

APO-Pravastatin Tablets

Contains the active ingredient pravastatin (as pravastatin sodium)

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information

You can also download the most up to date leaflet from www.apotex.com.au.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want 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)
- people who have had a heart attack (including people whose blood cholesterol levels are normal)
- people who have had an episode of unstable angina.

In these people, pravastatin can reduce the risk of having a stroke, further heart disease, or needing a bypass operation.

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). This is in combination with diet and lifestyle changes.

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.

How it works

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

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. Blood vessels that become blocked in this way can lead to further heart disease, angina or stroke.

There is no evidence that this medicine is addictive.

Use in children

Pravastatin can be used in children and adolescents aged 8 years and over, if they need treatment for heterozygous familial hypercholesterolaemia (a genetic disorder causing high cholesterol levels).

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

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You have liver disease or unexplained high levels of liver enzymes called serum transaminases.**
- **You have been prescribed any medicine containing fusidic acid.**
- **You are pregnant or there is a chance that you could become pregnant (i.e. you are not using adequate contraception).**

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

- **You are hypersensitive to, or have had an allergic reaction to, pravastatin or any of the ingredients listed at the end of this leaflet.**

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 hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- The expiry date (EXP) printed on the pack has passed.
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - 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
 - allergies
 - 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.
3. You drink alcohol every day or you have, or have had, any problems with drug or alcohol dependence.
 4. You have had an organ transplant (e.g. kidney or heart).
 5. You plan to become pregnant. Do not take this medicine whilst pregnant. You should also check with your doctor about your contraceptive use, to ensure that you don't become pregnant accidentally.
 6. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding.
 7. You are planning to have surgery or an anaesthetic.
 8. You are currently receiving or are planning to receive dental treatment.
 9. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with pravastatin. These include:

- other medicines used to lower cholesterol, for example,

- gemfibrozil, nicotinic acid (niacin), cholestyramine and colestipol
- cyclosporin, used to suppress the immune system
- ketoconazole, used to treat certain fungal infections
- spironolactone, a diuretic, used to reduce water in the body
- cimetidine, used to treat ulcers or acid indigestion
- erythromycin, used to treat bacterial infections
- antacids
- colchicine, a medicine used to treat a disease with painful, swollen joints caused by uric acid crystals
- niacin (vitamin B3)
- fusidic acid, used to treat some infections, you must not take this medicine with fusidic acid.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with pravastatin.

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.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

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 once a day, 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).

Take your medicine at about the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.

How long to take it for

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

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. 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 missed doses.

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)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 for Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

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, lose weight and/or generally feel tired.

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

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you plan to have any vaccinations or immunisations
- you become pregnant or plan to breastfeed (stop taking it and tell your doctor immediately)
- you are about to have any blood tests
- you are going to have surgery or an anaesthetic or are going into hospital.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects. Go to your doctor regularly for a check-up.

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

Things you must not do

Do not:

- give this medicine to anyone else, even if their symptoms seem similar to yours
- take your medicine to treat any other complaints unless your doctor tells you to
- stop taking your medicine, or change the dosage, without checking with your doctor.

Things to be careful of

Be careful while 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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking pravastatin or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:

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

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, problems breathing, temperature, losing weight and/or generally feel tired, these may be signs of a potentially fatal condition called interstitial lung disease
- 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
- sunburn type rash after only a short time in the sun
- pinkish, itchy swellings on the skin, also called hives or nettle rash
- 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.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

- 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.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to pravastatin, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hay fever-like symptoms.

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 or pharmacist tells you to stop taking this medicine or it has passed its expiry date, your

pharmacist can dispose of the remaining medicine safely.

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.

20 mg tablets:

Off-white to light yellow, round, unscored tablets, imprinted "APO" on one side and "PRA" over "20" on the other side.

40 mg tablets:

Light green, round, unscored tablets, imprinted "APO" on one side and "PRA" over "40" on the other side.

80 mg tablets:

Off-white to light yellow, round, unscored tablets, imprinted "APO" on one side and "PRA" over "80" on the other side.

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

The tablets may also be available in bottles containing 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.

Australian Registration Numbers

APO-Pravastatin 10 mg tablets:

AUST R 118735 (blister)

AUST R 166255 (bottle).

APO-Pravastatin 20 mg tablets:

AUST R 118736 (blister)

AUST R 166256 (bottle).

APO-Pravastatin 40 mg tablets:

AUST R 118737 (blister)

AUST R 166257 (bottle).

APO-Pravastatin 80 mg tablets:

AUST R 145169 (blister)

AUST R 145178 (bottle).

Sponsor

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