

Patient Information Leaflet

SCHEDULING STATUS: S4

APOTRIGON 40/ 160 mg hard capsules

40 mg pravastatin sodium and 160 mg fenofibrate

Contains sugar (lactose monohydrate: 19 mg per capsule)

Read all of this leaflet carefully before you start taking APOTRIGON.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- APOTRIGON has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What APOTRIGON is and what it is used for
2. What you need to know before you take APOTRIGON
3. How to take APOTRIGON
4. Possible side effects
5. How to store APOTRIGON
6. Contents of the pack and other information

1. WHAT APOTRIGON is and what it is used for:

APOTRIGON contains two active substances: pravastatin and fenofibrate. Both are cholesterol/lipid modifying medicines.

APOTRIGON is used in adults in conjunction with a low fat diet and exercise:

- to lower the level of your 'bad' cholesterol (LDL cholesterol). It does this by lowering the level of total cholesterol, and fatty substances called triglycerides in the blood
- to raise the level of your 'good' cholesterol (HDL cholesterol).

2. What you need to know before you take APOTRIGON

Do not take APOTRIGON:

- if you are hypersensitive (allergic) to fenofibrate, pravastatin or any of the other ingredients of APOTRIGON (listed in section 6)
- if you suffer from liver disease
- if you are under 18 years old
- if you suffer from kidney disease
- if you have had photoallergy (allergic reaction caused by sunlight or exposure to UV light) or phototoxic reactions (damage to skin caused by exposure to sunlight or UV light) during treatment with fibrates (lipid-modifying medicines) or ketoprofen (an anti-inflammatory medicine that can be used orally or on the skin for muscle and bone disorders, and orally for gout or period pain)
- if you suffer or have suffered from gallbladder disease
- if you suffer or have suffered from pancreatitis (inflammation of the pancreas leading to abdominal pain)
- if you are pregnant or breastfeeding your baby
- if you have a history of muscle problems (e.g. myopathy or rhabdomyolysis) during treatment with cholesterol-controlling medicines called 'statins' (such as simvastatin, atorvastatin, pravastatin or rosuvastatin) or fibrates (such as fenofibrate and bezafibrate)
- do not APOTRIGON if you are going to receive treatment with an antibiotic called fusidic acid.

Do not take APOTRIGON if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking APOTRIGON.

Warnings and precautions

Talk to your doctor or pharmacist before taking APOTRIGON.

Before you take APOTRIGON you should tell your doctor if you have or have had any medical problems.

Special care should be taken with APOTRIGON:

- tell your doctor about all your medical conditions including allergies
- tell your doctor if you drink large amounts of alcohol (if you drink more than the recommended daily amount; ask your doctor or pharmacist if you are unsure) or have ever had liver disease. See also below section "Taking APOTRIGON with food and drink"
- a blood test will be done before you start taking APOTRIGON. This is to check how well your liver and your kidneys are working
- your doctor may also want you to have blood tests to check how well your liver is working after you start taking APOTRIGON.

Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness.

This is because APOTRIGON can cause muscle problems which can be serious, including muscle breakdown resulting in kidney damage.

Also tell your doctor or pharmacist if you have a muscle weakness that is constant.

Additional tests and medicines may be needed to diagnose and treat this.

The risk of muscle breakdown is greater in certain patients. Tell your doctor if any of the following applies to you:

- liver or kidney problems
- thyroid problems
- you are more than 70 years old
- you have ever had muscle problems during a treatment with cholesterol-lowering medicines such as a statin or fibrate
- you are taking or, in the last 7 days, have taken or been given a medicine called fusidic acid (a medicine for bacterial infection)

- you or your close family members have a hereditary muscle disorder
- you have alcohol problems (regularly drinking large amounts of alcohol)

Check with your doctor or pharmacist before taking APOTRIGON if you have serious respiratory problems, e.g. you have breathing problems including, persistent non-productive cough, deterioration in general health like fatigue (tiredness), weight loss and/or shortness of breath or fever.

If you feel any of these symptoms you should stop taking APOTRIGON and inform your doctor.

While you are on APOTRIGON your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

Children and adolescents

Do not take APOTRIGON if you are under 18 years old.

Other medicines and APOTRIGON

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

It is important that you inform your doctor if you are already being treated with any of the following:

- bile acid resins such as cholestyramine/colestipol (a medicine for lowering cholesterol), because it affects the way APOTRIGON works.
- ciclosporin (a medicine often used in organ transplant patients)
- medicines to prevent blood clots, such as warfarin, fluindione or other anticoagulant medicines
- an antibiotic such as erythromycin or clarithromycin to treat infections caused by bacteria
- fusidic acid: do not take or use fusidic acid (a medicine for bacterial infections) while using APOTRIGON. Also see section 4 of this leaflet.

APOTRIGON with food, drink and alcohol

- Always take APOTRIGON with food as APOTRIGON is less well absorbed from an empty stomach.
- You should always keep your alcohol intake to a minimum. If you are concerned about how much alcohol you can drink while you are taking APOTRIGON, you should discuss this with your doctor.

If you are not sure about this, please follow your doctor's advice.

Pregnancy and breastfeeding

If you are pregnant, think you may be pregnant or are planning to have a baby or become pregnant, please consult your doctor, pharmacist or other health care provider for advice before taking APOTRIGON.

Women who are potentially child bearing must use an effective form of contraception while taking APOTRIGON.

Do not take APOTRIGON if you are pregnant or trying to get pregnant or think you may be pregnant.

If you become pregnant inform your doctor immediately, APOTRIGON must be discontinued because of the potential risk to the foetus.

Do not take APOTRIGON if you are breastfeeding your baby.

Driving and using machines

If you experience any dizziness, blurred or double vision during treatment, do not drive or use machines until these symptoms resolve.

APOTRIGON contains lactose

APOTRIGON contains a sugar called lactose. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking APOTRIGON.

3. How to take APOTRIGON

Do not share medicines prescribed for you with any other person.

Always take APOTRIGON exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Before you start taking APOTRIGON, you should be on a diet to lower your cholesterol.
- You should keep to this diet while taking APOTRIGON.

The usual dose is one capsule taken daily during the evening meal. Swallow the capsule with water. It is important to take the capsule with food, as it won't work as well if your stomach is empty.

Your doctor will tell you how long your treatment with APOTRIGON will last. If you have the impression that the effect of APOTRIGON is too strong or too weak, tell your doctor or pharmacist.

When your doctor has prescribed APOTRIGON along with colestyramine or any other bile acid binding resins (medicines for lowering cholesterol), take APOTRIGON 1 hour before, or 4 to 6 hours after the resin. This is because colestyramine or other bile acid binding resins frequently reduce the absorption of medicines when taken too closely together and so may impede the absorption of APOTRIGON. If you take indigestion remedies (used to neutralise acid in your stomach), take APOTRIGON 1 hour after.

If you take more APOTRIGON than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take APOTRIGON

Do not take a double dose to make up for forgotten individual doses, just take your normal amount of APOTRIGON at the usual time the next day.

If you stop taking APOTRIGON

Do not stop taking APOTRIGON without first discussing it with your doctor.

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

4. POSSIBLE SIDE EFFECTS

APOTRIGON can have side effects.

Not all side effects reported for APOTRIGON are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking APOTRIGON, please consult your health care provider for advice.

If any of the following happens, stop taking APOTRIGON and tell your doctor immediately or go to the casualty department at your nearest hospital:

- unexplained muscular pain or cramps, tenderness, or weakness, especially if at the same time you feel unwell or have a high temperature. This is because these muscle problems can be serious, including muscle breakdown resulting in kidney damage, and death
- sudden severe allergic reactions including swelling of the face, lip, tongue or wind pipe which can cause great difficulty in breathing.

These are very serious side effects. If you have them, you may have had a serious reaction to APOTRIGON. You may need urgent medical attention or hospitalisation.

Contact a doctor as soon as possible:

Less frequent:

- abnormal heartbeat (palpitations), formation of blood clots is experienced as pain and swelling in your legs (deep vein thrombosis) and blockage of the lung arteries by blood clots (pulmonary embolism) experienced as chest pain and breathlessness
- problems with sight such as blurred or double vision
- muscle inflammation (myositis) experienced as muscular cramps and weakness
- inflammation of the liver (hepatitis), symptoms of which may be mild yellowing of the skin and whites of the eyes (jaundice), abdominal pain and itching

- muscle breakdown (rhabdomyolysis), some cases of tendon problems giving symptoms of pain in your legs, sometimes complicated by rupture.

Frequency unknown:

- muscle weakness that is constant.

Tell your doctor if you notice any of the following:

Frequent:

- digestive effects: gastric or intestinal disorders (abdominal pain, nausea, vomiting, diarrhoea and flatulence, constipation, dry mouth, upper abdominal pain with bloating (dyspepsia), burping (eructation))
- effects on liver: raised serum transaminases (seen on a blood test).

Less frequent:

- rashes, skin rash, itching, hives or reactions to sunlight or exposure to UV light (photosensitivity reactions), scalp/ hair abnormality (including hair loss)
- effects on nervous system: dizziness (sensation of unsteadiness), headache, sleep disturbances (including difficulty sleeping and nightmares), pins and needles sensation (paraesthesia)
- muscle and joint pain (myalgia, arthralgia), back pain, alterations in some laboratory blood tests for muscle function
- kidney problems (increased or decreased levels of certain enzymes within the body seen in a test), bladder problems (painful or frequent urination, having to pass water at night), sexual dysfunction
- tiredness, weakness, influenza-like illness
- increased blood cholesterol, increased blood triglycerides, increased LDL, increased gamma-glutamyl transferase (various liver enzymes): seen on a blood test
- liver pain (upper right abdominal pain with or without pain in the back), increased weight
- obesity

- decrease in haemoglobin (oxygen-carrying pigment in blood) and leukocytes (white blood cells): seen on a blood test
- tingling and numbness (peripheral polyneuropathy).

Possible side effects reported with some statins (same type of cholesterol-lowering medicines as pravastatin), as contained in APOTRIGON:

- memory loss
- depression
- breathing problems including persistent cough/or shortness of breath or fever
- diabetes: this is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking APOTRIGON.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of APOTRIGON.

5. HOW TO STORE APOTRIGON

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Keep in the original packaging until required for use.
- Do not use APOTRIGON after the expiry date which is stated on the carton and the blister/bottle after EXP.
- 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.

6. Contents of the pack and other information

What APOTRIGON contains

- The active substances are fenofibrate and pravastatin. Each hard capsule contains 40 mg pravastatin sodium (equivalent to 38,03 mg of pravastatin) and 160 mg fenofibrate.
- The other ingredients are:
 - capsule content: lactose monohydrate, cellulose microcrystalline, ascorbyl palmitate, povidone, sodium starch glycolate, magnesium stearate, talc, triacetin, sodium hydrogen carbonate, lauroyl macrogolglycerides, hydroxypropylcellulose, macrogol 20 000.
 - capsule shell: gelatine, indigo carmine (E132), black iron oxide (E172), titanium dioxide (E171), yellow iron oxide (E172).

What APOTRIGON looks like and contents of the pack

The capsules are hard gelatine capsule with olive cap and light green body containing a waxy white beige mass and a film-coated tablet.

APOTRIGON is supplied in Polyamide-Aluminium-PVC/aluminium blister packs containing 30, 60, or 90 capsules, and in opaque white HDPE containers containing either 14, 30, 60, 90 or 100 capsules.

Not all pack sizes and/or pack types may be marketed.

HOLDER OF CERTIFICATE OF REGISTRATION

Austell Laboratories (Pty) Ltd

1 Sherborne Road

Parktown

JOHANNESBURG

2193

South Africa

Tel: 0860287835

This leaflet was last revised in

April 2022

Registration number

55/7.5/0468