

TREDAPTIVE™

ER nicotinic acid/laropiprant

1 g/20 mg modified release tablet

What is in this leaflet

This leaflet answers some common questions about TREDAPTIVE. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking TREDAPTIVE against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What TREDAPTIVE is used for

TREDAPTIVE is a prescription medicine used to:

- Lower levels of LDL (bad) cholesterol and apo B (a part of LDL) in the blood.
- Raise levels of HDL (good) cholesterol and apo A-I (a part of HDL).
- Lower levels of triglycerides (fatty substances in the blood).

Laropiprant reduces symptoms of flushing, a common adverse effect of nicotinic acid. (See Adverse Effects.)

TREDAPTIVE is used for patients who cannot control their cholesterol levels by diet alone. It can be used either by itself or with other medicines to treat cholesterol problems. You should stay on a diet designed to lower cholesterol while you take this medicine.

Your doctor has prescribed TREDAPTIVE to help lower LDL (bad) cholesterol, triglycerides, and apo B and raise HDL (good) cholesterol and apo A-I in your blood. TREDAPTIVE can be used alone or in combination with certain other medicines that lower cholesterol, along with a recommended diet and exercise program.

Cholesterol

Cholesterol is one of several fatty substances found in the bloodstream. Your total cholesterol is made up mainly of LDL (bad) and HDL (good) cholesterol.

LDL cholesterol is often called "bad" cholesterol because it can build up in the walls of your arteries and form plaque. Over time, this plaque build-up can lead to a clogging of the arteries. This clogging can slow or block blood flow to vital organs such as the heart and brain. When blood flow is blocked, the result can be a heart attack or stroke.

HDL cholesterol is often called "good" cholesterol because it helps keep the bad cholesterol from building up in the arteries and because it protects against heart disease.

Triglycerides are another form of fat in your blood. They may raise your risk for heart disease.

In most people, there are no immediate symptoms of cholesterol problems. Your doctor can measure your cholesterol with a simple blood test. Visit your doctor regularly, keep track of your cholesterol, and discuss your goals with your doctor.

High Cholesterol

High cholesterol results from many factors, including eating foods high in saturated fats, certain diseases or genetic conditions, and lack of exercise. Lowering high levels of bad cholesterol can help reduce your chances of having coronary heart disease (CHD). Having higher levels of good cholesterol is related to a lower risk of CHD.

CHD can have many causes. Your chances of having CHD may also be increased by several factors, which include:

- high blood pressure
- cigarette smoking
- diabetes
- excess weight
- family history of CHD
- male gender
- post-menopause

You can help control the first four of these causes of CHD.

Before you take TREDAPTIVE

When you must not take it

Do not take TREDAPTIVE if you:

- are allergic to nicotinic acid, laropiprant, or any of the other ingredients of TREDAPTIVE
- have liver problems
- have an ulcer in your stomach
- have arterial bleeding
- the expiry date on the pack has passed.

If you take this medicine after the expiry date has passed, it may not work.

Before and while you take it

Tell your doctor if you:

- have any allergies
- have problems with your liver or kidneys
- drink large amounts of alcohol
- have unexplained muscle pain, tenderness, or weakness.

If you have these symptoms tell your doctor right away.

- have high blood sugar or diabetes
- have heart problems
- plan to have surgery
- have gout.

Taking other medicines

Tell your doctor if you are taking any other medicines, including prescription medicines or medicines that you buy without a prescription from your pharmacy, supermarket or health food shop, including vitamins and herbal supplements.

Know the medicines you take. Keep a list of them and show the list to your doctor and pharmacist when you get a new medicine.

Some medicines and TREDAPTIVE may interfere with each other. It is especially important to tell your doctor if you are taking:

- Medicines used to lower blood pressure.
- Bile acid sequestrants (such as cholestyramine, medicine used to lower cholesterol).
- AZT (azidothymidine, a medicine for HIV).
- Midazolam (a medicine to make you sleepy before some medical procedures).
- Vitamins or supplements that contain niacin or nicotinic acid.
- Clopidogrel (a medicine to help prevent harmful blood clots).
- Statins (a class of medicine that works in the liver to lower cholesterol).

These medicines may be affected by TREDAPTIVE, or may affect how well it works. You may need to take different amounts of your medicine, or you may need to take different medicines.

Also tell your doctor if you are taking simvastatin (a statin) or a medication containing simvastatin and are ethnic Chinese.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking TREDAPTIVE.

Use in children

TREDAPTIVE has not been studied in children who are under 18 years of age.

Use in the elderly

In studies, TREDAPTIVE worked well in and was well-tolerated by older adult patients. No dosage adjustment is necessary based on age.

Use in pregnancy and breast-feeding

Women who are pregnant or plan to become pregnant should talk with their doctor before taking TREDAPTIVE. It is not known if TREDAPTIVE will harm your unborn baby. Your doctor will decide if TREDAPTIVE is right for you.

Women who are breast-feeding or plan to breast-feed should talk with their doctor before taking TREDAPTIVE. It is not known if TREDAPTIVE will pass into your breast milk. However, nicotinic acid does pass into breast milk. Your doctor will decide if TREDAPTIVE is right for you. Do not take this medication without first talking to your doctor if you are breast-feeding a baby.

How to take TREDAPTIVE

How much to take

Your doctor will tell you how many tablets you need to take each day. You should start by taking one tablet. After 4 weeks, your doctor may raise your dose to two tablets daily. Take TREDAPTIVE only when prescribed by your doctor.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How to take it

- Take TREDAPTIVE exactly as your doctor tells you to take it.
- Take TREDAPTIVE once a day, in the evening or at bedtime.
- Take TREDAPTIVE with food.

- Swallow each tablet whole. In order for your medicine to work as intended, do not split, break, crush or chew the tablet before you swallow it.
- To reduce the possibility of flushing (redness of the skin, feeling warm, itching, or tingling, particularly in the head, neck, chest and upper back), you may want to avoid drinking alcohol or hot drinks or eating spicy food near the time you take your dose of TREDAPTIVE.
- Keep taking TREDAPTIVE unless your doctor tells you to stop. If you stop taking TREDAPTIVE, your cholesterol problem may return.

When to take it

Take TREDAPTIVE once a day in the evening or at bedtime.

If you forget to take it

If you miss a dose, do not take an extra dose. Continue with your usual dose the next evening or at bedtime. However, if you do not take TREDAPTIVE for 7 or more days in a row, talk to your doctor before restarting TREDAPTIVE.

If you take too much (overdose)

Immediately telephone your doctor or National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much TREDAPTIVE. Do this even if there are no signs of discomfort or poisoning.

While you are using TREDAPTIVE

Things you must do

If you become pregnant while you are taking TREDAPTIVE, contact your doctor immediately.

(See Before You Take TREDAPTIVE for additional considerations.)

Things that would be helpful to stay healthy and reduce your chances of Coronary Heart Disease

- Stop smoking.
Smoking increases your chances of a heart attack.
- Exercise.
Exercise may raise your levels of "good" cholesterol and reduce your chances of having CHD. Ask your doctor for advice before starting exercise.
- See your doctor regularly.
Your doctor will check your cholesterol.
- Take your medication.
Keep up with your therapy to keep your cholesterol under control.
- Maintain the diet recommended by your doctor.
Your diet will not only help you manage your cholesterol but will also help you lose weight (if appropriate).

Things you must not do

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

Effects on the Ability to Drive and Use Machinery

TREDAPTIVE is not expected to interfere with your ability to drive or to use machinery. However, when driving or operating machinery, it should be taken into account that

dizziness has been reported.

Adverse Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking TREDAPTIVE.

All medicines can have adverse effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Like all prescription medicines, TREDAPTIVE may cause adverse effects. In clinical studies, TREDAPTIVE was generally well tolerated. The adverse effects were usually mild and temporary.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following and they worry you:

- flushing (this usually includes redness of the skin, feeling warm, itching, or tingling. Flushing is the most common side effect of TREDAPTIVE. It is helpful to know what you can expect if you experience flushing. Flushing most often occurs in the head, neck, chest and upper back. Although not everyone experiences flushing with each dose of TREDAPTIVE, symptoms are generally temporary, most noticeable at first, and usually lessen over time.)
- diarrhoea
- nausea
- dizziness
- rash
- hives
- upset stomach or heartburn
- vomiting
- headache
- tingling or numbness of the hands or feet

These are the more common adverse effects of TREDAPTIVE.

Tell your doctor immediately if you notice any of the following allergic reaction symptoms:

- shortness of breath
- loss of control over urine and stool
- cold sweats
- shivering
- chills
- increased blood pressure
- swelling of the lips
- burning sensation
- whole body rash
- joint pain
- swelling of legs
- rapid heart rate

These may be serious adverse effects. You may need urgent medical attention. Serious adverse effects are rare.

Additionally, during post-marketing experience with TREDAPTIVE and/or other niacin products (alone and/or with certain other cholesterol-lowering medicines), a sudden serious allergic reaction (anaphylactic shock) was reported.

Tell your doctor immediately or go to accident and emergency at your nearest hospital, if you notice the following:

- fainting
- shortness of breath
- wheezing or trouble breathing
- swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing
- itching or hives on the skin

These may be the symptoms of anaphylactic shock. This condition requires immediate medical attention.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

See your doctor regularly to check your LDL (bad) and HDL (good) cholesterol levels and triglyceride level and to check for adverse effects. Your doctor may do blood tests to check your liver before you start taking TREDAPTIVE and during treatment.

After using TREDAPTIVE

Storage

Store TREDAPTIVE in the original packaging until you need to use it.

Keep TREDAPTIVE in a cool dry place where the temperature stays below 30°C. Do not store it or any other medicine in the bathroom or near a sink. Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep it where children cannot reach it. A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking TREDAPTIVE or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

TREDAPTIVE comes as a white to off-white bi-layer capsule-shaped modified release tablet debossed with 552 on one side.

TREDAPTIVE (ER nicotinic acid/laropiprant, MSD) is a tablet that contains 1 g ER (extended-release) nicotinic acid (also known as niacin) and 20 mg laropiprant as active ingredients.

TREDAPTIVE contains the following ingredients:

Ingredients

Active ingredient:

- ER nicotinic acid/laropiprant

Inactive ingredients:

- hypromellose USP/NF
- colloidal silicon dioxide USP/NF
- sodium stearyl fumarate USP/NF
- hydroxypropyl cellulose USP/NF
- microcrystalline cellulose USP/NF
- croscarmellose sodium USP/NF
- lactose hydrous NF
- magnesium stearate NF

Supplier

TREDAPTIVE is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited
P O Box 99851
Newmarket
Auckland
NEW ZEALAND
Tel: 0800 500 673

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