

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

Tambocor Tablet 100 mg

Tambocor Injection 10 mg/ml

Read all of this information carefully before you start taking/given Tambocor

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

1. What Tambocor contains

Tablets

The active substance is flecainide acetate 100 mg per tablet. The other ingredients are croscarmellose sodium, hydrogenated vegetable oil, magnesium stearate, microcrystalline cellulose and pregelatinised starch.

Injection

The active substance is flecainide acetate 15 ml per ampoule. The other ingredients are glacial acetic acid, purified water and sodium acetate.

2. WHAT TAMBOCOR IS USED FOR

Tambocor is a cardiac medicine (Class 1 anti – dysrhythmic [local anaesthetic])

Tambocor is used to regulate the rate and rhythm of the heart, when they are abnormal.

3. BEFORE YOU TAKE/ARE GIVEN TAMBOCOR

Do not take/you should not be given Tambocor if:

- You are hypersensitive (allergic) to flecainide acetate or any of the other ingredients of Tambocor
- You suffer from kidney disease, heart failure or heart block (missed heart beats)
- You have ever had a heart attack, or wear a heart pacemaker, or suffer from liver disease or heart valve disease.

Please tell your doctor if you suffer from high blood pressure or angina.

Tambocor should not be used by children under 18 years old.

Take special care with Tambocor:

Please tell your doctor is:

- You have a heart disease
- You have pre-existing conduction disorders.

Tambocor should be stopped if all of the above occur during treatment.

Pregnancy and breast-feeding

Do not use Tambocor if you are pregnant or breastfeeding.

If you are pregnant or breast feeding your baby while taking Tambocor, please consult your doctor, pharmacist or other health care professional for advice.

Taking other medicines with Tambocor

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of Tambocor CR with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice if you are taking:

- Any other medicine used to treat heart arrhythmias or heart problems such as cardiac glycosides, beta-blockers, verapamil or amiodarone
- Medicines to treat high blood pressure
- Antidepressants (medicines used to treat depression), such as tricyclic antidepressants, Prozac, fluoxetine or reboxetine
- Anticonvulsants (medicines used to prevent epileptic fits) such as phenytoin, phenobarbital or carbamazepine
- Cimetidine (medicine used to treat stomach ulcers)
- Local anaesthetics
- Digoxin (medicine used to regulate your heart beat.)

4. HOW TO TAKE/RECEIVE TAMBOCOR

Always take Tambocor exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Your doctor will check on the dosage that is suitable for you.

If you take more Tambocor than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.

If you forget to take Tambocor

Do not take a double dose to make up for forgotten individual doses.

5. POSSIBLE SIDE EFFECTS

Tambocor can have the following side effects.

- feeling dizzy
- Giddy or lightheaded

- weak or tired
- swelling
- double vision or blurring of vision
- feeling sick and vomiting
- yellowing of the skin (jaundice)
- sensitivity to the effects of sunlight.

Not all side effects reported for Tambocor are included in this leaflet. Should your general health worsen while taking Tambocor, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF TAMBOCOR

Tablets

Store the tablets in a cool, dry place below 30 °C.

In order to protect from light, keep blister pack in the outer carton.

Injection

Store in a cool place below 30 °C

Protect from light

Keep the container in the outer carton in order to protect from light

Keep all medicines out of the reach and sight of children. Return all unused medicine to your pharmacist. Do not dispose of unused medicine in drains or sewerage systems (eg toilets)

7. PRESENTATION OF TAMBOCOR

Tablets

Blister pack of 60 tablets

Injection

Boxes containing 5 x 15 ml ampoules

8. IDENTIFICATION OF TAMBOCOR

Tablets

White, circular, biconvex tablets coded TR 100 on one side and 3M on the other.

Injection

A clear, colourless solution contained in a clear glass ampoule. The normal fill volume is 15.0 ml.

9. REGISTRATION NUMBERS

Tablets: S/6.1/17

Injection: S/6.1/16

10. NAME AND ADDRESS OF REGISTRATION HOLDER

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11. DATE OF PUBLICATION

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