

PRAVACHOL(R)

Pravastatin sodium

CONSUMER MEDICINE INFORMATION

What is in this leaflet?

This medicine your doctor has prescribed for you is called PRAVACHOL. The information in this leaflet will answer some of the questions you may have about PRAVACHOL. This leaflet does not tell you everything about PRAVACHOL. 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. This information is not intended to replace your doctor's advice.

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

What is PRAVACHOL used for?

PRAVACHOL 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 PRAVACHOL can reduce the risk of further heart disease, reduce the possibility of needing a bypass operation, or reduce the risk of having a stroke.

PRAVACHOL 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.

PRAVACHOL 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.

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

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

How does PRAVACHOL work?

PRAVACHOL tablets contain 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.

What should I know before I take Pravachol?

Before taking PRAVACHOL, you should be aware of the following:

You should not take PRAVACHOL

- * 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 PRAVACHOL to any one else even if they have the same condition as you have.

What should I tell my doctor before I take PRAVACHOL?

Before you take PRAVACHOL for the first time you should tell your doctor

- * If you are taking other medicines or treatment.
- * If you drink alcohol regularly
- * If you have ever had liver problems.
- * If you have a problem with your kidneys.
- * If you are or may become pregnant.
- * If you are breastfeeding.

- * If you suffer from hormonal disorders.
- * If you suffer from central nervous system vascular lesions.
- * If you suffer from allergies.
- * If you suffer from homozygous familial hypercholesterolaemia, (a doctor will have told you this).
- * If you have increased triglycerides in your blood (a doctor will have told you this also).
- * If you suffer from muscle disease (including pain, tenderness or weakness).

Should I take PRAVACHOL with other medicines?

Some medicines can affect the way PRAVACHOL 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.

Should I drive or operate machinery while taking PRAVACHOL?

PRAVACHOL 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 PRAVACHOL before you drive a car, or operate machinery.

How should I take PRAVACHOL?

PRAVACHOL should only be used as directed by your doctor. Your doctor will decide on the dose of PRAVACHOL, this will depend on many factors including your cholesterol level. The dose for lowering cholesterol is 10 - 80mg, and is 40mg for reducing the possibility of a stroke or heart attack.

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

Take PRAVACHOL once a day in the evening before bed-time. To help you to remember to take your tablet, take it at the same time each day.

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

What side effects might PRAVACHOL cause?

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

The most common side effects of PRAVACHOL are: upset stomach, nausea, diarrhoea, wind, constipation, headache and dizziness.

If you have any of these side effects or any other problem while taking PRAVACHOL tell your doctor as soon as possible. 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 or weakness.

It is also possible to suffer from an allergic reaction to PRAVACHOL, so tell your doctor if you develop a skin rash or itchiness, fever, joint pain or shortness of breath.

What should I do if someone takes an overdose of PRAVACHOL?

Call your doctor immediately if you or someone else has taken too much PRAVACHOL. If your doctor is not available call your nearest hospital or a Poisons Information Centre on 13 11 26.

Is there any other information that I should know about?

PRAVACHOL is not addictive or habit forming. PRAVACHOL is only available upon prescription from your doctor.

How should I store PRAVACHOL?

Store PRAVACHOL in a cool dry place, and keep the tablets in the blister until it is time to take them.

The expiry date for PRAVACHOL is printed on the pack. Do not take PRAVACHOL after the expiry date or if PRAVACHOL tablets have changed in appearance colour or taste. Ask your pharmacist about disposal of unused tablets.

Keep all medicines out of reach of children.

Product description.

What it looks like:

Pravachol 10mg tablet - engraved '10'. AUST R 68706

Pravachol 20mg tablet - engraved '20'. AUST R 68704

Pravachol 40mg tablet - engraved '40'. AUST R 58075

Pravachol 80mg tablet – engraved '80'. AUST R 101491

Pravachol tablets are yellow capsule shaped tablets supplied in blister packs containing 30 tablets per pack.

Active ingredients -

Pravachol 10mg tablets - 10mg pravastatin sodium

Pravachol 20mg tablets - 20mg pravastatin sodium

Pravachol 40mg tablets - 40mg pravastatin sodium

Pravachol 80mg tablets - 80mg pravastatin sodium

Additives -

PRAVACHOL tablets also contain lactose, povidone, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, magnesium oxide and iron oxide-yellow

How current is this information and where can I find out more ?

This leaflet was produced in February 2005 and was based on information known to Bristol-Myers Squibb Pharmaceuticals. You need to consult your doctor regularly as your doctor has access to information on any changes that may affect you.

Who makes PRAVACHOL

PRAVACHOL is made by
Bristol-Myers Squibb
Pharmaceuticals
Division of Bristol-Myers Squibb
Australia Pty Ltd,
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Noble Park VIC 3174,
Australia.

Telephone (03) 9213 4000

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This leaflet in no way replaces the advice of your doctor or pharmacist.

This Consumer Product Information leaflet is produced by Bristol-Myers Squibb to help you understand your medicines better. If you have any queries please ask your doctor or pharmacist.

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