

Core CMI for Nicotinic Acid (*Text in italics is instructional for the CMI writer only*)

Nicotinic acid

Nicotinic acid (nik-o-TIN-ic AS-id)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Nicotinic acid.

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 or pharmacist has weighed the risks of you taking this med 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 Nicotinic acid is used for

Nicotinic acid is used to treat:

- high levels of low-density lipoprotein (LDL) cholesterol and triglycerides which are fat-like substances in the blood
- pellagra, a Nicotinic acid deficiency which is very rare in Australia. Symptoms of pellagra include loss of appetite, lethargy, weakness, diarrhoea, dermatitis and mental changes.

Cholesterol and triglycerides

Everyone has cholesterol in their blood. It is a type of blood fat needed by the body for many things, such as making bile acids (which help to digest food) and some hormones.

Some people have a family history of high cholesterol.

However, having too much cholesterol in the blood can contribute to the development of heart disease.

Cholesterol is present in many foods and is also made in your body by the liver. If your body does not balance the amount of cholesterol it needs with the amount of cholesterol eaten, then your cholesterol becomes too high.

There are different types of cholesterol, called LDL (low-density lipoprotein) and HDL (high-density lipoprotein). LDL cholesterol is the 'bad' cholesterol that can block your blood vessels. HDL cholesterol is the 'good' cholesterol that is thought to remove the 'bad' cholesterol from the blood vessels.

There is another type of fat called triglyceride, which is a source of energy. High levels of triglyceride can be associated with a low level of 'good' cholesterol and may increase your risk of heart disease.

Having high levels of 'bad' cholesterol and triglycerides can be a problem. Over time, this can form hard areas, called plaque, on the walls of your blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to heart disease (such as heart attack or angina), and stroke.

In most people, there are no signs of high cholesterol [or triglycerides]. Your doctor can measure your cholesterol [and triglycerides] with a simple blood test.

Treating high cholesterol and triglycerides

High cholesterol and triglyceride levels can be treated in two main ways:

The first is lifestyle changes – this includes a low-fat diet, increasing physical exercise, and weight management.

If lifestyle changes do not work, your doctor will prescribe a medicine to help lower your cholesterol and triglyceride levels.

How [Medicine name] works

Nicotinic acid (also known as niacin) is vitamin B3, which occurs naturally in food. Used as a medicine, it can improve levels of blood fats (lipids) such as cholesterol and triglycerides.

Nicotinic acid works by reducing the amount of 'bad' cholesterol and triglycerides made by the liver.

In most people, there are no symptoms of high cholesterol or triglycerides. Your doctor can measure your cholesterol and triglycerides with a simple blood test.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Do not give Nicotinic acid to a child.

The safety and effectiveness of this medicine have not been established in this age group.

Nicotinic acid is not addictive.

It is available from your pharmacist without a doctor's prescription.

Before you take Nicotinic acid

When you must not take it

Do not take Nicotinic acid if you have an allergy to:

- any medicine containing Nicotinic acid
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not take this medicine if you have or have had:

- significant liver problems
- bleeding of any artery (a blood vessel)
- recent heart attack.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not take this medicine if you are breast-feeding.

This medicine passes into breast milk and may affect your baby.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor or pharmacist if you have or have had any of the following medical conditions:

- liver disease. Your doctor will do a blood test to make sure you have no problems with your liver.
- heart attack
- heart, gallbladder, kidney or liver problems
- bleeding problems
- glaucoma (increased pressure in the eye)
- stomach ulcer
- diabetes
- gout.

If you have not told your doctor or pharmacist about any of the above, tell them before you start taking this medicine.

Taking other medicines

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

Some medicines and Nicotinic acid may interfere with each other. These include:

- certain medicines used to lower high blood pressure
- insulin or other medicines used to treat diabetes
- aspirin
- ‘statins’, medicines used to lower cholesterol, e.g. pravastatin, simvastatin
- colestipol, a medicine used to lower cholesterol
- nicotine patches
- isoniazid, a medicine used for tuberculosis
- clonidine, a medicine used for high blood pressure and migraine.

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Nicotinic acid.

How to take Nicotinic acid

Carefully follow all directions given to you by your doctor or pharmacist.

They may differ from the information contained in this leaflet.

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

How much to take

In adults:

Pellagra: One tablet twice a day.

High cholesterol and triglyceride levels: Initially one tablet three times a

day; increased by one tablet every four days to a maximum daily dose of 12-18 tablets or as directed by your doctor.

Your doctor or pharmacist will tell you how many tablets you will need to take each day. This depends on your condition and whether or not you are taking any other medicines.

How to take it

Swallow the tablets whole with a glass of water. Do not chew the tablets.

When to take it

Take Nicotinic acid after meals.

How long to take it

Take your medicine for as long as your doctor or pharmacist tells you to.

Nicotinic acid helps lower your cholesterol and triglyceride. It does not cure your condition. Therefore, you must continue to take it as directed by your doctor or pharmacist to keep your cholesterol and triglyceride levels controlled. If you stop taking it, your cholesterol and triglyceride levels may become out of control.

If you forget to take it

Take the dose as soon as you remember, and then go back to taking your medicine as directed.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or pharmacist or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital,

if you think that you or anyone else may have taken too much Nicotinic acid. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Too much Nicotinic acid may cause red or itchy skin, vomiting, diarrhoea, stomach discomfort or cramps, or fainting.

While you are using Nicotinic acid

Things you must do

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are taking Nicotinic acid.

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor or pharmacist immediately.

If you are about to have any blood or urine tests, tell your doctor that you are taking this medicine.

Nicotinic acid may affect the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may recommend that you have regular blood tests while taking Nicotinic acid to monitor the effect on your blood cholesterol and triglyceride levels.

If you are taking this medicine to lower your blood cholesterol and triglyceride levels:

- Reduce your saturated fat intake and eat plenty of fruit and vegetables. Doing this will help control your cholesterol (and triglyceride) levels, as well as your weight.
- Be active by maintaining an exercise program that your doctor or other health professional recommends. This will also help control your cholesterol levels and weight

Things you must not do

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

Do not take the medicine to treat any other complaints unless your doctor or pharmacist tells you to.

Do not stop taking the medicine, or lower the dosage, without checking with your doctor or pharmacist.

Things to be careful of

Avoid alcohol and hot drinks when you take Nicotinic acid.

Alcohol and hot drinks can increase side effects such as flushing and itching.

Side effects

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

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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

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

- skin flushing, which is a warmth, redness, itching or tingling that typically occurs on the face, neck, chest and back.

Flushing is the most common side effect of Nicotinic acid products. For most patients, the flushing episodes will become less frequent and milder within a few weeks after starting therapy, or may stop altogether.

- irregular or rapid heart beat
- headache
- dizziness
- itch, rash
- dry or scaly skin, boils

- darkening or thickening of the skin
- nausea (feeling sick), vomiting
- diarrhoea
- heartburn or flatulence
- nervousness.

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- yellowing of the skin and/or eyes
- shortness of breath
- signs of gout, e.g. painful swollen joints
- difficulty seeing
- fainting, dizziness when getting up from a sitting or lying position.

The above list includes serious side effects, which may require medical attention. Serious side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

- signs of an allergic reaction include swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some side effects can only be found when your doctor does blood, urine or other tests from time to time to check your progress.

After using Nicotinic acid

Storage

Keep your tablets in the bottle until it is time to take them.

If you take the tablets out of the bottle they may not keep as well.

Keep your tablets in a cool dry place where the temperature stays below 30 °C.

Do not store this medicine or any other medicine in the bathroom or near a sink. Do not leave it in the car or on windowsills.

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 or pharmacist tells you to stop taking this medicine 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

Nicotinic acid tablets are white, flat tablets with a break bar on one side. The tablets are available in bottles of 200's.

Ingredients

The tablets contain 250mg of Nicotinic acid as the active ingredient. They also contain:

- lactose
- wheat starch
- povidone
- talc
- magnesium stearate.

The medicine does not contain tartrazine or any other azo dyes.

Supplier

Alphapharm Pty Limited
(ABN 93 002 359 739)
Chase Building 2
Wentworth Park Road
Glebe NSW 2037
Phone: (02) 9298 3999
www.alphapharm.com.au

Medical Information
Phone: 1800 028 365

Australian registration number:
AUST R 27193

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Addendum:

The information in this core CMI for Statin Lipid Lowering Agents has been endorsed by the CMI Content/Quality Assurance Reference Group (QARG) as a guide to writing product specific CMIs.

The core CMI provides the basic information that should be included in CMIs to ensure consistency across products in this therapeutic category.

Any additional lifestyle information, such as information on how to reduce saturated fat content or build up an exercise program, may be included by individual companies at their own discretion, and preferably after testing with consumers.

Following is an example of information that has been suggested:

Reduce your saturated fat intake and eat plenty of vegetables and fruit.

Reducing your saturated fat intake means eating less:

- fatty meals
- full fat dairy products
- butter
- coconut and palm oils
- most take-away foods, and
- commercially baked products.

Doing this will help control your cholesterol and triglyceride levels, as well as your weight.

Be active by maintaining an exercise program that your doctor or other health professional recommends.

It is best to start slowly, progressing to at least 30 minutes of moderate-intensity physical activity on 5 or more days each week. Physical activity can be accumulated in shorter 10-minute bouts. If you have been prescribed anti-angina medicine, carry it with you when being physically active.