

## Package leaflet: Information for the patient

### 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 pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### 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 beating 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 this medicine (listed in Section 6)
- have heart failure
- have cardiogenic shock (your heart is unable to pump as much blood as your body needs)
- have heart block (your heart misses beats)
- have long-standing atrial fibrillation (rapid contractions of muscles in the heart)
- have or have ever had any heart problems, including problems with the valves in your heart or conduction problems
- have sinus node dysfunction (a specific condition where your heart beats abnormally)
- have had a myocardial infarction (heart attack)
- 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
- are pregnant or breast-feeding.

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

**Before you take Tambocor tablets your doctor 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.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Tambocor tablets if you:

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

**Children**

Tambocor tablets are not recommended for children under 12 years of age.

**Other medicines and Tambocor tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including those obtained without a prescription, and in particular, any of the following:

- 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, 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 you stop smoking).

These medicines may interfere with your treatment.

**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

**Driving and using machines**

Do not drive or operate machinery if you feel dizzy or drowsy, or have eyesight problems while taking this medicine.

**Information about ingredient of Tambocor tablets**

This medicine contains less than 1 mmol sodium (23mg) per tablet, that is to say essentially 'sodium-free'.

**3. How to take Tambocor tablets**

Always take Tambocor tablets exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**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 recommended dose is one tablet twice a day
  - Tambocor 100mg tablets: The recommended 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 recommended dose is two tablets twice a day
  - Tambocor 100mg tablets: The recommended 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 flecainide acetate 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 on the use of this medicine, ask your doctor or pharmacist.

## **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 (may affect up to 1 in 10 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 (may affect up to 1 in 1,000 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 (may affect more than 1 in 10 people):**

- Dizziness
- Double or blurred vision

**Common (may affect up to 1 in 10 people):**

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

**Uncommon (may affect up to 1 in 100 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 (may affect up to 1 in 1,000 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 sleeping for long periods
- Headache

**Very rare (may affect up to 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
- Joint pain and muscle pain

**Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. 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](http://www.mhra.gov.uk/yellowcard), or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

**5. How to store Tambocor tablets**

Keep this medicine out of the sight and reach 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 which is stated on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

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

- The active substance 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 and contents of the pack**

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.

**Marketing Authorisation Holder**

TEVA UK Limited, Eastbourne, BN22 9AG, United Kingdom

**Manufacturer**

3M Health Care Limited, Derby Road, Loughborough, LE11 5SF, UK

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