Approved Patient Information Leaflet for Medicines for Human Use:

PRAVAFEN 40 / 160 mg

SCHEDULING STATUS: S4

PRAVAFEN 40 / 160 mg hard capsules

40 mg pravastatin sodium and 160 mg fenofibrate

Contains sugar (lactose monohydrate: 19 mg per capsule)

Contains sodium (33,3 mg per capsule)

Read all of this leaflet carefully before you start taking PRAVAFEN 40 / 160 mg.

- 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.
- PRAVAFEN 40 / 160 mg 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 PRAVAFEN 40 / 160 mg is and what it is used for
2. What you need to know before you take PRAVAFEN 40 / 160 mg
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1. WHAT PRAVAFEN 40 / 160 mg is and what it is used for

PRAVAFEN 40 / 160 mg contains two active substances: pravastatin and fenofibrate. Both are cholesterol/lipid modifying medicines.

PRAVAFEN 40 / 160 mg 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 PRAVAFEN 40 / 160 mg

Do not take PRAVAFEN 40 / 160 mg:

- if you are hypersensitive (allergic) to fenofibrate, pravastatin or any of the other ingredients of PRAVAFEN 40 / 160 mg (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 take PRAVAFEN 40 / 160 mg if you are going to receive treatment with an antibiotic called fusidic acid or if you received fusidic acid in the last 7 days.

Do not take PRAVAFEN 40 / 160 mg if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking PRAVAFEN 40 / 160 mg.

Warnings and precautions

Talk to your doctor or pharmacist before taking PRAVAFEN 40 / 160 mg.

Before you take PRAVAFEN 40 / 160 mg you should tell your doctor if you have or have had any medical problems.

Special care should be taken with PRAVAFEN 40 / 160 mg:

- 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 PRAVAFEN 40 / 160 mg with food and drink"
- a blood test will be done before you start taking PRAVAFEN 40 / 160 mg. 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 PRAVAFEN 40 / 160 mg.
- if you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease which causes eye muscle weakness) as statins (such as pravastatin in PRAVAFEN 40 / 160 mg) may sometimes aggravate the condition or may cause myasthenia or ocular myasthenia (see section 4).

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

This is because PRAVAFEN 40 / 160 mg 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 PRAVAFEN 40 / 160 mg 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 PRAVAFEN 40 / 160 mg and inform your doctor.

While you are on PRAVAFEN 40 / 160 mg 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 PRAVAFEN 40 / 160 mg if you are under 18 years old.

Other medicines and PRAVAFEN 40 / 160 mg

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 PRAVAFEN 40 / 160 mg 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 PRAVAFEN 40 / 160 mg. Also see section 4 of this leaflet
- a particular class of medicines to treat diabetes (such as rosiglitazone, pioglitazone).
- glecaprevir/pibrentasvir (used to treat hepatitis C virus infection) because it can increase some adverse events including muscle problems.

PRAVAFEN 40 / 160 mg with food, drink and alcohol

- Always take PRAVAFEN 40 / 160 mg with food as PRAVAFEN 40 / 160 mg 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 PRAVAFEN 40 / 160 mg, 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 PRAVAFEN 40 / 160 mg.

Women who are potentially child bearing must use an effective form of contraception while taking PRAVAFEN 40 / 160 mg.

Do not take PRAVAFEN 40 / 160 mg if you are pregnant or trying to get pregnant or think you may be pregnant.

If you become pregnant inform your doctor immediately, PRAVAFEN 40 / 160 mg must be discontinued because of the potential risk to the foetus.

Do not take PRAVAFEN 40 / 160 mg 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.

PRAVAFEN 40 / 160 mg contains lactose and sodium

PRAVAFEN 40 / 160 mg contains a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking PRAVAFEN 40 / 160 mg. PRAVAFEN 40 / 160 mg contains 33,3 mg sodium (main component of cooking/table salt) in each capsule (excipients and active substance). This is equivalent to 1,7 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take PRAVAFEN 40 / 160 mg

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

Always take PRAVAFEN 40 / 160 mg exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- Before you start taking PRAVAFEN 40 / 160 mg, you should be on a diet to lower your cholesterol.
- You should keep to this diet while taking PRAVAFEN 40 / 160 mg.

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 PRAVAFEN 40 / 160 mg will last. If you have the impression that the effect of PRAVAFEN 40 / 160 mg is too strong or too weak, tell your doctor or pharmacist.

When your doctor has prescribed PRAVAFEN 40 / 160 mg along with colestyramine or any other bile acid binding resins (medicines for lowering cholesterol), take PRAVAFEN 40 / 160 mg 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 PRAVAFEN 40 / 160 mg. If you take indigestion remedies (used to neutralise acid in your stomach), take PRAVAFEN 40 / 160 mg 1 hour after.

If you take more PRAVAFEN 40 / 160 mg 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 PRAVAFEN 40 / 160 mg

Do not take a double dose to make up for forgotten individual doses, just take your normal amount of PRAVAFEN 40 / 160 mg at the usual time the next day.

If you stop taking PRAVAFEN 40 / 160 mg

Do not stop taking PRAVAFEN 40 / 160 mg without first discussing it with your doctor.

If you have any further questions on the use of PRAVAFEN 40 / 160 mg, ask your doctor or pharmacist.

4. Possible side effects

PRAVAFEN 40 / 160 mg can have side effects.

Not all side effects reported for PRAVAFEN 40 / 160 mg are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PRAVAFEN 40 / 160 mg, please consult your health care provider for advice.

If any of the following happens, stop taking PRAVAFEN 40 / 160 mg 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 PRAVAFEN 40 / 160 mg. 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:

- weakness in the eyes, seeing double, having difficulty focusing, droopy eyes
- muscle weakness that is constant, muscle rupture.
- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease causing eye muscle weakness).

Talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

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)
- a condition characterised by an inflammation of the muscles and the skin (dermatomyositis).
- skin rash, possibly with pain in the joints (erythematous lupus like syndrome).
- 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).

Frequency not known:

- skin rash (lichenoid eruption)

Possible side effects reported with some statins (same type of cholesterol-lowering medicines as pravastatin), as contained in PRAVAFEN 40 / 160 mg:

- 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 PRAVAFEN 40 / 160 mg.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of PRAVAFEN 40 / 160 mg.

Suspected side effects can also be reported directly to the Holder of the Certificate of Registration via medsafety@austell.co.za

5. How to store PRAVAFEN 40 / 160 mg

- 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 PRAVAFEN 40 / 160 mg 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 PRAVAFEN 40 / 160 mg contains

- The active substances are fenofibrate and pravastatin sodium. 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 PRAVAFEN 40 / 160 mg 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.

PRAVAFEN 40 / 160 mg 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

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Access to the corresponding Professional Information and Afrikaans Patient Information Leaflet

Professional Information and Afrikaans Patient Information Leaflet for this medicine is available on the following URL: https://austell.co.za/product-info/

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