

# **APO-Pravastatin**

Contains the active ingredient pravastatin (as pravastatin sodium)

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## **Consumer Medicine Information**

**For a copy of a large print leaflet, Ph: 1800 195 055**

## **What is in this leaflet**

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

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

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

**Keep this leaflet with the medicine.**

You may need to read it again.

## **What this medicine is used for**

The name of your medicine is APO-Pravastatin. It contains the active ingredient pravastatin (as pravastatin sodium).

It is used to treat people who have:

- high blood cholesterol levels (in combination with changes in diet)
- had a heart attack (including people whose blood cholesterol levels are normal)
- had an episode of unstable angina.

If you have had a heart attack, an episode of unstable angina, or you have too much cholesterol in your blood, then you have an increased risk of a blood clot forming in your blood vessels and causing a blockage. In these people, pravastatin can reduce the risk of having a stroke, further heart disease, or needing a bypass operation.

Pravastatin works by lowering high blood cholesterol levels (hypercholesterolaemia). It is more effective if it is taken with a cholesterol lowering diet.

It is also used to treat children and adolescent patients aged 8 years and older who have heterozygous familial hypercholesterolaemia (an inherited disorder which produces high blood cholesterol levels).

There is not enough information to recommend the use of this medicine in children less than 8 years of age.

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

Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

There is no evidence that this medicine is addictive.

## **Before you take this medicine**

### **When you must not take it**

**Do not take this medicine if you have an allergy to:**

- pravastatin
- or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

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

- fainting; or may have fever-like symptoms.

**Do not take this medicine if you have ever had liver disease or unexplained high levels of liver enzymes called serum transaminases.**

**Do not take this medicine if you have been prescribed any medicine containing fusidic acid.**

**Do not take this medicine if you are pregnant or there is a chance that you may become pregnant (i.e. you are not using adequate contraception)**

Pravastatin may affect your developing baby if you take it during pregnancy. You should also check with your doctor about your contraceptive use, to ensure that you don't become pregnant accidentally.

**Do not breastfeed if you are taking this medicine.**

Pravastatin may pass into breast milk and there is a possibility that your baby may be affected.

**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.**

## **Before you start to take it**

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

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

- liver problems
- kidney problems
- diabetes
- thyroid problems or any type of hormonal disorder
- central nervous system vascular lesions, especially if this happened after taking a different type of cholesterol lowering drug
- homozygous familial hypercholesterolaemia (a doctor will have told you this)
- increased triglycerides in your blood (a doctor will have told you this)
- muscle problems (including pain, tenderness or weakness), especially if this happened after taking a different type of cholesterol lowering drug
- have had an organ transplant (e.g. kidney or heart).

**Tell your doctor if you drink alcohol every day or you have, or have had, any problems with drug or alcohol dependence.**

**Tell your doctor immediately if you become pregnant or start breastfeeding.**

## **Taking other medicines**

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

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

- other medicines used to lower cholesterol (e.g. gemfibrozil, nicotinic acid (niacin), cholestyramine and colestipol)
- cyclosporin, used to suppress the immune system
- ketoconazole or fusidic acid, used to treat some infections
- erythromycin, used to treat bacterial infections
- spironolactone, a diuretic used to reduce water in the body
- cimetidine or antacids, used to treat ulcers or acid indigestion
- colchicine, a medicine used to treat gout
- niacin (vitamin B3)

These medicines may be affected by pravastatin or may affect how well it works. You may need different amounts of your medicines, 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 this medicine.

## **How to take this medicine**

**Follow carefully all directions given to you by your doctor.**

Their instructions may be different to the information in this leaflet.

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

## **How much to take**

This will depend on your condition and whether you are taking any other medicines.

The recommended dose for lowering cholesterol in adults is 10-80 mg daily.

The recommended dose for reducing the possibility of a stroke or heart attack is 40 mg daily.

If you are over 65 and/or have liver or kidney disease, or you are taking cyclosporin, you may be prescribed a lower dose.

The recommended dose for heterozygous familial hypercholesterolaemia is 20 mg once daily for children 8-13 years of age and 40 mg once daily for adolescents 14-18 years of age.

## **How to take it**

**Swallow the tablets whole with a glass of water.**

## **When to take it**

**Take your medicine at about the same time each day, usually in the evening before bed-time.**

For best results, take your medicine on an empty stomach (i.e. two or more hours after your last meal).

## **How long to take it for**

**Continue taking your medicine for as long as your doctor tells you.**

Pravastatin helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

## **If you forget to take it**

**If it is almost time to take your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

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

This may increase the chance of you experiencing side effects.

**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 the Poisons Information Centre (telephone 13 11 26) for advice or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.**

## **While you are taking this medicine**

### **Things you must do**

**Tell your doctor immediately if you experience any unexplained muscle pain, tenderness or weakness.**

**Stop taking your medicine and tell your doctor or go to a hospital immediately if you have dark or brown urine, together with the symptoms above.**

**Tell your doctor immediately if you have a dry cough, problems breathing, have a temperature, losing weight and/or generally feeling tired.**

These may be signs of a potentially fatal condition called interstitial lung disease.

**If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.**

**Tell your doctor that you are taking this medicine if you plan to have any vaccinations or immunisations**

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

**If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.**

It may affect other medicines used during surgery.

**If you become pregnant or plan to breastfeed while taking this medicine, tell your doctor immediately.**

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

It may interfere with the results of some tests.

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

Your doctor may do tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

## **Things you must not do**

**Do not take this medicine to treat any other complaints unless your doctor tells you to.**

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

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

## **Things to be careful of**

**Be careful driving or operating machinery until you know how this medicine affects you.**

Pravastatin generally does not interfere with your ability to drive or operate machinery. However, as with many other medicines, this medicine may cause dizziness in some people. Make sure you know how you react to this medicine before you drive a car or operate machinery.

**Avoid drinking large quantities of alcohol. Drinking large amounts of alcohol may increase the chance of this medicine causing liver problems.**

## **Side effects**

**Tell your doctor as soon as possible if you do not feel well while you are taking pravastatin.**

All medicines can have side effects. Sometimes they are serious but most of the time they are not.

**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 if you notice any of the following:**

- constipation, diarrhoea, flatulence (wind)
- stomach upset or pain, feeling of being sick (nausea or vomiting)
- headache; dizziness; giddiness
- feeling unusually tired or weak
- unable to sleep, nightmares
- hair loss or change in hair condition
- muscle cramps or joint pain
- swollen breasts
- sexual problems
- itchy or dry skin; mild skin rash
- loss of appetite or weight loss
- numbness; trembling
- anxiety; forgetfulness
- problems with sight (e.g. cataracts) or with moving the eye
- problems with hearing

- strange taste
- problems with face muscles

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

These may be serious side effects and you may need medical attention:

- dry cough, difficulty breathing, have a temperature, losing weight and/or generally feeling tired
- tingling in the hands or feet, or numbness
- sharp pain in the upper stomach (pancreatitis)
- feeling depressed
- yellowing of the skin or eyes, and/or pale stools, dark urine, these may be signs of jaundice
- signs of anaemia, such as tiredness, being short of breath and looking pale
- fever, flushing and/or generally feeling unwell
- frequent, unexplained infections such as fever, severe chills, sore throat or mouth ulcers
- bleeding or bruising more easily than normal
- severe skin rash, itchiness; pinkish, itchy swellings on the skin, also called hives or nettle rash

- sunburn type rash after only a short time in the sun
- muscle problems (myopathy)

Medications such as pravastatin can impair the production of certain proteins involved in muscle metabolism and function. This can result in aching muscles, muscle tenderness, stiffness or weakness

On rare occasions, muscle problems can be serious including muscle breakdown resulting in kidney damage.

**If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to Accident and Emergency at your nearest hospital.**

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

- shortness of breath
- severe skin rash which may involve blistering and/or peeling of large amounts of skin
- brown or dark coloured urine, with severe muscle aching all through the body, and muscle weakness (due to muscle breakdown)
- mousy odour to the breath, problems with balance and walking, tremor and impaired speech, confusion, unconsciousness.

**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.

## **Storage and Disposal**

### **Storage**

**Keep your medicine in its original packaging until it is time to take it.**

If you take your medicine out of its original packaging it may not keep well.

**Keep your medicine in a cool dry place where the temperature will stay below 25°C. Protect it from light and moisture.**

**Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep this medicine 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 this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.**

## **Product description**

### **What APO-Pravastatin looks like**

10 mg tablets: Light pink, round, unscored tablets, imprinted "APO" on one side and "PRA" over "10" on the other side. AUST R 118735. AUST R 166255.

20 mg tablets: Off-white to light yellow, round, unscored tablets, imprinted "APO" on one side and "PRA" over "20" on the other side. AUST R 118736. AUST R 166256.

40 mg tablets: Light green, round, unscored tablets, imprinted "APO" on one side and "PRA" over "40" on the other side. AUST R 118737. AUST R 166257.

80 mg tablets: Off-white to light yellow, round, unscored tablets, imprinted "APO" on one side and "PRA" over "80" on the other side. AUST R 145169. AUST R 145178.

Each tablet strength is contained in a blister pack containing 30 tablets.

The tablets may also be available in bottles containing 30, 100 or 500 tablets.

## Ingredients

Each tablet contains 10 mg, 20 mg, 40 mg or 80 mg of pravastatin sodium as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- iron oxide red (10 mg tablets)
- iron oxide yellow (20 mg, 40 mg and 80 mg tablets)
- brilliant blue FCF (40 mg tablets).

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

## Sponsor

Apotex Pty Ltd

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