

## TAMBOCOR INJECTION

הרכב:

FLECAINIDE ACETATE 10 MG/ML

ההתוויה הרשומה לתכשיר בישראל:

Serious sustained life threatening ventricular arrhythmias that have not responded to other drugs.

בהודעה זו כלולים השינויים המהותיים בלבד. בעלונים ישנם שינויים נוספים.  
טקסט חדש מסומן בקו תחתני. טקסט המהווה החמרה מודגש בצהוב.

להלן העדכונים העיקריים בעלון לרופא:

### 4.3 Contraindication

Patients with structural heart disease and/or impaired left ventricular function (manifest heart failure with a left ventricular ejection fraction of less than 35%) should not be treated with flecainide due to the increased risk of pro-arrhythmic effects. Flecainide is also contraindicated for use in:

[...]

- Severe bradycardia
- SA blocks
- Sinus node dysfunction or tachy-brady syndrome if no pacemaker is implanted
- Concomitant use of class I antiarrhythmics

[...]

### 4.4 Special warnings and special precautions for use

[...]

Direct hospital or specialist supervision is also required for:

- Patients with 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

[...]

In case of pronounced cardiac output disturbance (heart failure NYHA class III-IV and/or LVEF less than 35%), treatment of life-threatening ventricular cardiac arrhythmias with flecainide should only occur once the heart failure is compensated through the use of additional medications to increase cardiac output.

[...]

### 4.5 Interactions with other medicinal products and other forms of interaction

[...]

Antidepressants

Concurrent use of flecainide and fluoxetine, paroxetine or moclobemide can increase the flecainide plasma level. Concurrent use of flecainide and tricyclics increases the risk of arrhythmias.

[...]

Antimalarials

Quinine and quinidine increase the plasma concentration of flecainide.

Antifungals

Terbinafine may increase plasma concentrations of flecainide.

[...]

### 4.6 Fertility, pregnancy and lactation

[...]

Flecainide should therefore not be used during breast-feeding

[...]

### 4.8 Undesirable effects

[...]

Psychiatric disorders:

Common: Depression, anxiety, insomnia

Uncommon: Confusion, amnesia, hallucinations

Nervous system disorders:

Common: Headache, paraesthesia, hypoaesthesia, ataxia, syncope, flushing, increased sweating, tremor

Uncommon: Dyskinesia, muscle twitching, peripheral neuropathy, cramps

[...]

Diseases of the ear and labyrinth:

Common: Tinnitus

[...]

Cardiac disorders:

Common: [...]

Both ventricular arrhythmias and ventricular tachycardia have been reported, e.g. an increase in ventricular extrasystoles, increased frequency of premature ventricular contractions, increased frequency and severity of ventricular tachycardia, ventricular fibrillation.

Patients with atrial flutter receiving flecainide have developed 1:1 AV conduction after an initial slowing of atrial activity and subsequent acceleration of ventricular activity.

Conduction disorders may worsen under treatment with flecainide. AV blocks (second- and third- degree), bundle branch block or SA block have been observed. Treatment with flecainide should be stopped in such cases.

Bradycardia or sinus arrest can occur.

Treatment with flecainide can cause heart failure. Previously undetected heart failure (latent heart failure, NYHA I) may worsen under treatment with flecainide (clinical manifestation). In this case, a dose reduction or compensation through co-administration of medications to increase cardiac output is required (see section 4.2).

[...]

Respiratory, thoracic and mediastinal disorders:

Common: Respiratory distress

Uncommon: Interstitial pneumonitis

[...]

Gastrointestinal disorders:

Common: Nausea, vomiting, diarrhoea, digestive disturbance, constipation

Uncommon: Dry mouth, taste disorders, abdominal pain, loss of appetite, flatulence

[...]

Skin and subcutaneous tissue disorders:

Common: Rash

[...]

Musculoskeletal and connective tissue disorders:

Uncommon: Arthralgia, myalgia (possibly with fever)

[...]

Reproductive system and breast disorders:

Uncommon: Impotence

### 6.3 Shelf life

[...]

Chemical and physical in-use stability of the diluted solutions have been demonstrated for 24 hours at room temperature. From a microbiological point of view, the product should be used immediately.

If not used immediately, in-use storage times and conditions would normally not be longer than 24 hours at 2 to 8°C, unless dilution has taken place in controlled and validated aseptic conditions.

העלון לרופא/לצרכן מפורסם במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום.

בברכה,  
ד"ר יודי וגנר  
רוקח ממונה  
מגאפארם בע"מ