

NOVAMTEL TABLETS

Amlodipine/Telmisartan (5mg/40mg, 10/40mg, 5mg/80mg, 10mg/80mg)

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What NOVAMTEL is used for

NOVAMTEL is a prescription medicine that contains amlodipine and telmisartan.

NOVAMTEL tablets may be used to treat high blood pressure (hypertension):

- in adult patients whose blood pressure is not controlled enough with amlodipine or telmisartan alone.
- in adult patients who already receive amlodipine and telmisartan from separate tablets and who wish to take instead the same doses in one tablet for convenience.
- as the first medicine to lower your high blood pressure if your doctor decides you are likely to need more than one medicine.

High blood pressure, if not treated, can damage blood vessels in several organs, which puts patients at risk of serious events such as heart attack, heart or kidney failure, stroke, or blindness. There are usually no symptoms of high blood pressure before damage occurs. Thus, it is important to regularly measure blood pressure to verify if it is within the normal range.

How NOVAMTEL works

NOVAMTEL tablets contain two active substances called amlodipine and telmisartan. Both of these substances help to control your high blood pressure:

- Telmisartan belongs to a group of substances called “angiotensin-II receptor antagonists”. Angiotensin II is a substance produced in the body which causes

blood vessels to narrow, thus increasing blood pressure. Telmisartan works by blocking the effect of angiotensin II.

- Amlodipine belongs to a group of substances called “calcium channel blockers”. Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening.

This means that both of these active substances work together to help stop your blood vessels tightening. As a result, the blood vessels relax and blood pressure is lowered.

Before you use NOVAMTEL

– When you must not use it

- if you are allergic to telmisartan or amlodipine or any of the other ingredients of this medicine (listed in section 8 Product Description – Ingredient).
- if you are allergic to other medicines of the dihydropyridine type (one type of calcium channel blocker).
- if you are more than 3 months pregnant. (It is also better to avoid NOVAMTEL in early pregnancy.)
- if you have severe liver problems or biliary obstruction (problems with drainage of the bile from the liver and gall bladder).
- if you have narrowing of the aortic heart valve (aortic stenosis) or cardiogenic shock (a condition where your heart is unable to supply enough blood to the body).
- if you suffer from heart failure after a heart attack.
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

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

Pregnancy and lactation

Pregnancy

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

NOVAMTEL 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

Amlodipine has been shown to pass into breast milk in small amounts. Tell your doctor if you are breast-feeding or about to start breast-feeding. NOVAMTEL is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is newborn, or was born prematurely. Ask your doctor or pharmacist for advice before taking any medicine.

Children and adolescents

NOVAMTEL is not recommended in children and adolescents up to the age of 18 years.

– Before you start to use it

Talk to your doctor before taking NOVAMTEL if you are suffering or have ever suffered from any of the following conditions or illness:

- Kidney disease or kidney transplant.
- Narrowing of the blood vessels to one or both kidneys (renal artery stenosis).
- Liver disease.
- Heart trouble.
- Raised aldosterone levels (which lead to 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 (excessive loss of body water) or have salt deficiency due to diuretic therapy (“water tablets”), low-salt diet, diarrhoea, or vomiting.
- Elevated potassium levels in your blood.
- Diabetes.
- Narrowing of the aorta (aortic stenosis).
- Heart-associated chest pain also at rest or with minimal effort (unstable angina pectoris).
- A heart attack within the last four weeks.

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Talk to your doctor before taking NOVAMTEL:

- if you are taking any of the following medicines used to treat high blood pressure:
 - an ACE-inhibitor (for example Enalapril, Lisinopril, Ramipril), in particular if you have diabetes-related kidney problems.
 - Aliskiren.
 Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals. See also section 3 “When you must not use it”.
- If you are elderly and your dose needs to be increased.

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

– Taking other medicines

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

Your doctor may need to change the dose of these other medicines or take other precautions. In some cases you may have to stop taking one of the medicines. This applies especially to the medicines listed below:

- Lithium-containing medicines to treat some types of depression.
- Medicines that may increase blood potassium levels such as salt substitutes containing potassium, potassium-sparing diuretics (certain ‘water tablets’).
- Angiotensin II receptor antagonists.
- ACE-inhibitors or aliskiren
- NSAIDs (non steroidal anti-inflammatory medicines, e.g. acetylsalicylic acid or ibuprofen), heparin, immunosuppressives (e.g. cyclosporin or tacrolimus), and the antibiotic trimethoprim.
- Rifampicin, erythromycin, clarithromycin (antibiotics).
- St. John’s wort.
- Dantrolene (infusion for severe body temperature abnormalities).
- Medicines used to alter the way your immune system works (e.g. sirolimus, temsirolimus and everolimus).
- Medicines used for HIV/AIDS (e.g. ritonavir) or for treatment of fungal

infections (e.g. ketoconazole).

- Diltiazem (cardiac medicine).
- Simvastatin to treat elevated levels of cholesterol.
- Digoxin.

As with other blood pressure lowering medicines, the effect of NOVAMTEL may be reduced when you take NSAIDs (e.g. acetylsalicylic acid or ibuprofen) or corticosteroids.

NOVAMTEL may increase the blood pressure lowering effect of other medicines used to treat high blood pressure or of medicines with blood pressure lowering potential (e.g. baclofen, amifostine, neuroleptics or antidepressants).

How to use NOVAMTEL

– How much to use

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

The recommended dose is one tablet a day. Try to take the tablet at the same time each day.

Remove your NOVAMTEL tablet from the blister only directly prior to intake.

If your liver is not working properly, the usual dose should not exceed one 5mg/40mg tablet or one 10mg/40mg tablet per day.

– When to use it

Use as directed by your doctor or pharmacist.

You can take NOVAMTEL with or without food. The tablets should be swallowed with some water or other non-alcoholic drink.

– How long to use it

It is important that you take NOVAMTEL every day until your doctor tells you otherwise. If you have the impression that the effect of NOVAMTEL is too strong or too weak, talk to your doctor or pharmacist.

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

– If you forget to use it

If you forget to take a dose, take it as soon as you remember and then carry on as before. If you do not take your tablet on one day, take your normal dose on the next day. **Do not** take a double dose to make up for forgotten individual doses.

– If you use too much (overdose)

If you accidentally take too many tablets, contact your doctor, pharmacist, or your nearest hospital emergency department immediately. You might experience low blood pressure and rapid heart beat.

Slow heart beat, dizziness, reduced kidney function including kidney failure, marked and prolonged low blood pressure including shock and death have also been reported. Excess fluid may accumulate in your lungs (pulmonary oedema) causing shortness of breath that may develop up to 24-48 hours after intake.

While you are using it

– Things you must do

Take your medicine exactly as your doctor has told you.

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

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

– Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

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

– Things to be careful of **Taken with food and drink**

Low blood pressure may be aggravated by alcohol. You may notice this as dizziness when standing up.

Grapefruit juice and grapefruit should not be consumed when you take NOVAMTEL. This is because grapefruit and grapefruit juice may lead to increased blood levels of the active ingredient amlodipine in some patients and may increase the blood pressure lowering effect of NOVAMTEL.

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Driving and using machines

Some people may experience side effects such as fainting, sleepiness, dizziness or a feeling of spinning (vertigo) when they are treated for high blood pressure. If you experience these side effects, do not drive or use machines.

Side Effects

Like all medicines, NOVAMTEL 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:

Common side effects:

Dizziness, ankle swelling (oedema).

Uncommon side effects:

Sleepiness, migraine, headache, tingling or numbness of the hands or feet, feeling of spinning (vertigo), slow heart rate, palpitations, low blood pressure (hypotension), dizziness on standing up (orthostatic hypotension), flushing, cough, stomach ache (abdominal pain), diarrhoea, feeling sick (nausea), itching, joint pain, back pain, muscle cramps, muscle pain, inability to obtain an erection, weakness, chest pain, tiredness, swelling, increased levels of hepatic enzymes.

These are not all the possible side effects of NOVAMTEL tablets. Tell your doctor if you have any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects.

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 NOVAMTEL

– Storage

Keep out of the reach and sight of children.

Store below 30°C. Store in the original

package. Protect from light and moisture.

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.

– 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

NOVAMTEL 5mg/40mg - White-blue, oval biconvex bilayer tablets, possibly with blue specks in the white layer. The blue layer is debossed with 'C 54' and white layer is plain.

NOVAMTEL 5mg/80mg - White-blue, oval biconvex bilayer tablets, possibly with blue specks in the white layer. The blue layer is debossed with 'C 52' and white layer is plain.

NOVAMTEL 10mg/40mg - White-blue, oval biconvex bilayer tablets, possibly with blue specks in the white layer. The blue layer is debossed with 'C 53' and white layer is plain.

NOVAMTEL 10mg/80mg - White-blue, oval biconvex bilayer tablets, possibly with blue specks in the white layer. The blue layer is debossed with 'C 51' and white layer is plain.

– Ingredients

– Active ingredient(s)

NOVAMTEL 5mg/40mg – Each tablet contains 6.93mg of Amlodipine Besylate equivalent to Amlodipine 5mg and Telmisartan 40mg.

NOVAMTEL 5mg/80mg – Each tablet contains 6.93mg of Amlodipine Besylate equivalent to Amlodipine 5mg and Telmisartan 80mg.

NOVAMTEL 10mg/40mg – Each tablet contains 13.87mg of Amlodipine Besylate equivalent to Amlodipine 10mg and Telmisartan 40mg.

NOVAMTEL 10mg/80mg – Each tablet contains 13.87mg of Amlodipine Besylate equivalent to Amlodipine 10mg and Telmisartan 80mg.

– Inactive ingredient

Mannitol

Sodium hydroxide

Meglumine

Povidone

Sodium Stearyl Fumarate

Magnesium Stearate

Microcrystalline Cellulose

Colloidal Silicon Dioxide

Pregelatinized starch

Crospovidone

Corn starch

Ferric oxide

FD&C Blue No 1 Alum Lake 11-13

– MAL numbers

MALXXXXXXXXXX

Manufacturers

Novugen Pharma Sdn. Bhd.

No. 27, Jalan Lengkok Teknologi 2, Taman Teknologi Enstek Fasa 1, 71760 Bandar Baru Enstek, Negeri Sembilan, Malaysia.

Product Registration Holder

Novugen Pharma Sdn. Bhd.

No. 3, Jalan Jururancang U1/21, Hicom Glenmarie Industrial Park, 40150, Shah Alam, Selangor, Malaysia.

Date of revision

11/09/2023

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