Patient Information Leaflet
Tambocor 10 mg/ml Solution for injection or infusion
Flecainide acetate

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you. This medicine is an injection and will only be given to you by a doctor:

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

1. What Tambocor injection is and what it is used for

Tambocor injection belongs to a group of medicines called anti-arrhythmics. Anti-arrhythmics work by controlling the rate and rhythm of the heart. Tambocor injection is used to treat arrhythmias (irregular heart beat), tachycardia (heart beat too fast), and atrial fibrillation (rapid contractions of muscles in the heart). Tambocor injection is used by your doctor when a rapid response is required to control one or more of these conditions.

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

2. What you need to know before you are given Tambocor injection

Do not use Tambocor injection if:
You are allergic to flecainide acetate or any of the other ingredients of Tambocor, constipation, diarrhoea, dyspnoea, flatulence
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 or have 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 beat is abnormal)
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 injection is 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 Injection is absorbed in children and infants. If any of the above applies to you tell your doctor or nurse.
Before you are given Tambocor injection your doctor or nurse may check:
Your fluid levels are correct
Your liver and kidney function tests are normal.

Check with your doctor or nurse before they give you Tambocor injection if:
You have high blood pressure
You have angina (chest pains)
You have heart disease

Tell your doctor 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 to treat depression), such as tricyclic antidepressants, Prozac, paroxetine, fluoxetine 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)
• Propranolol (a medicine to help you stop 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 your doctor or nurse for advice before being given Tambocor.

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.

Important: Your doctor will choose the dose that is right for your condition. The doctor will also decide whether you receive Tambocor as an injection from the syringe, or in the form of an infusion (drip). The doctor or nurse will monitor the drip if this is chosen for you.

If you have switched from a different formulation (e.g. from Tambocor tablets) your doctor should do so with caution and monitor you closely.

3. How you will be given Tambocor injection

Tambocor injection will only be given to you by a doctor in hospital.

Important: Your doctor will choose the dose that is right for your condition. The doctor will also decide whether you receive Tambocor as an injection from the syringe, or in the form of an infusion (drip). The doctor or nurse will monitor the drip if this is chosen for you.

If you have switched from a different formulation (e.g. from Tambocor tablets) your doctor should do so with caution and monitor you closely.

Adults
The usual dose is 2 mg per kg body weight
The doctor will give the injection slowly into your vein over at least 10 minutes by slow injection
If the medicine is given via a drip, the maximum dose should not exceed 600 mg over 24 hours
When given as a drip, Tambocor injection is diluted with a sterile solution containing 5% dextrose.

The elderly and patients with kidney/hindar problems
For elderly patients, and patients with kidney or heart problems, the doctor may give a lower dose and perform the injection over 30 minutes.
During your treatment with Tambocor injection the doctor or nurse will monitor your heart with an electrocardiogram (ECG).
This is to make sure that your medicine is working properly and that the dose you are taking is right for you.

Handling and storage: Tambocor injection should be diluted with, or injected into, sterile solutions of 5 % glucose. If chloride containing solutions, such as sodium chloride or Ringer’s lactate are used, the injection should be added to a volume of not less than 300 ml, otherwise a precipitate will form.

Do not store above 30°C. Do not freeze. Protect from light.

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• Antiepileptics: Known enzyme inducers (phenytoin, phenobarbital, carbamazepine) increase the rate of flecainide elimination by approximately 30%.
• Antipsychotics: Clozapine increases the risk of arrhythmias
• Antibacterials: Macrolides and tetraenrifline increase the risk of ventricular arrhythmias
• Antimalarials: Quinine increases plasma flecainide concentration
• Antivirals: plasma flecainide concentrations are increased by ritonavir, lopinavir and indinavir to increase risk of ventricular arrhythmias. Avoid concomitant use
• Diuretics: Hypokalaemia may cause cardiac toxicity
• Cimetidine: Increases plasma flecainide by approximately 30%
• Ant-smoking aids: Bupropion: May increase flecainide plasma concentration by inhibitory effects on CYP2D6, the isoenzyme responsible for flecainide metabolism.

• Neurological: Giddiness, dizziness, light-headedness, • Ear and labyrinth disorders: Tinnitus, vertigo
elevated liver enzymes, jaundice, • Gastrointestinal: Nausea, vomiting, abdominal pain, neuropathy, paraesthesia, ataxia, flushing, headache, • Ophtalmological: Double vision, blurred vision, corneal deposits
diabetes, neuropathy, paraesthesia, ataxia, • Respiratory: Dyspnoea, pneumonitis, pulmonary fibrosis, hypoaesthesia, increased sweating, somnolence, syncope, tinnitus, tremor, vertigo
elevated liver enzymes, jaundice, • Ear and labyrinth disorders: tinnitus, vertigo
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Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.

Overdosage: No specific antidote or rapid method of removing flecainide from the system is known. Forced acid diuresis may be helpful (theoretically), but dialysis and haemoperfusion are not recommended. Treatment of flecainide overdosage may include use of an isotropic agent, intravenous calcium, circulatory assistance (e.g. balloon pumping), mechanically assisting respiration, or temporarily inserting a transvenous pacemaker if there are severe conduction disturbances or the patient’s left ventricular function is otherwise compromised.

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Antivirals: plasma flecainide concentrations are increased by ritonavir, lopinavir and indinavir to increase risk of ventricular arrhythmias. Avoid concomitant use
Common side effects could be serious. If you have any of these side effects listed below, seek immediate medical help:

• Headache
• A strong desire to sleep or sleep for long periods
• Shaking (tremors)
• Reduced sense of touch
• Forgetfulness
• Feeling anxious (worried)
• Confusion and hallucinations

Rare (affects 1 in 10,000 people):

• Hair loss
• Red, itchy or swollen skin rash
• Diarrhoea
• Loss of appetite
• Stomach pain or indigestion
• Constipation
• Feeling or being sick

Uncommon (affects 1 in 1,000 people):

• Swelling (fluid retention)
• Lack of energy and strength

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

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

• Allergic reaction (swelling of the face, lips, tongue or throat)
• Double or blurred vision

Common (affects 1 in 100 people):

• Feeling week or tired
• Lack of energy
• Palpitations

Uncommon (affects 1 in 1,000 people):

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

Rare (affects 1 in 10,000 people):

• Parathesis (feeling like the room is spinning)
• Confusion and hallucinations
• Depression
• Feeling anxious (worried)
• Forgetfulness
• Difficulty sleeping
• Numbness, tingling, tickling, pricking or burning sensation
• Unsteady walking, uncontrolled movements or poor coordination
• Difficulty speaking
• Excessive sweating
• Shaking (tremors)
• A strong desire to sleep or sleep for long periods
• Headache

If you are given more Tambocor injection than you should

This is unlikely as Tambocor will be injected slowly by a doctor who will monitor your heart continuously during treatment. If any problems occur, Tambocor injection should be stopped and any symptoms of overdose treated urgently. If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Tambocor injection 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:

• Headache
• A strong desire to sleep or sleep for long periods
• Shaking (tremors)
• Reduced sense of touch
• Forgetfulness
• Feeling anxious (worried)
• Confusion and hallucinations

Rare (affects 1 in 10,000 people):

• Hair loss
• Red, itchy or swollen skin rash
• Diarrhoea
• Loss of appetite
• Stomach pain or indigestion
• Constipation
• Feeling or being sick

Uncommon (affects 1 in 1,000 people):

• Swelling (fluid retention)
• Lack of energy and strength

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Uncommon (affects 1 in 1,000 people):

• Blood disorders (red blood cells count and white blood cell count reduced)
• Feeling or being sick
• Constipation
• Stomach pain or indigestion
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Technical Information Leaflet for Professionals

Tambocor 10 mg/ml Solution for injection or infusion

Flecainide acetate

Presentation:

Each ampoule contains 15 ml of flecainide acetate 10 mg/ml, solution for injection or infusion. The other ingredients are: glacial acetic acid and water.

Therapeutic indications:

For the rapid control of the following arrhythmias:

• Treatment-resistant ventricular tachycardia
• AV nodal reciprocating tachycardia; arrhythmias associated with Wolff-Parkinson-White Syndrome and similar conditions with accessory pathways
• Paroxysmal atrial fibrillation in patients with disabling symptoms. Recent onset arrhythmias respond more readily.

Directions for use:

Tambocor injection may be given as a bolus injection in an emergency or for rapid effect, or as a slow intravenous infusion when prolonged administration is required.

a) Bolus injection: Administer 2 mg/kg over not less than 10 minutes, or in divided doses. Alternatively, dilute with 5-10% glucose and give as a mini-infusion. Continuous ECG monitoring is recommended. Stop the injection when the arrhythmia is controlled.

For sustained ventricular tachycardia, or people with a history of cardiac failure (who may become decompensated during administration) give the initial dose over 30 minutes and monitor the ECG carefully. The maximum recommended bolus dose is 150 mg.

b) Intravenous infusion: The recommended procedure is to start with a slow injection of 2.5 mg/kg over 30 minutes, then continue intravenous infusion at the following rates:

First hour: 1.5 μg/ml per kg per hour
Second and later hours: 0.1-0.25 μg/ml per kg per hour

The maximum recommended infusion duration is 24 hours; if exceeded, and in patients receiving high doses, monitor plasma levels. The maximum cumulative dose over the first 24 hours should not exceed 60 mg.

In severe renal impairment (creatinine clearance <35 ml/min/1.73 m²) the reduction of the above dosage recommendations by half.

Oral maintenance dosing should be started as soon as possible after stopping the infusion.

Children: Not recommended in children under 12 years, however, dairy products such as milk, infant formula and possibly yoghurt may reduce how much Tambocor injection is absorbed in children and infants.

Elderly Patients: The rate of elimination of flecainide may be reduced, so dose adjustment may be necessary.

Contraindications:

• Hypersensitivity to flecainide or to any of the excipients
• History of myocardial infarction with either asymptomatic ventricular ectopics, or asymptomatic non-sustained ventricular tachycardia.
• Long-standing atrio-ventricular block, bundle branch block or distal block.
• In the presence of cardiacogenic shock.
• Known Brugada syndrome.

Unless pacing reserve is available, do not give to patients with sino-atrial dysfunction, atrial conduction defects, second degree or complete atrio-ventricular block, bundle branch block or diltial block.

Precautions:

• Correct any electrolyte disturbances before using Tambocor injection

• Plasma elimination of flecainide may be markedly slower in patients with such reduced renal function. Do not use, unless the potential benefits clearly outweigh the risks.
• Careful plasma level monitoring is recommended.
• Flecainide should be used with caution in patients with impaired renal function (creatinine clearance ≤35 ml/min/1.73 m²) and therapeutic drug monitoring is recommended.

• The rate of flecainide elimination from plasma may be reduced in the elderly. This should be taken into consideration when making dose adjustments.

• Severe bradycardia or pronounced hypotension should be corrected before using flecainide.

• Flecainide has been shown to increase mortality risk of post-myocardial infarction patients with asymptomatic ventricular arrhythmia.

• Flecainide, like other antiarrhythmics, may cause proarrhythmic effects, i.e. it may cause the appearance of a more severe type of arrhythmia, increase the frequency of an existing arrhythmia or the severity of the symptoms (see 4.8).

• Decreased endocardial pacing sensitivity may occur; this effect is reversible and more marked on the acute pacing threshold than on the chronic.

• Use with caution in all patients with permanent pacemakers or temporary pacing electrodes. Do not administer to patients with existing poor thresholds, or non-programmable pacemakers, unless is available.

• Flecainide’s minor negative inotropic effect may become important in patients predisposed to cardiac failure. Difficulty in defibrillating some patients has been reported.

• The majority of these cases had pre-existing heart disease with cardiac enlargement, a history of myocardial infarction, arteriosclerotic heart disease and cardiac failure.

• Use cautiously in patients with acute onset atrial fibrillation following cardiac surgery.

• Flecainide as a narrow therapeutic index drug requires caution and close monitoring when switching a patient to a different formulation.

Use in pregnancy and lactation: Flecainide crosses the placenta; however, the safety of Tambocor injection in pregnancy has not been established. Flecainide is excreted in human milk and appears in concentrations which reflect those in maternal blood. The risk of adverse effects to the nursing infant is very low.

Drug interactions: Flecainide is a class I antiarrhythmic. Possible interactions include:

• Additive effects with other anti-arrhythmic drugs or with drugs affecting the metabolism of flecainide
• Carbamazepine can cause plasma digoxin to rise by about 15%. Digoxin plasma level in digitalised patients should be measured not less than six hours after any digoxin dose, before or after administration of flecainide
• Class II antiarrhythmics: additive negative inotropic effects of beta-blockers and other cardiac depressants with concomitant flecainide should be recognised
• Class III antiarrhythmics: Reduce the dose of flecainide by 50% in the presence of amiodarone to avoid additive effects. Monitor patients for adverse effects and plasma level monitoring is strongly recommended.
• Class IV antiarrhythmics: use of flecainide with other sodium channel blockers is not recommended.
• Antiadrenergics: Fluoxetine, paroxetine and other antidepressants increases plasma flecainide concentration. Tocyclone increases the risk of arrhythmias. Rosbaxine manufacturer advises caution.