

Consumer Medicine Information**What is in this Leaflet**

The information in this leaflet will answer some of the questions you may have about *APX-PRAVASTATIN*. This leaflet does not tell you everything about the 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 *APX-PRAVASTATIN* and keep it in a safe place to refer to later.

What is it used for

APX-PRAVASTATIN 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 *APX-PRAVASTATIN* can reduce the risk of further heart disease, reduce the possibility of needing a bypass operation, or reduce the risk of having a stroke.

It 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.

It 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.

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

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

It is not addictive or habit forming.

It is only available upon prescription from your doctor.

How does it work

APX-PRAVASTATIN 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.

Before I take it

Before taking *APX-PRAVASTATIN*, 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 any one else even if they have the same condition as you have.

Before you 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 *APX-PRAVASTATIN* 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
- Macrolides
- Propanol
- Bile acid sequestrants
- Digoxin
- Warfarin or other Coumarin anticoagulants

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

It 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 *APX-PRAVASTATIN* before you drive a car, or operate machinery.

How to take it**How much to take**

APX-PRAVASTATIN should only be used as directed by your doctor. Your doctor will decide on the dose, 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.

How to take it

Take *APX-PRAVASTATIN* **once a day** in the evening before bed-time.

For best results, take *APX-PRAVASTATIN* on an empty stomach (ie. two or more hours after your last meal).

Take *APX-PRAVASTATIN* 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 *APX-PRAVASTATIN*, take the next dose normally at your usual time.

Side Effects

All medicines, including *APX-PRAVASTATIN*, can sometimes cause unwanted effects. This is not an exhaustive list.

The most common side effects 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 *APX-PRAVASTATIN*.

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 *APX-PRAVASTATIN*, so tell your doctor if you develop a skin rash or itchiness, fever, joint pain or shortness of breath.

In few cases, statins have been reported to induce de novo or aggravate pre-existing myasthenia gravis or ocular myasthenia.

If you take too much (Overdose)

Call your doctor immediately if you or someone else has taken too much *APX-PRAVASTATIN*.

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

Storage

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

The expiry date is printed on the pack. **Do not take it after the expiry date or if the 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

APX-PRAVASTATIN 10mg tablet - engraved '10'.

AUST R 335750

APX-PRAVASTATIN 20mg tablet - engraved '20'.

AUST R 335751

APX-PRAVASTATIN 40mg tablet - engraved '40'.

AUST R 335752

APX-PRAVASTATIN 80mg tablet – engraved '80'.

AUST R 335753

APX-PRAVASTATIN tablets are yellow capsule shaped tablets supplied in blister packs containing 30 tablets per pack.

Active ingredients

APX-PRAVASTATIN 10mg tablets - 10mg pravastatin sodium

APX-PRAVASTATIN 20mg tablets - 20mg pravastatin sodium

APX-PRAVASTATIN 40mg tablets - 40mg pravastatin sodium

APX-PRAVASTATIN 80mg tablets - 80mg pravastatin sodium

Additives

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

Sponsor & Distributor

Arrow Pharma Pty Ltd
15 – 17 Chapel Street
Cremorne Victoria 3121

This leaflet was revised in October 2023.