, microcrystalline cellulose, povidone, croscarmellose sodium, gelatin, shellac, propylene glycol and the colours titanium dioxide (E171) and iron oxide (E172).

What Nivadil looks like and contents of the pack

Nivadil capsules are prolonged release hard gelatin capsules.

Nivadil Capsules 8 mg are brown and pink colour marked Nv8 in white, and each capsule contains 8 mg of nilvadipine.

Nivadil Capsules 16 mg are brown and brown/red colour marked Nv16 in white, and each capsule contains 16 mg of nilvadipine.

Nivadil 8 mg prolonged release capsules are available in packs of 14 and 28 capsules.

Nivadil 16mg prolonged release capsules are available in packs of 28 capsules.

Marketing Authorisation Holder and Manufacturer**M.A. Holder:**

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