

# APX-PRAVASTATIN

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

### 1. Why am I taking APX-PRAVASTATIN?

APX-PRAVASTATIN contains the active ingredient pravastatin sodium, pravastatin sodium 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.

For more information, see Section [1. Why am I taking APX-PRAVASTATIN?](#) in the full CMI.

### 2. What should I know before I take APX-PRAVASTATIN?

Do not use if you have ever had an allergic reaction to APX-PRAVASTATIN or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I take APX-PRAVASTATIN?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with APX-PRAVASTATIN and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I take APX-PRAVASTATIN?

- APX-PRAVASTATIN should only be taken as directed by your doctor.
- Your doctor will decide on the dose, this will depend on many factors including your cholesterol level.

More instructions can be found in Section [4. How do I take APX-PRAVASTATIN?](#) in the full CMI.

### 5. What should I know while taking APX-PRAVASTATIN?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Call your doctor straight away if you suffer from an allergic reaction to APX-PRAVASTATIN, tell your doctor if you develop a skin rash or itchiness, fever, joint pain or shortness of breath.</li><li>• Call your doctor straight way if you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking this medicine suddenly.</li><li>• Do not give your medicine to anyone else even if they have the same condition as you have.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how APX-PRAVASTATIN affects you.</li><li>• APX-PRAVASTATIN may cause dizziness in some people. It generally does not interfere with your ability to drive or operate machinery.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store below 25°C and protect from light and moisture.</li></ul>

For more information, see Section [5. What should I know while taking APX-PRAVASTATIN?](#) in the full CMI.

### 6. Are there any side effects?

There are a number of side effects associated with APX-PRAVASTATIN. It is important to be aware of them so that you can identify any symptoms if they occur. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# APX-PRAVASTATIN

Active ingredient: *Pravastatin sodium*

## Consumer Medicine Information (CMI)

This leaflet provides important information about taking APX-PRAVASTATIN. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking APX-PRAVASTATIN.**

**Where to find information in this leaflet:**

- [1. Why am I taking APX-PRAVASTATIN?](#)
- [2. What should I know before I take APX-PRAVASTATIN?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I take APX-PRAVASTATIN?](#)
- [5. What should I know while taking APX-PRAVASTATIN?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I taking APX-PRAVASTATIN?

APX-PRAVASTATIN contains the active ingredient pravastatin sodium. 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 medicine every day.

It is not addictive or habit forming.

It is only available upon prescription from your doctor.

## 2. What should I know before I take APX-PRAVASTATIN?

### Warnings

**Do not take APX-PRAVASTATIN if:**

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

**Check with your doctor if you:**

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

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

## 3. What if I am taking other medicines?

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

**Some medicines may interfere with APX-PRAVASTATIN and affect how it works.** It is especially important that you tell your doctor if you are taking any of the following:

- Any other medicine to lower cholesterol.
- Ciclosporin.
- Ketoconazole.
- Spironolactone.
- Cimetidine.
- Fibrates e.g. gemfibrozil, fenofibrate.
- Cholestyramine and colestipol.
- Antacids.
- Macrolide antibiotics (e.g. erythromycin, clarithromycin, roxithromycin).
- Propranolol.
- Bile acid sequestrants.
- Digoxin.
- Warfarin or other Coumarin anticoagulants.
- Lenalidomide.
- Fusidic acid.
- Colchicine.
- Nicotinic acid.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APX-PRAVASTATIN.**

## 4. How do I take APX-PRAVASTATIN?

### How much to take

APX-PRAVASTATIN should only be taken 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 - 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 - 13 years of age and 40 mg once daily in adolescents 14 - 18 years of age, with heterozygous familial hypercholesterolemia. Follow the instructions provided and use APX-PRAVASTATIN until your doctor tells you to stop.

### How to take APX-PRAVASTATIN

Take APX-PRAVASTATIN once a day in the evening before bedtime. For best results, take APX-PRAVASTATIN on an empty stomach (i.e. 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 APX-PRAVASTATIN

APX-PRAVASTATIN should be taken regularly at the same time each day. If you forget to take a dose of APX-PRAVASTATIN, take the next dose normally at your usual time.

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

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

## If you take too much APX-PRAVASTATIN

If you think that you have taken too much APX-PRAVASTATIN, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while taking APX-PRAVASTATIN?

### Things you should do

**Call your doctor straight away if you:**

- suffer from an allergic reaction to APX-PRAVASTATIN, tell your doctor if you develop a skin rash or itchiness, fever, joint pain or shortness of breath.
- have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia.

Remind any doctor, dentist or pharmacist or other health professionals you visit that you are taking APX-PRAVASTATIN.

### Things you should not do

- Do not stop taking this medicine suddenly.
- Do not give your medicine to anyone else even if they have the same condition as you have.

### Driving or using machines

**Be careful before you drive or use any machines or tools until you know how APX-PRAVASTATIN affects you.**

APX-PRAVASTATIN may cause dizziness and visual disturbances in some people. It generally does not interfere with your ability to drive or operate machinery.

### Drinking alcohol

**Tell your doctor if you drink alcohol.**

### Looking after your medicine

- Store in the blister pack until it is time to take them.
- Store below 25°C and protect from light and moisture.

Follow the instructions on the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

**Keep it where young children cannot reach it.**

## When to discard your medicine

**The expiry date is printed on the carton. Do not take it after the expiry date or if the tablets have changed in appearance colour or taste.**

## Getting rid of any unwanted medicine

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Nervous system related</b></p> <ul style="list-style-type: none"> <li>• Dizziness.</li> <li>• Tiredness.</li> <li>• Headache or sleep disturbances including insomnia.</li> </ul> <p><b>Vision related</b></p> <ul style="list-style-type: none"> <li>• Blurred or double vision.</li> </ul> <p><b>Gastrointestinal related</b></p> <ul style="list-style-type: none"> <li>• Indigestion.</li> <li>• Nausea.</li> <li>• Vomiting.</li> <li>• Stomach pain or discomfort.</li> <li>• Diarrhoea.</li> <li>• Constipation.</li> <li>• Wind.</li> </ul> <p><b>Skin and hair related</b></p> <ul style="list-style-type: none"> <li>• Itching.</li> <li>• Pimples.</li> <li>• Hives.</li> <li>• Rashes.</li> <li>• Scalp and hair problems (including hair loss).</li> </ul> <p><b>Urinary Related</b></p> <ul style="list-style-type: none"> <li>• Bladder problems (painful or more frequent urination, having to pass urine at night).</li> </ul> <p><b>Genital Related</b></p> <ul style="list-style-type: none"> <li>• Sexual dysfunction.</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p> <p><b>Your doctor may arrange blood tests.</b></p>

## Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• Unexplained muscle pain.</li> <li>• Muscle rupture.</li> <li>• Tenderness.</li> <li>• Weakness.</li> <li>• Muscle cramps.</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people. If you take too much (Overdose), call your doctor immediately if you or someone else has taken too much APX-PRAVASTATIN.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

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

### What APX-PRAVASTATIN contains

<b>Active ingredient (main ingredient)</b>	Pravastatin sodium
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• Lactose</li> <li>• Povidone</li> <li>• Microcrystalline cellulose</li> <li>• Croscarmellose sodium</li> <li>• Magnesium stearate</li> <li>• Magnesium oxide</li> <li>• Iron oxide yellow</li> </ul>
<b>Potential allergens</b>	Contains sugars as lactose.

APX-PRAVASTATIN is gluten and sucrose free.

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What APX-PRAVASTATIN looks like**

### **APX-PRAVASTATIN 10 mg Tablet\***

Yellow capsule shaped tablet with “10” engraved on one side.

Blister pack of 3, 30 and 100 tablets\*. AUST R 335750.

### **APX-PRAVASTATIN 20 mg Tablet\***

Yellow capsule shaped tablet with “20” engraved on one side.

Blister pack of 3, 30 and 100 tablets\*. AUST R 335751.

### **APX-PRAVASTATIN 40 mg Tablet\***

Yellow capsule shaped tablet with “20” engraved on one side.

Blister pack of 3, 5, 7 and 30 tablets\*. AUST R 335752.

### **APX-PRAVASTATIN 80 mg Tablet\***

Yellow capsule shaped tablet with “80” engraved on one side.

Blister pack of 30 tablets\*. AUST R 335753.

\*Not all strengths and pack sizes may be available.

## **Who distributes APX-PRAVASTATIN**

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne

VIC 3121

[www.arrotex.com.au](http://www.arrotex.com.au)

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