Package Leaflet: Information for the user
Tambocor 50 mg and 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.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. WHAT TAMBOCOR TABLETS ARE AND WHAT IT IS USED FOR

Tambocor tablets contain the active ingredients flecainide, which belongs to a group of medicines called anti-arrhythmics, which control the speed and rhythm of the heart.

Tambocor tablets are used to treat:
- Arrhythmias (irregular heart beat such as Wolff-Parkinson White Syndrome)
- Tachycardia (fast heart beat)
- Fibrillation (rapid contraction of muscles in the heart)

2. WHAT YOU NEED TO KNOW BEFORE YOU USE TAMBOCOR TABLETS

Do not take Tambocor tablets:
- If you are allergic to flecainide or any of the other ingredients of this medicine (listed in section 6). An allergic reaction may include rash, itching, difficulty breathing or swelling of the face, lips, throat or tongue.
- If you are using class 1 anti-arrhythmics (e.g., quinidine, procainamide)
- If you have had heart problems such as heart failure, heart attack, heart valve or conduction problems - your doctor will study your medical history
- If you have been told you have an electrolyte imbalance (altered blood salts)
- If you have cardiogenic shock
- If you suffer from known Brugada syndrome

Warnings and precautions
Talk to your doctor or pharmacist before taking Tambocor tablets if you have any of the following conditions:
- If you have liver disease
- If you have a pacemaker
- If you have or have had heart failure
- If you have an enlarged heart
- If you have ever had a heart attack
- If you have or have had angina
- If you have heart disease

- If you have rapid and irregular heart beat after surgery
- If you have severe hepatic disease
- If you have impaired renal function

You will be monitored to check your fluid balance and salts.

Children
Tambocor is not recommended in children under 18 as there is not enough evidence of its use.

Other medicines and Tambocor tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You should tell your doctor if you are taking or have taken any of the following medicines as they may interact with your Tambocor tablets:

- Digoxin (used to treat heart failure)
- Drugs that affect the heart such as beta blockers or verapamil (used to treat high blood pressure)
- Other anti-arrhythmic drugs such as amiodarone
- Antidepressants such as fluoxetine, paroxetine, reboxetine and tricyclic antidepressants
- Drugs for epilepsy such as phenytoin, Phenobarbital, carbamazepine
- Clozapine (used to treat mental illness)
- Antihistamines such as mizolastine or terfenadine (used to treat hayfever and allergies)
- Quinine (used to treat and prevent malaria)
- Ritonavir (used to treat HIV [AIDS])
- Diuretics (water tablets)
- Cimetidine (an ulcer healing drug)
- Bupropion (an anti-smoking aid)
- Terbinafine (an antifungal drug)

It may still be all right for you to be given Tambocor and your doctor will be able to decide what is suitable for you.

Pregnancy and breast-feeding
You should not take Tambocor while pregnant or breast-feeding unless your doctor tell you to.
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
It is advisable not to drive, operate machinery or do anything that requires you to be alert until you know how Tambocor affects you. This is because Tambocor can cause blurred vision or dizziness in some people.

Tambocor tablets contain sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially ‘sodium-free’.

3. HOW TO USE TAMBOCOR TABLETS

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Treatment should take place in hospital.

Adults
The usual dose is 100 mg twice a day up to a maximum dose of 400 mg per day.
Some patients, particularly those with supra-ventricular tachycardia will be adequately controlled on 50 mg twice daily.
Your dose will be adjusted so that you benefit from the lowest dose.

Elderly and patients with liver or kidney disease
Elderly patients or patients with liver or kidney disease may need a lower dose.
Patients with liver or kidney disease may need a reduced dose.

If you take more Tambocor tablets than you should
It is unlikely that you will be given the wrong dose of Tambocor as treatment is usually given in hospital.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

All medicines can cause allergic reactions, although serious allergic reactions are very rare. Tell your doctor straight away if you get any sudden wheeziness, difficulty in breathing, swelling of the eyelids, face or lips, rash or itching (especially affecting your whole body).

The following side effects have been reported:

Weakness, tiredness, fever, swelling, missed heart beats, slow heart beat, heart failure, chest pain, low blood pressure, heart attack, fast or irregular heart beat, rash, hair loss, light sensitivity, feeling sick, vomiting, tummy pain, anorexia (loss of appetite), constipation, diarrhoea, indigestion, flatulence (wind).

Also, raised liver enzymes and changes in the numbers of blood cells (your doctor can detect these with a blood test), yellow eyes and skin, itching, liver failure, dizziness, light-headedness, headache, muscle weakness and cramps, muscle pain, pins and needles, lack of co-ordination, joint pain, flushing, numbness, and increased sweating.

Sleepiness, fainting, ringing in the ears, tremor, spinning sensation, double vision, blurring of vision, corneal deposits (spots on the eye surface), breathlessness, inflammation of the lungs, depression, anxiety, confusion, hallucination and sleeplessness.

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 reporting systems listed below:

Ireland
HPRA Pharmacovigilance
Website: www.hpra.ie

Malta:
ADR Reporting
Website: www.medicinesauthority.gov.mt/adrportal

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 use this medicine after the expiry date which is stated on the original carton and blister after "EXP". The expiry date refers to the last day of that month.
In order to protect from light and moisture keep the tablets in the outer carton.

Store in the original package below 30°C.
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
Each tablet contains 50 mg or 100 mg of the active ingredient flecainide acetate. The tablet can be divided into equal halves.
The other ingredients are: microcrystalline cellulose, pregelatinised maize starch, magnesium stearate, croscarmellose sodium, hydrogenated vegetable oil.

What Tambocor tablets look like and contents of the pack
Tambocor 100 mg are white, circular, biconvex tablets with a break-line.
Tambocor 50 mg are white, circular, biconvex tablets.

Tambocor tablets come in blister packs of 60 tablets.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Mylan IRE Healthcare Limited,
Unit 35/36, Grange Parade,
Baldoyle Industrial Estate,
Dublin 13,
Ireland

Manufacturer
Rottapharm Ltd.
Damastown Industrial Park,
Mulhuddart,
Dublin 15
Ireland

Mylan Hungary Kft.
Mylan utca 1
Komárom H-2900
Hungary

This leaflet was last revised in December 2020