

Package leaflet: Information for the patient

NIF-TEN® 50 mg / 20 mg Capsules

atenolol / nifedipine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What NIF-TEN is and what it is used for
2. What you need to know before you take NIF-TEN
3. How to take NIF-TEN
4. Possible side effects
5. How to store NIF-TEN
6. Contents of the pack and other information

1. What NIF-TEN is and what it is used for

NIF-TEN contains the active substances atenolol and nifedipine. Each of these works in a different way.

- Atenolol belongs to a group of medicines called beta-blockers. It works by making your heart beat more slowly and with less force. This helps to prevent chest pain.
- Nifedipine belongs to a group of medicines called dihydropyridines. Dihydropyridines are a type of calcium channel blocker. They work by making your blood vessels widen. This helps to prevent chest pain and lowers your blood pressure.

NIF-TEN is used to treat high blood pressure (hypertension) or to prevent chest pain (angina).

2. What you need to know before you take NIF-TEN

Do not take NIF-TEN:

- If you are allergic to atenolol or nifedipine, or any of the other ingredients of this medicine (listed in section 6).
- **If you are having an angina attack (sudden chest pain).** NIF-TEN cannot treat an angina attack, but it can help you get fewer attacks if you take it regularly.
- If you are allergic to other dihydropyridines such as amlodipine or felodipine.
- If you have any of the following heart problems:
 - heart failure which is not under control (this usually makes you breathless and causes your ankles or legs to swell)
 - second- or third-degree heart block (a condition which may be treated with a pacemaker)

- a very slow or very uneven heart beat, very low blood pressure or very poor circulation
- a heart attack within the last month
- a heart condition called sick sinus syndrome, or unstable angina, or aortic stenosis
- a condition where the heart is unable to supply enough blood to the body (cardiogenic shock)
- within one month of a heart condition (e.g. chest pain, angina, heart attack).
- If you have restricted blood flow caused by blockage of the arteries. This can cause leg pain or numbness or tingling in the legs (severe peripheral arterial disease).
- If you have problems with your kidneys.
- If you have a tumour called phaeochromocytoma that is not being treated. This is usually near your kidney and can cause high blood pressure.
- If your doctor has told you that you have higher than normal levels of acid in your blood (metabolic acidosis).
- If you are taking a medicine called rifampicin.
- If you are taking a medicine that is a certain type of calcium channel blocker such as verapamil or diltiazem.
- If you are pregnant, think you may be pregnant or are planning to have a baby (see “Pregnancy, breast-feeding and fertility” below).
- If you are breast-feeding (see “Pregnancy, breast-feeding and fertility” below).
- If you have severe liver failure.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking NIF-TEN.

Warnings and precautions

Talk to your doctor or pharmacist before taking NIF-TEN:

- **If you have asthma, wheezing or similar breathing problems, or you get allergic reactions, such as to insect stings. If you have ever had asthma or wheezing, do not take this medicine without first checking with your doctor.**
- If you have a type of chest pain (angina) called Prinzmetal’s angina.
- If you have poor blood circulation or controlled heart failure.
- If you have first-degree heart block (a condition which may be treated by a pacemaker).
- If you have liver problems. Your doctor may need to do tests during your treatment with NIF-TEN to check how well your liver is working.
- If you have diabetes. Your medicine may change how you respond to having low blood sugar. You may feel your heart beating faster. Your medicine may hide the symptoms of low blood sugar.
- If you suffer from treated phaeochromocytoma (high blood pressure due to a tumour near your kidney). Your blood pressure will be monitored closely by your doctor.
- If you have thyrotoxicosis (a condition caused by an overactive thyroid gland). Your medicine may hide the symptoms of thyrotoxicosis.
- If you have a history of serious allergic reactions which causes difficulty in breathing or dizziness, such as to bee stings. NIF-TEN may cause the serious allergic reaction to be more severe.
- If you are to be given an anaesthetic agent.
- If you are giving a urine sample for a doping test. NIF-TEN may cause a positive result.
- If you are a man whose female partner is having IVF (in-vitro fertilisation treatment). This is because NIF-TEN can affect your sperm.

If you give a urine sample, it is important to tell your doctor that you are taking NIF-TEN. This is because NIF-TEN may interfere with the urine test results.

Other medicines and NIF-TEN

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes herbal medicines and medicines that you buy without a prescription. NIF-TEN can affect the way that some other medicines work and some medicines can have an effect on NIF-TEN.

You must not take NIF-TEN if you are taking any of the following medicines:

- Rifampicin (for tuberculosis).
- Other dihydropyridines such as amlodipine or felodipine (for high blood pressure or heart problems).
- Certain calcium channel blockers such as verapamil or diltiazem (for high blood pressure or chest pain).

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

- Diuretics such as furosemide, beta-blockers such as atenolol, ACE-inhibitors such as enalapril, angiotensin 1 (AT1) receptor- antagonists such as candesartan, other calcium antagonists such as nifedipine, α -adrenergic blocking agents such as doxazosin, PDE5 inhibitors such as sildenafil, anti-sympathomimetics such as guanethidine (other medicines to treat high blood pressure).
- Baclofen (a medicine used for muscle relaxation).
- MAO Inhibitors e.g. moclobemide (medicines used for the treatment of depression).
- Macrolide antibiotics e.g. erythromycin (antibiotics used to treat bacterial infections).
- Anti-HIV protease inhibitors e.g. ritonavir (used to treat HIV).
- Ketoconazole, itraconazole or fluconazole (anti-fungal medicines).
- Fluoxetine or nefazodone (to treat depression).
- Quinupristin/dalfopristin (a combination antibiotic).
- Phenytoin, carbamazepine, phenobarbitone or valproic acid (to treat epilepsy).
- Cisapride (used to treat heart burn).
- Clonidine (for high blood pressure or migraine). If you are taking clonidine and NIF-TEN together, do not stop taking clonidine unless your doctor tells you to do so. If you have to stop taking clonidine, your doctor will tell you how to do it.
- Disopyramide, quinidine or amiodarone (for an uneven heart beat).
- Digoxin or digitoxin (for heart problems).
- Tacrolimus (to prevent the rejection of transplanted organs).
- Adrenaline, also known as epinephrine (a medicine that stimulates the heart).
- Ibuprofen or indometacin (for pain and inflammation).
- Insulin or medicines that you take by mouth for diabetes.
- Cimetidine (for stomach problems).

Operations

If you go into hospital to have an operation, tell the anaesthetist or doctor that you are taking NIF-TEN. This is because you can get low blood pressure (hypotension) if you are given certain anaesthetics while you are taking NIF-TEN.

NIF-TEN with food and drink

Do not drink grapefruit juice throughout the whole period of time you take NIF-TEN. This is because your blood pressure may be reduced too much, which may make you feel dizzy.

Pregnancy, breast-feeding and fertility

- Do not take NIF-TEN if you are pregnant think you may be pregnant or are planning to have a baby. This is because NIF-TEN can harm your unborn baby.
- Do not take NIF-TEN if you are breast-feeding.
- Take special care with NIF-TEN if you are a man whose female partner is having IVF (in-vitro fertilisation treatment). This is because NIF-TEN can affect your sperm.

Driving and using machines

- Your medicine is not likely to affect driving or using tools or machines. However, it is best to wait to see how this medicine affects you before trying these activities.
- If you feel dizzy or tired when taking this medicine, ask your doctor or pharmacist for advice.

NIF-TEN contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

NIF-TEN contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

3. How to take NIF-TEN

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- Swallow the capsules with a drink of water.
- Your doctor or pharmacist will tell you how many capsules to take each day and when to take them. Also read the label on the carton.

Adults with high blood pressure (hypertension)

The recommended dose is 1 capsule each day.

Adults with chest pain (angina)

The recommended dose is 1 capsule every 12 hours.

Elderly (aged over 65 years)

High blood pressure (hypertension): The dose should not be more than 1 capsule each day.

Chest pain (angina): The dose should not be more than 1 capsule every 12 hours.

People with liver problems

The dose should not be more than 1 capsule each day.

Use in children

This medicine must never be given to children.

If you take more NIF-TEN than you should

If you have taken more of your medicine than prescribed by your doctor, tell your doctor or go to the nearest hospital casualty department straight away. Take the medicine packaging with you.

If you forget to take NIF-TEN

If you forget to take a dose, take it as soon as you remember. If it is almost time to take the next dose, wait until then. Do not take a double dose to make up for the forgotten dose.

If you stop taking NIF-TEN

Do not stop taking this medicine without first talking to your doctor. In some cases, you may need to stop taking it gradually.

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

4. Possible side effects

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

Important side effects to look out for:

If you get any of the following, see a doctor straight away:

- **Raised lumps on your skin (weals) or swelling of your face, lips, mouth, tongue or throat. This means that you are having an allergic reaction.**
- **Pain in your chest when you start taking NIF-TEN.**

Other possible side effects:**Common (may affect up to 1 in 10 people)**

- Headache**
- Slow heart beat*
- Cold hands and feet*
- Relaxation of blood vessels, possibly leading to flushing**
- Upset stomach or gut such as stomach pains, diarrhoea, heartburn and feeling sick*
- Constipation**
- Feeling tired*
- Feeling unwell**
- Swelling, particularly of the ankles and legs.**

Uncommon (may affect up to 1 in 100 people)

- Allergic reactions (raised lumps on your skin (weals) or swelling of your face, lips, mouth, tongue or throat)**
- Swelling of eyes & lips resulting in painful responses with attempts to speak**
- Sleep disturbances such as difficulty sleeping*
- Anxiety or nervousness**
- Sleep disorders**
- Spinning feeling (vertigo)**
- Migraine**
- Dizziness**
- Shaking (tremor)**

- Fainting**
- Disturbances of vision**
- Fast heartbeat**
- Irregular heartbeats (palpitations)**
- Low blood pressure**
- Nose bleeds**
- Blocked nose**
- Stomach pain**
- Feeling sick (nausea)**
- Indigestion**
- Wind (flatulence)**
- Dry mouth**
- Increased levels of liver enzymes**
- Swelling of the face, lips, mouth, tongue and/or throat**
- Skin rash or redness of skin**
- Muscle cramps**
- Swelling of your joints**
- Increase in the need to pass water (urinate)**
- Difficulty in passing water**
- Inability to achieve or maintain an erection**
- Unspecific pains**
- Chills**
- Increased levels of liver transaminases (enzymes).*

Rare (may affect up to 1 in 1,000 people)

- Reduced number of platelets in your blood which may make you bleed more easily*
- Mood changes (including depression)*
- Nightmares*
- Confusion*
- Changes in personality (psychoses) or hallucinations*
- Dizziness*
- Headache*
- Tingling feeling such as ‘pins and needles’*
- Loss of sense of touch**
- Dry eyes*
- Disturbances of vision*
- Worsening of heart failure*
- Increased heart block (which can cause an abnormal heart beat, dizziness, tiredness or fainting)*
- Feeling faint (especially when standing up)*
- Numbness and spasm in your fingers which is followed by warmth and pain (Raynaud’s disease)*
- Suddenly feeling wheezy or short of breath (bronchospasm)*
- Enlarged gums**
- Dry mouth*
- Liver problems including inflammation of liver and jaundice (yellowing of the skin or the whites of your eyes)*
- Hair loss (alopecia)*

- Psoriasis-like rash (a skin condition)*
- Worsening of psoriasis (a skin condition)*
- Skin rash*
- Itching**
- Itchy rash**
- Rash**
- Being unable to get an erection.*

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

- Increase in Antinuclear Antibodies (ANA).*

Not known (frequency cannot be estimated from the available data)

- Severe decrease of the blood cells (agranulocytosis). You may notice tiredness, an infection or easy bruising**
- Decrease in the number of white blood cells (leucopenia), increasing the chances of an infection**
- Purplish marks on your skin
- Severe allergic reactions**
- Increase in the amount of sugar (glucose) in your blood**
- Reduced feeling in the skin**
- Feeling sleepy**
- Dizziness
- Headache
- Eye pain**
- Chest pain or tightness in the chest (angina pectoris)**
- Flushing of the skin
- Swelling caused by a build up of fluid. This is also known as 'oedema'
- Difficulty breathing**
- Being sick (vomiting)**
- Heartburn or indigestion (gastro-oesophageal sphincter insufficiency)**
- Constipation*
- Upset stomach or gut such as stomach pains, diarrhoea, heartburn and feeling sick
- Yellowing of your skin or whites of your eye (jaundice)**
- Severe rash, that develops quickly, with blistering or peeling of the skin and possibly blistering in the mouth**
- Sensitivity to light (photosensitivity allergic reaction)**
- Small, raised areas of bleeding in the skin (palpable purpura)**
- Scaling of the skin (exfoliative dermatitis)**
- Joint pains (arthralgia)**
- Muscle pain (myalgia)**
- Being unable to get an erection
- Lupus-like syndrome (a disease where the immune system produces antibodies that attacks mainly skin and joints).

** Frequency for side effect for atenolol*

*** Frequency for side effect for nifedipine*

Conditions that may get worse

If you have any of the following conditions, they may get worse when you start to take your medicine:

- Psoriasis (a skin condition), rarely (may affect up to 1 in 1,000 people).
- Being short of breath or having swollen ankles (if you have heart failure), rarely (may affect up to 1 in 1,000 people).
- Asthma or breathing problems, rarely (may affect up to 1 in 1,000 people).
- Poor blood circulation, rarely (may affect up to 1 in 1,000 people).

Do not be concerned by this list of possible side effects. You may not get any of them.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

HPRA Pharmacovigilance

Website: www.hpra.ie

5. How to store NIF-TEN

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Store in the original package. Keep the blister pack in the outer carton. This will protect your medicine from light and moisture.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What NIF-TEN contains

- The active substances are 50 mg atenolol and 20 mg nifedipine per capsule.
- The other ingredients are gelatin, red iron oxide (E172), lactose monohydrate, macrogol, heavy magnesium carbonate, magnesium stearate, maize starch, hypromellose, microcrystalline cellulose, polysorbate 80, sodium laurilsulfate and titanium dioxide (E171) and printing ink (ink 1 - titanium dioxide (E171), shellac or ink 2 – titanium dioxide (E171), shellac povidone). See section 2 ‘NIF-TEN contains lactose’ and ‘NIF-TEN contains sodium’ for more information.

What NIF-TEN looks like and contents of the pack

NIF-TEN Capsules are a reddish-brown colour. They come in a blister pack containing 28 capsules.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for NIF-TEN Capsules is held by AstraZeneca AB, SE-151 85 Södertälje, Sweden.

NIF-TEN Capsules are manufactured by AstraZeneca UK Ltd., Silk Road Business Park, Macclesfield, Cheshire, SK10 2NA, UK.

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