

Consumer Medicine Information (CMI) summary

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

1. Why am I taking Tambocor?

Tambocor contains the active ingredient flecainide acetate. Tambocor tablets and injection are used to treat a heart condition called arrhythmia. Arrhythmia is an irregular or abnormal heartbeat.

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

2. What should I know before I use Tambocor?

Do not use if you have ever had an allergic reaction to Tambocor 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 use Tambocor?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Tambocor 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 use Tambocor?

- The usual starting dose of Tambocor tablets is 50 mg to 100 mg every 12 hours. The usual maximum dose is 300 mg a day. However, some patients may need up to 400 mg a day. Follow your doctor's instructions exactly.
- The dose for Tambocor IV injection is usually around 2 mg/kg body weight and is given in a hospital. Your doctor may vary the dose to suit your condition.

More instructions can be found in Section [4. How do I use Tambocor?](#) in the full CMI.

5. What should I know while taking Tambocor?

Things you should do	<ul style="list-style-type: none">• If you are about to start on any new medicines, remind your doctor and pharmacist that you are taking Tambocor tablets or are being given Tambocor injection• If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Tambocor.
Things you should not do	<ul style="list-style-type: none">• Follow your doctor's instructions exactly. Do not stop taking Tambocor or lower the dose without first checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Tambocor can cause dizziness, light headedness, faintness and problems with your vision, therefore do not drive or use any machines or tools.
Looking after your medicine	<ul style="list-style-type: none">• Tambocor tablets: keep in their blister pack and carton until it is time to take them. Store in a cool dry place where the temperature stays below 30°C.• Keep out of reach of children.• Tambocor injection: will usually be stored in the hospital pharmacy and the pharmacist will ensure that it is safely stored before use.

For more information, see Section [5. What should I know while using Tambocor?](#) in the full CMI.

6. Are there any side effects?

Common side effects include minor and temporary dizziness, blurred eyesight, double vision and not able to stand bright lights, nausea, difficulty breathing, tiredness, headache and chest pain.

Serious side effects include irregular or rapid heartbeat and dizziness.

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.

Tambocor[®] (tam-bo-core)

Active ingredient: *Flecainide acetate* (fleck-ain-ide-ass-e-tate)

Consumer Medicine Information (CMI)

This leaflet provides important information about using Tambocor tablets and injection. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Tambocor tablets and injections.**

Where to find information in this leaflet:

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

1. Why am I taking Tambocor?

Tambocor contains the active ingredient flecainide acetate. Tambocor belongs to a group of drugs called antiarrhythmic medicines which slow down the impulses that cause the heart to beat in an irregular or abnormal way.

Tambocor is used to treat a heart condition called arrhythmia. Arrhythmia is an irregular or abnormal heartbeat.

2. What should I know before I take Tambocor?

Warnings

Do not use Tambocor:

- If you are allergic to flecainide acetate, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
- 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
- Always check the ingredients to make sure you can use this medicine
- If you have heart, liver, or kidney disease unless your doctor says it is suitable for you
- If the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- Have used Tambocor before and had any problems you think may have been caused by it
- Have problems with your heart, liver or kidney
- Take any medicines for any other condition.

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

Do not take Tambocor tablets or be given Tambocor injection if you are pregnant or intend to become pregnant. Tambocor may affect your developing baby if you take it during pregnancy.

Talk to your doctor if you are breastfeeding or intend to breastfeed. There is a possibility that the active ingredient in Tambocor passes into breast milk and may affect your baby.

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.

It is particularly important to tell your doctor or pharmacist if you are taking any medicines to treat:

- High blood pressure, angina or other heart conditions
- Stomach ulcers.

Some medicines may interfere with Tambocor and affect how it works.

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

4. How do I take Tambocor?

How much Tambocor to take

Tablets

- In adults the usual starting dose of Tambocor tablets is 50 mg to 100 mg every 12 hours. Your doctor may gradually increase this dose. The usual maximum dose is 300 mg a day. However, some patients may need up to 400 mg a day
- Follow your doctor's instructions exactly. Never change the dose yourself. Do not stop taking Tambocor unless your doctor tells you to because if you suddenly stop taking Tambocor it may make your condition worse.

Injection

- The dose for Tambocor IV injection is usually around 2 mg/kg body weight and is given in a hospital. Your doctor may vary the dose to suit your condition.

How to take Tambocor

Tablets

Swallow your tablets with plenty of water. You can take Tambocor tablets before or after meals.

If you forget to take Tambocor

Tablets

Take Tambocor tablets regularly at the same time each day. If you miss your dose at the usual time, take them as soon as you remember.

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 miss two or more doses, talk to your doctor.

Injection

Your doctor will ensure that you are given the correct dose at the required time.

If you take too much Tambocor

Tablets

If you think that you have taken too many Tambocor tablets, 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.

Injection

The hospital doctor will ensure you are given the correct dose of Tambocor injection but if you are worried about receiving too much Tambocor injection speak to the doctor.

5. What should I know while taking Tambocor?

Things you should do

If you are about to start on any new medicines, remind your doctor and pharmacist that you are taking Tambocor tablets or are being given Tambocor injection.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking Tambocor. It may affect other medicines used during surgery.

Call your doctor straight away if you:

Become pregnant while taking Tambocor tablets or are being given Tambocor injection.

Remind any doctor, dentist or pharmacist you visit that you are taking Tambocor.

Things you should not do

Do not stop taking Tambocor or lower the dose without first checking with your doctor.

Driving or using machines

Tambocor can cause dizziness light headedness, faintness and problems with your vision, therefore do not drive or use any machines or tools.

Looking after your medicine

Tablets

- Store below 30 °C.
- Keep Tambocor tablets in their blister pack and carton until it is time to take them.

Follow the instructions in 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 window sills.

Keep it where young children cannot reach it.

Injection

- Tambocor injection will usually be stored in the hospital pharmacy and the pharmacist will ensure that it is safely stored before use

Getting rid of any unwanted medicine

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

Do not use 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
<ul style="list-style-type: none"> • Minor and temporary dizziness • Blurred eyesight, double vision, cannot stand bright lights • Nausea • Difficulty breathing • Tiredness • Headache • Chest pain 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Irregular or rapid heartbeat • Dizziness (do not stop taking Tambocor but see your doctor or pharmacist) 	<p>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.</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.

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. 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 Tambocor Tablets contain

Active ingredient (main ingredient)	Flecainide acetate
Other ingredients (inactive ingredients)	Starch Croscarmellose sodium Cellulose Vegetable oil Magnesium stearate
Potential allergens	None

What Tambocor Injections contain

Active ingredient (main ingredient)	Flecainide acetate
Other ingredients (inactive ingredients)	Acetic acid Sodium acetate Water for injections
Potential allergens	None

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

What Tambocor looks like

Tambocor 50 mg tablets are white, round tablets marked TR50 on one side and plain on the other packed in blisters. Each pack contains 60 tablets (AUST R 41001).

Tambocor 100 mg tablets are white, round tablets marked TR100 on one side and plain on the other packed in blisters. Each pack contains 60 tablets (AUST R 41002).

Tambocor IV injection is a clear, colourless solution in a clear glass ampoule. Each pack contains 5 ampoules (AUST R 10592).

Who distributes Tambocor

iNova Pharmaceuticals (Australia) Pty Limited

Level 10, 12 Help Street

Chatswood NSW 2067

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