Reporting 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.

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 500 ml, otherwise a precipitate will form.

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

PL 15142/0077

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.

What is in this leaflet:
1. What Tambocor injection is and what it is used for
2. What you need to know before you are given Tambocor injection
3. How you will be given Tambocor injection
4. Possible side effects
5. How to store Tambocor injection
6. Contents of the pack and other information.

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 (regular 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 or any of the other ingredients of Tambocor, including diacerein, diacerepsis, flutelen
• you have heart failure
• you have cardiogenic shock (your heart is unable to pump as much blood as your body needs)
• you have block heart (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 beats abnormally)
• 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.
• 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 beats abnormally)
• 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.
• you have heart block (your heart misses beats)

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 Tambocor tablets) your doctor should do so with caution and monitor you closely.

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 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/heart problems
• Elderly patients, and patients with kidney or heart problems, the doctor may give a lower dose and perform the injection more slowly.

During your treatment with Tambocor injection the doctor 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.
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.

- Common (affects 1 in 100 people):
  - Very rapid or irregular heart beat seems to get worse
  - You have chest pain
  - You become breathless
  - You have a fever, become flushed or sweat.
  - You faint or feel faint

Rare (affects 1 in 10,000 people):

- You have fits (convulsions)
- You have a fever, become flushed or sweat.
- You become breathless
- You have chest pain
- You have a feeling of being breathless
- You faint or feel faint

Very rare (affects less than 1 in 10,000 people):

- Small cloudy spots on the eyelid
- Sensitivity of the skin to sunlight

Other side effects (how often they happen is unknown):

- Lung disease and scarring of the lungs
- Liver disease

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 Yellow Card Scheme at: www.mhra.gov.uk/yellows.

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

5. How to store Tambocor injection

Keep out of the reach and sight of children.

For single use only.

Do not use Tambocor injection after the expiry date on the carton. The expiry date refers to the last day of that month.

Do not store above 30°C.

Do not freeze.

Protect from light.

Medicines should not be disposed of via wastewater or household waste. Return any medicine you no longer need to your pharmacist.

6. Contents of the pack and other information

What Tambocor injection contains

- The active ingredient is flecainide acetate. Each millilitre (ml) of solution contains
  - 1 milligram (mg) of flecainide acetate.
- The other ingredients are: sodium acetate, glacial acetic acid and water.

What Tambocor injection looks like

Tambocor injection comes in sealed 15 ml glass containers called ampoules.

Marketing Authorisation Holder:

Meda Pharmaceuticals Ltd, Skyway House, Parsonage Road, Takeley, Bishop’s Stortford, CM22 6PU, United Kingdom.

Manufacturer:

Gencis
52, rue Marcel et Jacques Gaucher
84102 Fonteyn-Sous-Bois (France)

This leaflet was last revised 12/2014.

If this leaflet is difficult to see or read, or you would like it in a different format, please contact Meda Pharmaceuticals Ltd, Skyway House, Parsonage Road, Takeley, Bishop’s Stortford, CM22 6PU, United Kingdom.

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 tachycardias
- 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 atrhythmias 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 no less than 10 minutes, or in divided doses. Alternatively, dilute with 5% glucose and give as a mini-infusion. Continuous ECG monitoring is recommended. Stop the injection when the arrhythmia is controlled.

b) Intravenous infusion:

The recommended procedure is to start with a slow injection of 2 mg/kg over 30 minutes, then continue intravenous infusion at the following rates:

- First hour: 1.5 mg/kg per hour
- Second and later hours: 0.1-0.25 mg/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/kg.

In severe renal impairment (creatinine clearance <5 ml/min/1.73 m²) and when administered in patients with high flecainide plasma levels, reduce 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 yoghurts 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
- Cardiac failure
- History of myocardial infarction with either asymptomatic ventricular ectopics, or asymptomatic non-sustained ventricular tachycardia.
- Long-standing atrial fibrillation where there has been no attempt to convert to sinus rhythm
- Haemodynamically significant valvular heart disease
- In the presence of cardiacogenic shock
- Known Brugada syndrome
- Unless pacing rescue is available, do not give to patients with sinus node dysfunction, atrial conduction defects, second degree or greater atrio-ventricular block, bundle branch block or dialysis block.

Precautions:

- Correct any electrolyte disturbances before using Tambocor injection.
- Plasma elimination of flecainide may be markedly slower in patients with such impairment. Do not use, unless the potential benefits clearly outweigh the risks.
- Careful plasma monitoring is recommended.
- Flecainide should be used with caution in patients with impaired renal function (creatinine clearance <5 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 antiarrhythmic drugs, 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).
- Increased endocardial pacing safety 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 name or 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
- Concurrent digoxin 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 I antiarrhythmics: additive negative inotropic effects of beta-blockers or a calcium antagonist 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.
- Antidiuretics: Fluoxetine, paroxetine and other antidepressants increase plasma flecainide concentration.
- Tricyclics increase the risk of arrhythmias. Reboxetine manufacturer advises caution.