

Tigel® 90

Ticagrelor
Tablet

Description

Ticagrelor is intended for use in adults only, for reducing the risk of cardiovascular events (stroke, myocardial infarction, death) in patients after myocardial infarction or after unstable angina pectoris.

Indications

Ticagrelor is indicated to reduce the rate of cardiovascular death, myocardial infarction, and stroke in patients with acute coronary syndrome (ACS) or a history of myocardial infarction (MI).

Ticagrelor also reduces the rate of stent thrombosis in patients who have been stented for treatment of ACS.

Dosage and Administration

Adults:

- Initiate treatment with 180 mg (two 90 mg tablets) oral loading dose.
- Continue treatment with 90 mg twice daily.
- After the initial loading dose of aspirin (usually 325 mg), use Tigel® 90 with a daily maintenance dose of aspirin of 75-100 mg.

Children:

Not recommended for children and adolescents under 18 years of age.

Contraindication

- You have a known sensitivity to ticagrelor or to any of its ingredients.
- You are suffering, or have recently suffered, from active internal bleeding, such as, bleeding in the stomach or intestine, due to an ulcer.
- You are suffering from a moderate to severe liver disease.
- You are suffering from a stroke caused by intracranial bleeding.
- You are taking any of the following medicines: ketoconazole (antifungal), clarithromycin (for treatment of bacterial infections), nefazodone (antidepressant), ritonavir and atazanavir (for treatment of HIV infections and AIDS).
- If you had a stroke caused by intracerebral bleeding.

Special warnings regarding use of Tigel® 90 Tablet

Before treatment with Tigel® 90 Tablet, inform the doctor if:

- You are at risk of bleeding due to:

- Recent severe injury or surgery (including dental work)
- Recent bleeding in the stomach or intestine or colon polyps
- Disease/condition that may affect blood clotting
- You are due to undergo surgery (including dental work) – during the course of treatment with this medicine, the doctor may instruct you to stop taking Tigel® 90 Tablet 5 days before the planned surgery, to reduce the risk of bleeding. The doctor will tell you when to resume taking Tigel® 90 Tablet.
- You are suffering from slow heart rate (below 60 beats per minute) and you do not have a pacemaker.
- You are suffering from asthma, a lung disease, difficulty breathing.
- You are suffering from high levels of uric acid in the blood.
- If you are sensitive to any food or medicine, inform the doctor before taking this medicine.
- If you are taking this medicine as needed (as per the doctor's instructions), inform the attending doctor of any change in the symptoms.

Taking other medicines

Please inform the attending doctor if you are taking other medicines, or if you have just finished treatment with another medicine, including nonprescription medicines, vitamins, food supplements and herbal remedies. This is because Tigel® 90 may affect the way certain medicines work, and certain medicines may affect the way Tigel® 90 works.

Inform the doctor if you are taking:

- simvastatin or lovastatin (for treatment of high cholesterol) at doses higher than 40 mg per day
- rifampicin (antibiotic), phenytoin, carbamazepine and phenobarbital (for treatment of convulsions)
- dexamethasone (for treatment of inflammatory conditions and autoimmune diseases)
- digoxin (for treatment of heart failure and heart rhythm disorders)
- cyclosporine (immunosuppressant)
- quinidine and diltiazem (for treatment of heart rhythm disorders)
- Beta blockers and verapamil (for treatment of hypertension). Inform the doctor if you are taking medicines from the following groups that may increase the risk of bleeding:
- Oral anticoagulants including warfarin

- Non-steroidal anti-inflammatory drugs (NSAIDs), often taken as pain relievers, such as ibuprofen and naproxen
- Antidepressants from the SSRI group, such as paroxetine, sertraline and citalopram
- Ketoconazole (antifungal); do not use with Tigel® 90 Tablet
- Clarithromycin (for treatment of bacterial infections); do not use with Tigel® 90 Tablet
- Nefazodone (for treatment of depression); do not use with Tigel® 90 Tablet
- Ritonavir and atazanavir (for treatment of HIV infections and AIDS); do not use with Tigel® 90 Tablet
- Cisapride (for treatment of heartburn)
- Ergotamines (for treatment of migraine).

Pregnancy and Lactation

- It is not recommended to use Tigel® 90 tablet if someone pregnant or planning to become pregnant. Women taking Tigel® 90 must use appropriate contraceptive measures to prevent pregnancy.
- Many drugs are excreted in human milk, a decision should be made whether to continue or to discontinue Tigel® 90 Tablet.

Side Effects

As with any medicine, use of Tigel® 90 Tablet may cause side effects in some users.

Major Side Effects

If any of the following side effects occur while taking Tigel® 90 Tablet, check with your doctor immediately:

More common:

Difficult or labored breathing, tightness in the chest

Less common:

Blurred vision, chest pain or discomfort, confusion, dizziness, faintness, or light headedness when getting up suddenly from a lying or sitting position, fainting, fast or irregular heartbeat

Minor Side Effects

Some side effects may not need any medical attention. As your body gets used to the medicine these side effects may disappear. Your health care professional may be able to help you prevent or reduce these side effects, but do check with them if any of the following side effects continue, or if you are concerned about them:

Less common:

Back pain, cough, and diarrhea

Pharmaceutical Precautions

Keep out of the reach of children. Keep in a cool & dry place. Protect from light.

Commercial Pack

Tigel® 90 Tablet: Box containing 10 tablets in 1 x 10's blister strips. Each film coated tablet contains Ticagrelor INN 90 mg.



Manufactured by

BEXIMCO PHARMACEUTICALS LTD.

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