

Tambocor 50 mg & 100 mg Tablets

Flecainide acetate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet:

1. What Tambocor is and what it is used for
2. What you need to know before you take Tambocor tablets
3. How to take Tambocor tablets
4. Possible side effects
5. How to store Tambocor tablets
6. Contents of the pack and other information.

1. What Tambocor is and what it is used for

Tambocor tablets belong to a group of medicines called anti-arrhythmics. Anti-arrhythmics work by controlling the rate and rhythm of the heart.

Tambocor tablets are used to treat:

- Arrhythmias (irregular heart beat)
- Tachycardia (heart beat too fast)
- Atrial fibrillation (rapid contractions of muscles in the heart).

It is important for your doctor to treat these conditions quickly and effectively in order to prevent more serious heart problems from developing.

There are two strengths of tablet available, 50 mg and 100 mg.

2. What you need to know before you take Tambocor tablets

Do not take Tambocor tablets if:

- You are allergic to flecainide acetate or any of the other ingredients of Tambocor tablets (see Section 6)
- You have heart failure
- You have cardiogenic shock (your heart is unable to pump as much blood as your body needs)
- You have heart block (your heart misses beats)
- You have long-standing atrial fibrillation (rapid contractions of muscles in the heart)

- You have or have ever had any heart problems including problems with the valves in your heart or conduction problems
- You have sinus node dysfunction (a specific condition where your heart beats abnormally)
- You have had a myocardial infarction (heart attack)
- You have Brugada Syndrome, a genetic disease that causes severe disturbances of the rhythm of the heart and may lead to sudden death in apparently healthy individuals.
- You are pregnant or breast-feeding.

Tambocor tablets are not recommended for use in children under 12 years of age, however, dairy products such as milk, infant formula and possibly yoghurt, may reduce how much Tambocor is absorbed in children and infants.

If any of the above applies to you tell your doctor or nurse.

Before you take Tambocor tablets your doctor or nurse may check:

- Your fluid levels are correct
- Your liver and kidney functions.

This is to check that Tambocor tablets are right for you and to help the doctor calculate the dose you need.

Check with your doctor or nurse before taking

Tambocor tablets if:

- You have high blood pressure
- You have angina (chest pains)
- You have heart disease
- You have kidney disease or kidney problems
- You have liver disease or liver problems
- You wear a pacemaker.

Tell your doctor or nurse if you are taking any of the following medicines:

- Any other medicine used to treat heart arrhythmias or heart problems such as cardiac glycosides, beta-blockers, verapamil, propranolol or amiodarone
- Medicines to treat high blood pressure
- Antidepressants (medicines used to treat depression), such as tricyclic antidepressants, Prozac, fluoxetine, paroxetine or reboxetine
- Anticonvulsants (medicines used to prevent epileptic fits) such as phenytoin, phenobarbital or carbamazepine
- Antipsychotics (medicines to treat mental illness) such as clozapine
- Antihistamines (medicines to treat allergic reactions) such as mizolastine or terfenadine
- Quinine (medicine to treat malaria)

- Medicines to treat HIV such as ritonavir, lopinavir or indinavir
- Diuretics (water tablets)
- Cimetidine (medicine to treat stomach ulcers)
- Bupropion (a medicine to help stop you smoking)
- Any other medicine, including medicines obtained without a prescription.

These medicines may interfere with your treatment.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask the doctor or nurse for advice before taking Tambocor tablets.

Driving and using machines:

Driving ability, operation of machinery and work without a secure fit may be affected by adverse reactions such as dizziness and visual disturbances (if present).

3. How to take Tambocor tablets

Always take Tambocor tablets exactly as your doctor has told you.

Important:

Your doctor will choose the dose that is right for your condition. Usually your treatment with Tambocor tablets will be started in hospital.

If you have switched from a different formulation (e.g. from an injection of Flecainide) your doctor should do so with caution and monitor you closely.

Adults:

Supraventricular arrhythmias (Irregular heart beat that starts in the upper chambers of your heart)

- Tambocor 50mg tablets: The usual dose is one tablet twice a day.
- Tambocor 100mg tablets: The usual dose is half a tablet twice a day.

Your doctor may prescribe up to a total dose of 300 mg daily (3 x 100 mg tablets or 6 x 50 mg tablets).

Ventricular arrhythmias (Irregular heart beat that starts in the lower chambers of your heart)

- Tambocor 50mg tablets: The usual dose is two tablets twice a day.

Tambocor 100mg tablets: The usual dose is one tablet twice a day

Your doctor may prescribe up to a total dose of 400 mg daily (4 x 100 mg tablets or 8 x 50 mg tablets).

The elderly and patients with kidney or heart problems:

- For elderly patients, and patients with kidney or heart problems, the doctor may tell you to take a lower dose.

While you are taking this medicine, your doctor may ask you to have check-ups. These are to make sure that your medicine is working properly and that the dose you are taking is right for you.

Children:

- Tambocor tablets are not recommended for children under 12 years of age, however, dairy products such as milk, infant formula and possibly yoghurt, may reduce how much Tambocor is absorbed in children and infants.

If you take more Tambocor tablets than you should If you accidentally take too much, immediately go to the nearest hospital casualty department.

If you forget to take Tambocor tablets

Do not take a double dose to make up for a missed dose. Simply take the next dose as planned.

If you stop taking Tambocor tablets

Do not stop taking Tambocor tablets without first talking to your doctor. If you have any further questions about the use of this medicine, ask your doctor or nurse.

4. Possible side effects

Like all medicines Tambocor tablets can cause side effects, although not everybody gets them.

Some side effects could be serious. If you have any of the side effects listed below, seek immediate medical help:

Common (affects 1 in 100 people):

- Your heartbeat changes; it starts to pound, or it gets faster or slower
- You have chest pain
- You become breathless or have other breathing problems
- You have a fever, become flushed or sweat
- You faint or you feel faint

Rare (affects 1 in 10,000 people):

- You have ringing in your ears
- Your skin and eyes begin to go yellow (jaundice)
- You have fits (convulsions).

Other side effects (how often they happen is unknown):

- heart attack
- cardiac failure/arrest (loss of breathing, and consciousness and loss of heart function)

Other side effects include the following, if they get serious, please tell your doctor:

Very common (affects more than 1 in 10 people):

- Dizziness
- Double or blurred vision

Common (affects 1 in 100 people):

- Feeling weak or tired
- Lack of energy and strength
- Swelling (fluid retention)

Uncommon (affects 1 in 1,000 people):

- Blood disorders (reduced red and white blood cell count and reduced platelet count)
- Feeling or being sick
- Constipation
- Stomach pain or indigestion
- Loss of appetite
- Diarrhoea
- Wind
- Feeling bloated
- Red, itchy or swollen skin rash
- Hair loss

Rare (affects 1 in 10,000 people):

- vertigo (feeling like the room is spinning)
- Confusion and hallucinations

Depression

- Feeling anxious (worried)
- Forgetfulness
- Difficulty sleeping
- Numbness, tingling, tickling, prickling or burning sensation of the skin
- Unsteady walking, uncontrolled movements or poor coordination, difficulty speaking
- Reduced sense of touch
- Excessive sweating and flushed skin
- Shaking (tremors)
- A strong desire to sleep or sleep for long periods
- Headache

Very rare (affects less than 1 in 10,000 people):

- Small cloudy spots on the eyeball
- Sensitivity of the skin to sunlight

Other side effects (how often they happen is unknown):

- lung disease and scarring of the lungs
- liver disease

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tambocor tablets

Keep out of the reach and sight of children.

Do not store above 30°C.

Keep tablets in the outer carton in order to protect from light and moisture.

Do not use Tambocor tablets after the expiry date on the carton. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste.

Return any medicine you no longer need to your pharmacist.

6. Contents of the pack and other information What Tambocor tablets contain

- The active substance in Tambocor tablets is flecainide acetate. Each 50 mg tablet contains 50 mg of flecainide acetate. Each 100 mg tablet contains 100 mg flecainide acetate.
- The other ingredients are pregelatinised starch, croscarmellose sodium, microcrystalline cellulose (E460i), hydrogenated vegetable oil, magnesium stearate (E572).

What Tambocor tablets look like

Tambocor 50 mg tablets are round, white and marked '3M' on one side and 'TR50' on the other.

Tambocor 100 mg tablets are round, white and marked '3M' on one side and 'TR100' with a break line on the other.

Both strengths of Tambocor tablets come in blister packs containing 60 tablets.