

Package leaflet: Information for the user
Nipatra™ 25 mg Chewable Tablets
Nipatra™ 50 mg Chewable Tablets
Nipatra™ 100 mg Chewable Tablets
Sildenafil

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 4.4.

What is in this leaflet

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

1. WHAT NIPATRA IS AND WHAT IT IS USED FOR

Sildenafil belongs to a group of medicines called phosphodiesterase type 5 (PDE5) inhibitors. It works by helping to relax the blood vessels in your penis, allowing blood to flow into your penis when you get sexually excited. Sildenafil will only help you to get an erection if you are sexually stimulated.

You should not take sildenafil if you do not have erectile dysfunction. You should not take sildenafil if you are a woman.

Nipatra is a treatment for men with erectile dysfunction, sometimes known as impotence. This is when a man cannot get, or keep a hard, erect penis suitable for sexual activity.

You must talk to a doctor if you do not feel better or if you feel worse.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE NIPATRA

Do not take Nipatra:

- If you are allergic to sildenafil or any of the other ingredients of this medicine (listed in section 6).
- If you are taking medicines called nitrates, as the combination may cause a potentially dangerous decrease in your blood pressure. Tell your doctor if you are taking any of these medicines which are often given for relief of angina pectoris (or “chest pain”). If you are not certain, ask your doctor or pharmacist.
- If you are using any of the drugs known as nitric oxide donors such as amyl nitrite (“poppers”), as the combination may also lead to a potentially dangerous decrease in your blood pressure.
- If you are taking riociguat. This drug is used to treat pulmonary arterial hypertension (i.e., high blood pressure in the lungs) and chronic thromboembolic pulmonary hypertension (i.e., high blood pressure in the lungs secondary to blood clots). PDE5 inhibitors, such as Nipatra have been shown to increase the hypotensive effects of this medicine. If you are taking riociguat or are unsure tell your doctor.
- If you have a severe heart or liver problem.
- If you have recently had a stroke or a heart attack, or if you have low blood pressure.
- If you have certain rare inherited eye diseases (such as retinitis pigmentosa).
- If you have ever had loss of vision due to non-arteritic anterior ischaemic optic neuropathy (NAION).

Warnings and precautions

Talk to your doctor or pharmacist before taking Nipatra

- If you have sickle cell anaemia (an abnormality of red blood cells), leukaemia (cancer of blood cells), multiple myeloma (cancer of bone marrow).
- If you have a deformity of your penis or Peyronie’s Disease.
- If you have problems with your heart. Your doctor should in that case carefully check whether your heart can take the additional strain of having sex.
- If you currently have a stomach ulcer, or a bleeding problems (such as haemophilia).
- If you experience sudden decrease or loss of vision, stop taking Nipatra and contact your doctor immediately.

You should not use Nipatra with any other oral or local treatments for erectile dysfunction.

You should not use Nipatra with treatments for pulmonary arterial hypertension (PAH) containing sildenafil or any other PDE5 inhibitors.

You should not take Nipatra if you do not have erectile dysfunction.

You should not take Nipatra if you are a woman.

Special considerations for patients with kidney or liver problems

You should tell your doctor if you have kidney or liver problems. Your doctor may decide on a lower dose for you.

Children and adolescents

Special considerations for children and adolescents.

Nipatra should not be given to individuals under the age of 18.

Special considerations for patients with kidney or liver problems.

You should tell your doctor if you have kidney or liver problems. Your doctor may decide on a lower dose for you.

Other medicines and Nipatra

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Nipatra chewable tablets may interfere with some medicines, especially those used to treat chest pain. In the event of a medical emergency, you should tell any health care professional treating your condition that you have taken Nipatra and when you did. Do not take Nipatra with other medicines unless your doctor tells you that you can.

You should not take Nipatra if you are taking medicines called nitrates, as the combination of these products may cause a potentially dangerous decrease in your blood pressure. Always tell your doctor or pharmacist if you are taking any of these medicines that are often used for the relief of angina pectoris (or “chest pain”).

You should not take Nipatra if you are using any of the drugs known as nitric oxide donors such as amyl nitrite (“poppers”) as the combination may also lead to a potentially dangerous decrease in your blood pressure.

Tell your doctor or pharmacist if you are already taking riociguat.

If you are taking medicines known as protease inhibitors, such as for the treatment of HIV, your doctor may start you on the lowest dose (25 mg) of Nipatra.

Some patients who take alpha-blocker therapy for the treatment of high blood pressure or prostate enlargement may experience dizziness or light-headedness, which may be caused by low blood pressure upon sitting or standing up quickly. Certain patients have experienced these symptoms when taking Nipatra with alpha-blockers. This is most likely to occur within 4 hours after taking Nipatra. In order to reduce the likelihood that these symptoms occur, you should be on a regular daily dose of your alpha-blocker before you start Nipatra. Your doctor may start you on a lower dose (25 mg) of Nipatra.

Nipatra with food, drink and alcohol

Nipatra can be taken with or without food. However, you may find that Nipatra takes longer to start working if you take it with a heavy meal.

Drinking alcohol can temporarily impair your ability to get an erection. To get the maximum benefit from your medicine, you are advised not to drink excessive amounts of alcohol before taking Nipatra.

Pregnancy, breast-feeding and fertility

Nipatra is not indicated for use by women.

Driving and using machines

Nipatra can cause dizziness and can affect vision. You should be aware of how you react to Nipatra before you drive or use machinery.

Nipatra chewable tablets contain aspartame, a source of phenylalanine. If you suffer from phenylketonuria (a rare, hereditary disorder of the metabolism) you should take this into account. Nipatra chewable tablets contain 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.

Nipatra contains Aspartame and lactose

For 25mg - contains 2.15 mg aspartame in each chewable tablet.

For 50mg - contains 4.3 mg aspartame in each chewable tablet.

For 100mg - contains 8.6 mg aspartame in each chewable tablet.

Aspartame is a source of phenylalanine. It may be harmful if you have phenylketonuria (PKU), a rare genetic disorder in which phenylalanine builds up because the body cannot remove it properly.

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

For 25mg - contains 70.4575 mg lactose (35.22875 mg of glucose + 35.22875 mg of galactose) per dose.

For 50mg - contains 140.915 mg lactose (70.4575 mg of glucose + 70.4575 mg of galactose) per dose.

For 100mg - contains 281.83 mg lactose (140.915 mg of glucose + 140.915 mg of galactose) per dose.

This should be taken into account in patients with diabetes mellitus.

3. HOW TO TAKE NIPATRA

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

The recommended starting dose is 50 mg.

You should not take Nipatra more than once a day.

You should take Nipatra about one hour before you plan to have sex. The tablet should be chewed whole.

If you have the impression that the effect of Nipatra is too strong or too weak, talk to your doctor or pharmacist.

Nipatra will only help you to get an erection if you are sexually stimulated. The amount of time Nipatra takes to work varies from person to person, but it normally takes between half an hour and one hour. You may find that Nipatra takes longer to work if you take it with a heavy meal.

If Nipatra does not help you to get an erection, or if your erection does not last long enough for you to complete sexual intercourse you should tell your doctor.

If you take more Nipatra than you should

You may experience an increase in side effects and their severity. Doses above 100 mg do not increase the efficacy.

You should not take more tablets than your doctor tells you to.

Contact your doctor if you take more tablets than you should.

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. The side effects reported in association with the use of Nipatra are usually mild to moderate and of a short duration.

If you have chest pains during or after intercourse:

- Get in a semi-sitting position and try to relax.

- Do not use nitrates to treat your chest pain.

- Contact your doctor immediately.

All medicines including Nipatra can cause allergic reactions.

You should contact your doctor immediately if you experience any of the following symptoms after taking Nipatra: sudden wheeziness, difficulty in breathing or dizziness, swelling of the eyelids, face, lips or throat.

Prolonged and sometimes painful erections have been reported after taking Nipatra. If you have an erection which lasts for more than 4 hours, you should contact a doctor immediately.

If you experience a sudden decrease or loss of vision, stop taking Nipatra and contact your doctor immediately.

Very common (may affect more than 1 in 10 people):

Headache.

Common (may affect up to 1 in 10 people) include:

Nausea, facial flushing, hot flush (symptoms include a sudden feeling of heat in your upper body), indigestion, colour tinge to vision, blurred vision, visual disturbance, stuffy nose and dizziness.

Uncommon (may affect up to 1 in 100 people) include:

Vomiting, skin rash, bleeding at the back of the eye, eye irritation, bloodshot eyes /red eyes, eye pain, seeing flashes of light, visual brightness, light sensitivity, watery eyes, double vision, abnormal sensation in the eye, pounding heartbeat, rapid heartbeat, high blood pressure, low blood pressure, muscle pain, feeling sleepy, reduced sense of touch, vertigo, ringing in the ears, dry mouth, blocked or stuffy sinuses, inflammation of the lining of the nose (symptoms include runny nose, sneezing and

stuffy nose), upper abdominal pain, gastro-oesophageal reflux disease (symptoms include heartburn), presence of blood in urine, pain in the arms or legs, nosebleed, feeling hot, and feeling tired.

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

Fainting, stroke, heart attack, irregular heartbeat, temporary decreased blood flow to parts of the brain, feeling of tightening of the throat, numb mouth, bleeding at the back of the eye, double vision, reduced sharpness of vision, abnormal sensation in the eye, swelling of the eye or eyelid, small particles or spots in your vision, seeing halos around lights, dilation of the pupil of the eye, discolouration of the white of the eye, penile bleeding, presence of blood in semen, dry nose, swelling of the inside of the nose, feeling irritable and sudden decrease or loss of hearing.

Additional side effects reported from post-marketing experience include: unstable angina (a heart condition), pounding heartbeat, chest pain, sudden death, heart attack or temporary decreased blood flow to parts of the brain. Most, but not all, of these men had heart problems before taking this medicine. It is not possible to determine whether these events were directly related to Nipatra. Cases of convulsions or seizures and serious skin reactions characterised by rash, blisters, peeling skin and pain which require immediate medical attention have also been reported.

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 www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NIPATRA

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 on the blister after EXP. The expiry date refers to the last day of that month.

Store in the original container in order to protect from light.

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 Nipatra contains

- The active substance is sildenafil. Each tablet contains 25 mg, 50 mg or 100 mg sildenafil.
- The other ingredients are: polacrillin potassium, silica colloidal anhydrous, lactose monohydrate, povidone K-30, aspartame (E951), croscarmellose sodium, peppermint flavour, magnesium stearate, potassium hydroxide (for pH adjustment) or hydrochloric acid (for pH adjustment).

What Nipatra looks like and contents of the pack

25 mg: White, triangular, biconvex, embossed with “25” on one side.

50 mg: White, triangular, biconvex, embossed with “50” on one side.

100 mg: White, triangular, biconvex, embossed with “100” on one side

Blisters in packages of: 2, 4, 8, 10, 12 chewable tablets. Not all pack sizes may be marketed

Marketing Authorisation Holder

Mercury Pharmaceuticals Ltd., Capital House, 85 King William Street, London EC4N 7BL, UK.

Manufacturer

Geneparm S.A.

18 km Marathon Avenue, 15351 Pallini Attikis. Greece.

This leaflet was last revised in March 2020

Nipatra is the trademark of Mercury Pharma Group Ltd.