

PRAVASTATIN GENERICHEALTH

(pravastatin sodium) film-coated tablet

Consumer Medicine Information

What is in this leaflet

The information in this leaflet will answer some of the questions you may have about Pravastatin generichealth. This leaflet does not tell you everything about this medicine.

Your doctor and pharmacist have been provided with full information and can answer any questions you may have.

This leaflet is no substitute for talking with your doctor or pharmacist. You should follow all advice from your doctor when being treated with this medicine.

Ask your doctor or pharmacist if you have any concerns about taking this medicine.

You should read this leaflet carefully before starting Pravastatin generichealth and keep it in a safe place to refer to later.

What Pravastatin generichealth is used for

Pravastatin generichealth is used to treat people who have had a heart attack or an episode of unstable angina, or who have high blood cholesterol levels. In these people Pravastatin generichealth can reduce the risk of further heart disease, reduce the possibility of needing a bypass operation, or reduce the risk of having a stroke.

Pravastatin generichealth lowers high blood cholesterol levels (doctors call this hypercholesterolaemia). It is also used if your cholesterol levels are normal if you have had a heart attack or an episode of unstable angina.

Pravastatin generichealth is used to treat heterozygous familial hypercholesterolaemia in children and adolescent patients aged 8 years and older as an adjunct to diet and lifestyle changes.

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.

Pravastatin generichealth may be used to lower lipids in heart or kidney transplant patients, who are also being given immunosuppressive medicine.

Pravastatin generichealth is used to treat long-term (chronic) conditions so it is important that you take Pravastatin generichealth every day.

It is not addictive or habit forming.

It is only available upon prescription from your doctor.

How does Pravastatin generichealth work

Pravastatin generichealth contains pravastatin sodium, a drug that reduces the level of cholesterol in your blood and helps to protect you in other ways from heart attack or stroke. It is more effective if it is taken with a diet low in fat.

Before you take Pravastatin generichealth

When you must not take it

Before taking Pravastatin generichealth, you should be aware of the following:

You should not take it:

- if you are or may become pregnant;
- if you are breast feeding;
- if you have ever had an allergic reaction to pravastatin sodium or any other ingredient listed at the end of this leaflet;
- if you have ever had liver disease;
- if you have had muscle pain from any other medicine used to treat high cholesterol.

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

Before you start to take it

You must tell your doctor if:

- you are taking other medicines or treatment;
- you drink alcohol regularly;
- you have ever had liver problems;
- you have a problem with your kidneys;
- you are or may become pregnant;
- you are breastfeeding;
- you suffer from hormonal disorders;
- you suffer from central nervous system vascular lesions;
- you suffer from allergies;
- you suffer from homozygous familial hypercholesterolaemia, (a doctor will have told you this);
- you have increased triglycerides in your blood (a doctor will have told you this also);
- you suffer from muscle disease (including pain, tenderness or weakness).

Taking other medicines

Some medicines can affect the way Pravastatin generichealth works.

You should always tell your doctor about any other medicines you take, even those bought without a doctor's prescription.

It is especially important that you tell your doctor if you are taking any of the following:

- any other medicine to lower cholesterol;
- cyclosporin;
- ketoconazole;
- spironolactone;
- cimetidine;
- gemfibrozil;
- cholestyramine and colestipol;
- antacids.

Please discuss any of these with your doctor if you need to take any of them.

How to take Pravastatin generichealth

How much to take

Pravastatin generichealth should only be used as directed by your doctor.

Your doctor will decide on the dose of Pravastatin generichealth, this will depend on

many factors including your cholesterol level. The dose for lowering cholesterol is 10 mg to 80 mg, and is 40 mg* for reducing the possibility of a stroke or heart attack.

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

How to take it

Take Pravastatin generichealth once a day in the evening before bedtime.

For best results, take Pravastatin generichealth on an empty stomach (ie. Two or more hours after your last meal).

Take Pravastatin generichealth 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.

If you forget to take it

If you forget to take a dose of Pravastatin generichealth, take the next dose normally at your usual time.

If you take too much (overdose)

Call your doctor immediately if you or someone else has taken too much Pravastatin generichealth.

If your doctor is not available call your nearest hospital or a Poisons Information Centre on 13 11 26.

While you are taking Pravastatin generichealth

Things to be careful of

Pravastatin generichealth generally does not interfere with your ability to drive or operate machinery. However, some people may experience dizziness, so you should be sure how you react to Pravastatin generichealth before you drive a car or operate machinery.

Side effects

All medicines, including Pravastatin generichealth, can sometimes cause unwanted effects. This is not an exhaustive list.

The most common side effects of Pravastatin generichealth are:

- upset stomach;
- nausea;
- diarrhoea;
- wind;
- constipation;
- headache;
- dizziness.

Tell your doctor as soon as possible if you have any of these side effects or any other problem while taking Pravastatin generichealth.

Your doctor may arrange blood tests.

You must tell your doctor immediately, or go to the hospital, if you suffer any of the following:

- unexplained muscle pain;
- tenderness;
- weakness.

It is also possible to suffer from an allergic reaction to Pravastatin generichealth, so tell your doctor if you develop a skin rash or

itchiness, fever, joint pain or shortness of breath.

After taking Pravastatin generichealth

Storage

Store Pravastatin generichealth below 25°C, protected from light and moisture.

Keep the tablets in the blister until it is time to take them.

The expiry date for Pravastatin generichealth is printed on the pack.

Do not take Pravastatin generichealth after the expiry date or if the tablets have changed in appearance colour or taste.

Disposal

Ask your pharmacist about disposal of unused tablets.

Keep all medicines out of reach of children.

Product description

What it looks like

Pravastatin generichealth 10 mg tablets are yellow coloured, capsule shaped, biconvex, film-coated tablets debossed with '10' on one side and plain on the other side.

Pravastatin generichealth 20 mg tablets are yellow coloured, capsule shaped, biconvex, film-coated tablets debossed with '20' on one side and plain on the other side.

Pravastatin generichealth 80 mg tablets are yellow coloured, oval shaped, biconvex, film-coated tablets debossed with '80' on one side and 'PRV' on the other side.

Pravastatin generichealth tablets are supplied in blister packs containing 30 tablets.

Ingredients

Active ingredient

Pravastatin generichealth tablet contains 10 mg, 20 mg or 80 mg pravastatin sodium.

Other Ingredients

- lactose monohydrate;
- crospovidone;
- sodium bicarbonate;
- colloidal anhydrous silica;
- magnesium stearate;
- purified water;
- Opadry complete film coating system 03F52262 Yellow.

Australian Registration Numbers

Pravastatin generichealth 10 mg: AUST R 139595

Pravastatin generichealth 20 mg: AUST R 139600

Pravastatin generichealth 80 mg: AUST R 139602

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