



Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Tambocor 50, 100 mg Tablets

Each tablet contains Flecainide acetate 50, 100 mg, respectively.

Inactive ingredients and allergens in the medicine – see section 6 "Additional information".

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist. This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if you think that their illness is similar to yours.

1. What is the 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 the medicine

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (flecainide acetate) or to any of the other ingredients this medicine contains (see section 6).
- You suffer from heart failure or some types of heart rhythm disorders.
- You suffer from heart valve disease.
- You have a history of heart attacks.
- You have low blood pressure or a slow beating heart.
- You have a serious heart condition called cardiogenic shock, 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 heart condition called Brugada syndrome, which causes life-threatening heart rhythm disorder.
- You are already taking disopyramide to regulate your heartbeat.

Special warnings regarding the use of the 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 received 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 the treatment with Tambocor Tablets, tell the doctor if:

- You know you have high or low levels of salt (such as potassium) in your blood
- You suffer from kidney or liver problems

- You suffer from a heart rhythm disorder called "sick sinus syndrome"
- You have a pacemaker
- You suffer from an enlarged heart, or some types of heart disease

Your doctor may wish to start treatment with **Tambocor Tablets** in the hospital in order to perform an ECG and monitor the levels of the medicine in your blood. Your doctor may also wish to perform 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.

Drug interactions

If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Especially if you are taking:

- diuretics such as furosemide
- corticosteroids for inflammatory conditions such as arthritis, for example prednisolone
- laxatives to treat constipation
- additional anti-arrhythmic medicines or medicines to treat other heart problems such as: digoxin, quinidine, beta-blockers (e.g. atenolol, propranolol), amiodarone, verapamil
- anticonvulsants, for epilepsy, such as phenytoin, phenobarbital, carbamazepine
- cimetidine, to treat stomach ulcers
- antivirals such as ritonavir, fixed-combination products containing ritonavir
- anti-malarials e.g. quinine
- antihistamines for allergic reactions, such as: mizolastine, terfenadine
- antidepressants such as fluoxetine, paroxetine, reboxetine, and tricyclic anti-depressants such as imipramine
- bupropion, used as an antidepressant and anti-smoking aid
- antifungals e.g. terbinafine
- antipsychotics to treat some mental illnesses e.g. clozapine

Use of the medicine and food

Dairy products like milk, infant formula and yoghurt have been shown to reduce the absorption of flecainide in children and infants. It is unknown whether this effect on absorption is the same in adults. Talk to your pharmacist or doctor for advice.

Pregnancy and breastfeeding

Tambocor Tablets should not be given to pregnant or breastfeeding mothers unless the benefits to the mother outweigh the risk to the baby. If your doctor does decide to give you **Tambocor Tablets**, you will be monitored closely during your pregnancy.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to become pregnant, consult a doctor before taking any medicine.

Driving and using machines

Do not drive or operate machines if you feel that the medicine makes you feel dizzy or drowsy, or if it causes vision problems. As for children, they should be warned about riding a bicycle or playing near roads etc.

Important information about some of the ingredients of the medicine

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

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.
The dosage and manner of treatment will be determined by the doctor only.
Do not take a higher dose than the dose the doctor has prescribed you.

The usual recommended dosage is:

Adults:

Supraventricular arrhythmia:

The usual starting dose is 50 mg twice daily. If necessary, your doctor 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 of 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 treatment.

Patients with kidney failure:

In patients with significant kidney failure, the maximum starting dose is 100 mg daily (or 50 mg twice daily). The level of the medicine in the blood should be monitored regularly.

Elderly:

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

Children:

Use in children under 12 years is not recommended, as there is insufficient information on the use of the medicine 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.

Method of administration:

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

If you have accidentally taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the designated time, take the next dose as soon as you remembered, unless it is time for your next dose. Do not take a double dose to make up for a forgotten dose. consult your doctor.

Continue with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

If you stop taking the medicine

If you suddenly stop taking **Tambocor Tablets**, you may experience side effects.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have further questions on the use of this medicine, consult the doctor or pharmacist.

4. Side effects

Like any medicine, the use of **Tambocor Tablets** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

If you experience the following side effects, stop taking Tambocor Tablets and tell the doctor immediately or go to the nearest hospital emergency room:

Common side effects (effects that occur in 1-10 out of 100 users):

- fast or irregular heartbeat

Rare side effects (effects that occur in 1-10 out of 10,000 users):

- 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), usually reversible on stopping treatment
- fits (convulsions)

Very rare side effects (effects that occur in less than 1 in 10,000 users):

- worsening of eyesight

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

- 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 (effects that occur in more than 1 in 10 users):

- dizziness
- blurred or double vision

Common side effects (effects that occur in 1-10 out of 100 users):

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

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):

- 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
- reduction in platelet count, which can make you bruise or bleed more easily than normal
- nausea or vomiting
- constipation

- stomach pain or discomfort
- reduced appetite
- diarrhea
- indigestion
- feeling that your stomach is bloated, flatulence (wind)
- inflammation of the skin due to allergic reaction, including rash
- hair loss

Rare side effects (effects that occur in 1-10 out of 10,000 users):

- depression
- confusion or anxiety
- loss of memory
- difficulty sleeping or sleepiness
- 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, shaking
- decreased feeling or sensitivity, especially in the skin
- excessive sweating
- fainting
- redness of skin (flushing)
- headache
- ringing in the ears
- hives

Very rare side effects (effects that occur in less than 1 in 10,000 users):

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

Side effects with unknown frequency (effects for which a frequency has not yet been determined):

- low blood pressure
- palpitations
- liver disease

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the 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 throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Pregelatinized maize starch, microcrystalline cellulose, croscarmellose sodium, hydrogenated vegetable oil, magnesium stearate.

What the medicine looks like and what the package contains:

Tambocor 50 mg Tablets: white, round tablets.

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

Approved package size: 60 tablets

Revised in November 2024 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

Tambocor 50 mg Tablets: 111-73-29433

Tambocor 100 mg Tablets: 123-99-23293

Manufacturer and registration holder: Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel