NICOTINIC ACID

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

1. Why am I taking NICOTINIC ACID?

The active ingredient in this medicine is Nicotinic Acid (also known as niacin/vitamin B3). NICOTINIC ACID is used to treat high levels of cholesterol and triglycerides, and pellagra, a nicotinic acid deficiency. For more information, see Section <u>1. Why am I taking NICOTINIC ACID</u>? in the full CMI.

2. What should I know before I take NICOTINIC ACID?

Do not take if you have ever had an allergic reaction to nicotinic acid or any of the ingredients listed at the end of the CMI. **Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.** For more information, see Section <u>2. What should I know before I take NICOTINIC ACID?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with NICOTINIC ACID and affect how it works. A list of these medicines is in Section <u>3. What if I am</u> taking other medicines? in the full CMI.

4. How do I take NICOTINIC ACID?

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

More instructions can be found in Section <u>4. How do I take NICOTINIC ACID?</u> in the full CMI.

5. What should I know while taking NICOTINIC ACID?

Things you should do	 Remind any doctor, dentist or pharmacist you visit that you are taking NICOTINIC ACID. If you are about to have any blood or urine tests, tell your doctor that you are taking this medicine. Tell your doctor or pharmacist immediately if you are pregnant.
Things you should 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.
Drinking alcohol	 Avoid alcohol and hot drinks when you take NICOTINIC ACID. Alcohol and hot drinks can increase side effects such as flushing and itching.
Looking after your medicine	 Keep the tablets in the bottle, in a cool, dry place below 30°C. Keep your tablets where children cannot reach it.

For more information, see Section 5. What should I know while taking NICOTINIC ACID? in the full CMI.

6. Are there any side effects?

Tell your doctor or pharmacist if you notice any of the following: skin flushing (warmth, redness, itching or tingling that typically occurs on the face, neck, chest and back), 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. **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. **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 including swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing. For more information, including what to do if you have any side effects, see Section <u>6. Are there any side effects?</u> in the full CMI.

NICOTINIC ACID

Active ingredient(s): nicotinic acid

Consumer Medicine Information (CMI)

This leaflet provides important information about taking NICOTINIC ACID. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking NICOTINIC ACID.

Where to find information in this leaflet:

- 1. Why am I taking NICOTINIC ACID?
- 2. What should I know before I take NICOTINIC ACID?
- 3. What if I am taking other medicines?
- 4. How do I take NICOTINIC ACID?
- 5. What should I know while taking NICOTINIC ACID?
- 6. <u>Are there any side effects?</u>
- 7. Product details

1. Why am I taking NICOTINIC ACID?

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.

NICOTINIC ACID is used to treat:

- high levels of 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 (lowdensity 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.

Treating high cholesterol and triglycerides

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

Lifestyle changes:

• this includes a low-fat diet, increasing physical exercise, and weight management.

Medicines:

• such as cholesterol-lowering agents.

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.

2. What should I know before I take NICOTINIC ACID?

Warnings

Do not take NICOTINIC ACID if:

- you are allergic to nicotinic acid, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin.

Always check the ingredients to make sure you can take this medicine.

- you have or have had:
 - o significant liver problems
 - o bleeding of any artery (a blood vessel)
 - o recent heart attack.
- the expiry date printed on the pack has passed 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.

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes
- have or have had liver disease

Your doctor will do a blood test to make sure you have no problems with your liver.

- have or have had any of the following medical conditions:
 - o heart attack
 - o heart, gallbladder, kidney or liver problems
 - o bleeding problems
 - o glaucoma (increased pressure in the eye)
 - o stomach ulcer
 - o diabetes
 - o gout.
- take any medicines for any other condition.

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant.

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

Check with your doctor if you are pregnant or intend to become pregnant.

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

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

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

Some medicines may interfere with NICOTINIC ACID and affect how it works. 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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect NICOTINIC ACID.

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

4. How do I 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 NICOTINIC ACID

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

When to take NICOTINIC ACID

• Take NICOTINIC ACID after meals.

How long to take NICOTINIC ACID

Continue taking your medicine for as long as your doctor or pharmacist tells you.

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 NICOTINIC ACID

NICOTINIC ACID should be used regularly at the same time each day.

If you miss your dose at the usual time, 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 NICOTINIC ACID

If you think that you or anyone else may have taken too much NICOTINIC ACID, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

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

5. What should I know while taking NICOTINIC ACID?

Things you should 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 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, maintain a low fat diet and exercise program to control your weight.

When you are taking this medicine, it will be easier to control your cholesterol and triglyceride levels if you also exercise and follow a low fat diet, including plenty of fruit and vegetables.

Call your doctor straight away if you:

• become pregnant while taking this medicine.

Things you should 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.

Drinking alcohol

Avoid alcohol and hot drinks when you take NICOTINIC ACID.

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

Looking after your medicine

- Store below 30°C
- 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.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any 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. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Do not be alarmed by the following lists of side effects.

You may not experience any of them.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects		What to do
•	skin flushing (warmth, redness, itching or tingling that typically occurs on the face, neck, chest and back).	Speak to your doctor or pharmacist if you have any
	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.	of these less serious side effects and they worry you. This list includes the
•	irregular or rapid heart beat headache dizziness itch, rash dry or scaly skin, boils darkening or thickening of the	more common side effects of your medicine.
• • •	skin nausea (feeling sick), vomiting diarrhoea heartburn or flatulence nervousness	

Serious side effects

Serious side effects		What to do
•	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.	Tell your doctor as soon as possible if you notice any of the following serious side effects:
		This list includes serious side effects, which may require medical attention. Serious side effects are rare.

Very serious side effects

Very serious side effects		What to do
•	signs of an allergic reaction include swelling of the face, lips, mouth, throat or neck which may cause difficulty swallowing or breathing.	Tell your doctor immediately or go to Accident and Emergency at the nearest hospital if you notice any of the following:

Very serious side effects	What to do
	This 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 else that may be making you feel unwell.

Other side effects not listed here may 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.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What NICOTINIC ACID contains

Active ingredient (main ingredient)	Nicotinic acid 250 mg
Other ingredients (inactive ingredients)	 lactose monohydrate wheat starch povidone purified talc magnesium stearate
Potential allergens	Gluten, sulfites and sugars as lactose

Do not take this medicine if you are allergic to any of these ingredients.

What NICOTINIC ACID looks like

NICOTINIC ACID tablets are white, bevelled edge tablets with a breakline on one side (AUST R 27193).

NICOTINIC ACID is available in bottles of 100 tablets.

Who distributes NICOTINIC ACID

Alphapharm Pty Ltd trading as Viatris Level 1, 30 The Bond 30-34 Hickson Road Millers Point NSW 2000 <u>www.viatris.com.au</u> Phone: 1800 274 276

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