Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a physician's prescription only

Tambocor 50 mg Tablets
Tambocor 100 mg Tablets

Active ingredient:
Each tablet contains:
flecainide acetate 50 mg, 100 mg

For a list of inactive ingredients and allergens, see section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your physician or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

1. What is this medicine intended for?

Tambocor 50 mg Tablets: to treat serious sustained life-threatening supraventricular arrhythmias that have not responded to other drugs.
To treat paroxysmal atrial fibrillation and atrial flutter.
Tambocor 100 mg Tablets: to treat serious sustained life-threatening ventricular arrhythmias that have not responded to other drugs.
To treat paroxysmal atrial flutter.

Therapeutic group: antiarrhythmic agents.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to the active ingredient flecainide acetate or to any of the other ingredients in this medicine (see section 6 'Additional information').
- You have heart failure or certain types of heart rhythm disorders.
- You have heart valve disease.
- You have a serious heart condition called cardiogenic shock. This is a condition in which the heart is unable to supply the body its required amount of blood and this causes rapid breathing, weakness, looking pale, confusion and can lead to loss of consciousness.
- You have a history of heart attack.
- You have low blood pressure or slow heart rhythm.
- You have a genetic disease (Brugada syndrome), which causes serious heart rhythm disorders and may cause sudden death.
- You are already taking disopyramide to regulate your heartbeat.

Special warnings about using this medicine:

Please note, every time you get this medicine at the pharmacy, it is important that you make sure that you have been given the same medicine that your cardiologist has prescribed you. If the medicine you are given looks different from what you usually get, or if the instructions for use have changed, please consult your pharmacist immediately to make sure you received the correct medicine. Any change in medicine

or dosage of medicine containing flecainide acetate (the active ingredient in this medicine) must be made with the knowledge and approval of your cardiologist. Please compare the brand name of the medicine that your physician prescribed to the name of the medicine you got from the pharmacist, and make sure they are the same.

Before taking Tambocor Tablets, tell your physician if:

- You know you have high or low levels of salt (such as potassium) in your blood.
- You have an enlarged heart, or certain types of heart disease.
- You have a kidney disease or kidney problems.
- You have a liver disease or liver problems.
- You have a heart rhythm disorder called 'sick sinus syndrome'**.**
- You have a pacemaker.

Before you start treatment with Tambocor Tablets your physician may wish to start treatment in hospital in order to perform an ECG and monitor the levels of the medicine in your blood. You may be required to have these tests when the dosage of the medicine is changed or when the form of administration is switched (for example, when switching from Tambocor injection).

Children and adolescents
This medicine is not intended for children under 12 years old.

Other medicines and Tambocor Tablets:

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell the physician or pharmacist. Particularly if you are taking:

- additional anti-arrhythmic medicines or medicines to treat other heart conditions such as: digoxin, quinidine, beta-blockers (such as: atenolol, propranolol), amiodarone, verapamil
- antidepressant medicines such as: fluoxetine, paroxetine, reboxetine**,** and tricyclic anti-depressant medicines such as imipramine
- anti-epileptic medicines such as: phenytoin, phenobarbital, carbamazepine
- antipsychotic medicines such as: clozapine
- antihistamine medicines for allergic reactions, such as: mizolastine, terfenadine
- anti-malarial medicine such as quinine
- antiviral medicines such as: ritonavir, fixed-combination products containing ritonavir
- diuretic medicines such as: furosemide
- corticosteroids for inflammatory conditions such as: arthritis, for example prednisolone
- laxatives to treat constipation
- medicines for stomach ulcers such as: cimetidine
- antismoking aid and antidepressant medicine such as: bupropion
- antifungals such as: terbinafine

Using this medicine with food
Dairy products like milk, infant formula and yoghurt have been shown to reduce the absorption of **Tambocor Tablets** in children and infants.
It is unknown whether this effect on absorption is the same in adults.
Talk to your pharmacist or physician for advice.

Pregnancy, breastfeeding, and fertility
If you are pregnant, planning to become pregnant or are breastfeeding, ask your physician for advice before taking **Tambocor Tablets**.
Tambocor Tablets should not be given to pregnant or breastfeeding mothers unless the benefits to the mother outweigh the risks to the baby.
If your physician does decide to give you **Tambocor Tablets**, you must be monitored closely during your pregnancy.

Driving and using machines
Using this medicine may affect your ability to drive or operate dangerous machines. Avoid driving if you feel that this medicine makes you feel dizzy or drowsy, or if it causes vision problems. Additionally, use caution when riding a bicycle or playing near a road.

Important information about some of this medicine's ingredients
This medicine contains less than 1 mmol sodium (23 mg) per tablet, and can therefore be considered "*sodium free*".

3. How to use this medicine?
Always use according to your physician's instructions. If you are not sure about the dosage or treatment regimen, consult your physician or pharmacist.
Only your physician will determine your dose and how you should take this medicine.

Do not take a higher dose than the dose your physician has prescribed you.

The recommended dosage is usually:

Adults:
Supraventricular arrhythmia:
The usual starting dose is 50 mg twice daily. If necessary, your physician may increase this starting dose to a maximum dose of 300 mg a day.

Ventricular arrhythmia:
The usual starting dose is 100 mg twice daily. The maximum daily dose is 400 mg. In most cases, the maximum dose is given to patients with large build or if it is necessary to quickly control the rhythm disorders.

After 3-5 days of using the medicine, it is advisable to gradually adjust the dose to the lowest dose you need. It may be possible to continue lowering your dose over the course of this treatment.

Patients with kidney failure:
In patients with significant kidney failure, the maximum starting dose is 100 mg daily (or 50 mg twice daily). When used in such patients, frequent plasma level monitoring is strongly recommended.

Elderly
If you are elderly, your physician may prescribe a lower starting dose for you.

Children
Use in children under 12 years old is not recommended, as there is insufficient evidence of its use in this age group.

During treatment with the medicine, in certain cases, medical supervision may be required in the hospital or by a specialist.

Do not exceed the recommended dose.

How to take this medicine:

- This medicine must be taken orally (by swallowing).
- Do not chew! Swallow the medicine with water.
- **Tambocor 100 mg tablets** can be cut in half to get a dose of 50 mg.

If you have accidentally taken a higher dose, or if a child has accidentally swallowed some medicine, **immediately** see a physician or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine at the scheduled time, take the next dose as soon as you remember unless it is time for your next dose. Do not take a double dose; consult your physician.

Adhere to the treatment as recommended by your physician.
Even if your health improves, do not stop taking this medicine or change the dose without consulting your physician. **If you suddenly stop taking Tambocor Tablets** you may experience side effects.

Do not stop taking this medicine unless your physician has told you to stop.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your physician or pharmacist.

4. Side effects

Like with all medicines, using **Tambocor Tablets** may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Some of the side effects may be serious, if you experience the following side effects, stop taking Tambocor Tablets and tell your physician immediately or go to the nearest emergency room:

<u>Common side effects (may affect 1-10 in 100 users):</u>

- fast or irregular heartbeat

<u>Rare side effects (may affect up to 1-10 in 10,000 users):</u>

- inflammation of the lungs which can cause weakness, breathlessness, cough and fever (pneumonitis)
- changes in liver function with or without yellowing of the skin or whites of the eyes (jaundice). This condition is usually reversible on stopping treatment.
- fits (convulsions)

<u>Very rare side effects (affect less than one in 10,000 users):</u>

- deteriorating eyesight

<u>Side effects of unknown frequency (the frequency of these effects has not been established yet):</u>

- blocked electrical conductivity in the heart (heart block) which can cause light-headedness, fainting and irregular heart rhythm
- slower heart rhythm or dangerously fast heart rhythm
- heart attack
- a heart disease called 'sinus arrest'
- chest pain
- scarring of the lungs or lung disease which causes shortness of breath

- heart failure which can cause shortness of breath and swelling of the feet or legs due to fluid retention

The following side effects have also been reported:

Very common side effects (affect more than one in ten users):

- lightheadedness
- blurred or double vision

Common side effects (may affect 1-10 in 100 users):

- breathlessness, difficulty breathing
- tiredness or weakness
- fever
- swelling (accumulation of fluid in the body)

Uncommon side effects (may affect 1-10 in 1,000 users):

- Changes in your blood count:
  - reduction in red blood cell count, which may make the skin pale and cause weakness or breathlessness
  - reduction in white blood cell count, which makes you prone to infections
  - reduced level of platelets in your blood, which can make you bruise or bleed more easily than normal
- nausea or vomiting
- constipation
- stomach pain or digestive tract discomfort
- reduced appetite
- diarrhea
- indigestion
- feeling that your stomach is bloated, flatulence (wind)
- inflammation of the skin due to an allergic reaction, including rash
- hair loss

Rare side effects (may affect 1-10 in 10,000 users):

- confusion or anxiety
- depression
- anxiety
- forgetfulness
- difficulty sleeping or being very sleepy
- hallucinations seeing, hearing or feeling things that are not there
- nervousness
- numbness or weakness of the arms and legs
- tingling, pins and needles
- sudden uncontrollable or abnormal body movements
- decreased feeling or sensitivity, especially in the skin
- excessive sweating, redness of skin, and flushing
- fainting
- tremor
- headache
- ringing in the ears
- hives

Very rare side effects (affect less than one in 10,000 users):

- dry mouth or altered sense of taste
- sensitivity of the skin to sunlight
- painful, swollen joints or muscle pain
- impotence
- raised levels of certain antibodies, which may cause inflammation

Side effects of unknown frequency (the frequency of these effects has not been established yet):

- low blood pressure
- palpitations
- liver diseases

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your physician.

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a physician.
- Do not use the medicine after the expiry date (exp. date) which is stated on the outer package. The expiry date refers to the last day of that month.

Storage conditions:

- Store below 25°C.
- Store in the original package to protect from light.
- Do not discard medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. Additional information:

- In addition to the active ingredient flecainide acetate this medicine also contains: pregelatinized maize starch, microcrystalline cellulose, croscarmellose sodium, hydrogenated vegetable oil, magnesium stearate.
- What the medicine looks like and contents of the pack:
  Tambocor 50 mg Tablets: white, round tablets.

  Tambocor 100 mg Tablets: white, round tablets with a score line.

  Packaged in blisters, in packs of 60 tablets.

- **Registration holder and address:** MegaPharm Ltd., POB 519, Hod Hasharon 4510501, Israel
- **Manufacturer and address:** Rottapharm, Dublin, Ireland.
- Revised in November 2021 according to MOH guidelines.
- Registration number of the medicine in the Ministry of Health's National Drug Registry:

  Tambocor 50 mg Tablets: 111-73-29433

  Tambocor 100 mg Tablets: 123-99-23293