

NOVTEL TABLETS

Telmisartan (40mg, 80mg)

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What NOVTEL is used for

NOVTEL belongs to a group of medicines used:

- To treat essential hypertension (high blood pressure). 'Essential' means that the high blood pressure is not caused by any other condition.
- To reduce cardiovascular events (i.e. heart attack or stroke) in patients who are at risk because they have a reduced or blocked blood supply to the heart or legs, or have a stroke or have high risk of diabetes.

How NOVTEL works

NOVTEL belongs to a class of medicines known as angiotensin II receptor antagonists. Angiotensin II is a substance produced in your body which causes your blood vessels to narrow, thus increasing your blood pressure. NOVTEL blocks the effect of angiotensin II so that the blood vessels relax, and your blood pressure is lowered.

Before you use NOVTEL

– When you must not use it

Do not take NOVTEL if:

- you are allergic (hypersensitive) to telmisartan or any other ingredients included in the tablets (see section Product description for a list of other ingredients)
- you are pregnant (when pregnancy is detected, NOVTEL should be discontinued as soon as possible)
- you are breastfeeding
- you have biliary obstructive disorders (problem with the damage of the bile from the liver

and gall bladder)

- you have severe liver problems

If any of the above applies to you, tell your doctor or pharmacist before taking NOVTEL.

– Before you start to use it

Please tell your doctor if you are suffering or have ever suffered from any of the following conditions or illnesses:

- Kidney disease or kidney transplant
- Renal artery stenosis (narrowing of the blood vessels to one or both kidneys)
- Liver disease
- Heart problems
- Raised aldosterone levels (water and salt retention in the body along with imbalance of various blood minerals)
- Low blood pressure (hypotension), likely to occur if you are dehydrated or have salt deficiency due to diuretic therapy, low-salt diet, diarrhoea, or vomiting
- Elevated potassium levels in your blood
- Diabetes

In case of surgery or anaesthesia, you should tell your doctor that you are taking NOVTEL.

Pregnancy

You must tell your doctor if you think you are or might become pregnant. Your doctor will normally advise you to stop taking NOVTEL before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine.

NOVTEL is not recommended in early pregnancy and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. NOVTEL is not recommended for mothers who are breast-feeding.

The use of NOVTEL in children and adolescents below 18 years is not recommended.

– Taking other medicines

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

Your doctor may need to change the dose of these other medicines or take other precautions. This applies especially to the medicines listed below taken at the same time with NOVTEL:

- Digoxin, used to treat various heart conditions.
- Potassium-sparing diuretics or potassium supplements, used for treatment of hypertension and congestive heart failure.
- Lithium containing medicines used to treat some types of depression.
- NSAIDs (non-steroidal anti-inflammatory medicines) used to treat inflammation.
- Diuretics (thiazide or loop diuretics) used to treat hypertension and congestive heart failure.
- Other anti-hypertensive agents

As with other blood pressure lowering medicines, the effect of Telmisartan may be reduced when you take NSAIDs (non-steroidal anti-inflammatory medicines, e.g. aspirin or ibuprofen) or corticosteroids.

Telmisartan may increase the blood pressure lowering effect of other medicines used to treat high blood pressure.

How to use NOVTEL

– How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

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Treatment of high blood pressure

The usual recommended dose of NOVTEL is one 40mg tablet once a day. However, sometimes your doctor may recommend a higher dose of 80mg. Alternatively, NOVTEL may be used in combination with diuretics such as hydrochlorothiazide which has been shown to have an additive blood pressure lowering effect with NOVTEL.

Reduction of cardiovascular events

The recommended dose of NOVTEL is one 80mg tablet once a day. At the beginning of therapy with NOVTEL 80mg, blood pressure should be frequently monitored.

If your liver is not working properly, the usual dose should not exceed 40mg once daily.

Telmisartan may be taken with or without food.

– When to use it

Use as directed by your doctor or pharmacist.

Try to take the tablet at the same time each day. You can take NOVTEL with or without food. The tablets should be swallowed with some water or other non-alcoholic drink. It is important that you take NOVTEL every day until your doctor tells you otherwise. If you have the impression that the effect of NOVTEL is too strong or too weak, talk to your doctor.

– How long to use it

Continue taking Telmisartan for as long as your doctor recommends.

– If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

– If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using NOVTEL

– Things you must do

Take your medicine exactly as your doctor has told you. Try to take the tablet at the same time each day.

Tell all the doctors, dentists and pharmacists treating you that you are taking NOVTEL.

Tell your doctor immediately if you become pregnant while taking this medication.

– Things you must not do

Do not stop taking NOVTEL unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

Do not give NOVTEL to anyone else, even if they have the same symptoms or condition as you.

– Things to be careful of

Driving and using machines

Some people feel dizzy or drowsy when they are treated for high blood pressure. If you feel dizzy or drowsy, do not drive or operate machinery.

Side Effects

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

Some side effects can be serious and need immediate medical attention.

You should see your doctor immediately if you experience any of the following symptoms:

Sepsis (often called “blood poisoning”, is a severe infection with whole-body inflammatory response), rapid swelling of the skin and mucosa (angioedema); these side

effects are rare but are extremely serious and patients should stop taking the medicine and see their doctor immediately. If these effects are not treated they could be fatal.

Possible side effects of NOVTEL

Common

Low blood pressure (hypotension) in users treated for reduction of cardiovascular events

Uncommon

Urinary tract infections, upper respiratory tract infections (e.g. sore throat, inflamed sinuses, common cold), deficiency in red blood cells (anaemia), high potassium levels, difficulty falling asleep, depression, fainting (syncope), feeling of spinning (vertigo), slow heart rate (bradycardia), low blood pressure (hypotension) in users treated for high blood pressure, dizziness on standing up (orthostatic hypotension), shortness of breath, cough, abdominal pain, diarrhoea, discomfort in the abdomen, bloating, vomiting, itching, increased sweating, rash, back pain, muscle cramps, muscle pain (myalgia), kidney impairment including acute kidney failure, pain in the chest, feeling of weakness, and increased level of creatinine in the blood.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website www.npra.gov.my (Consumers → Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI)).

Storage and Disposal of NOVTEL

– Storage

Keep out of the reach and sight of children.

Store below 30°C. Store in the original package. Protect from moisture.

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Do not use this medicine after the expiry date which is stated on the carton and the label after EXP. The expiry date refers to the last day of that month.

Serial Number

NPRA (R2) 23/086

– Disposal

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.

Product Description

– What it looks like

Novtel 40mg Tablets - White to off white, capsule shaped tablets, debossed with 'C11' on one side and plain on other side.

Novtel 80mg Tablets - White to off white, capsule shaped tablets, debossed with 'C12' on one side and plain on other side.

– Ingredients

– Active ingredient(s)

Telmisartan

– Inactive ingredient

- Mannitol
- Sodium Hydroxide
- Meglumine
- Povidone
- Sodium Stearyl Fumarate
- Magnesium Stearate

– MAL numbers

MALXXXXXXXXXX

Manufacturers

Novugen Pharma Sdn. Bhd.
No. 27, Jalan Lengkuk Teknologi 2,
Taman Teknologi Enstek Fasa 1,
71760 Bandar Baru Enstek,
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Product Registration Holder

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Date of revision

16/01/2024