MEDICATION GUIDE

Ticagrelor (tye-KA-grel-or) Tablets

What is the most important information I should know about ticagrelor tablets?

Ticagrelor tablet is used to lower your chance of having, or dying from, a heart attack or stroke. **Ticagrelor tablets (and similar drugs) can cause bleeding that can be serious and sometimes lead to death.** In cases of serious bleeding, such as internal bleeding, the bleeding may result in the need for blood transfusions or surgery. While you take ticagrelor tablets:

- you may bruise and bleed more easily
- you are more likely to have nose bleeds
- it will take longer than usual for any bleeding to stop

Call your healthcare provider right away, if you have any of these signs or symptoms of bleeding while taking ticagrelor tablets:

- bleeding that is severe or that you cannot control
- pink, red or brown urine
- vomiting blood or your vomit looks like "coffee grounds"
- red or black stools (looks like tar)
- coughing up blood or blood clots

Do not stop taking ticagrelor tablets without talking to the healthcare provider who prescribes it for you. People who are treated with a stent, and stop taking ticagrelor tablets too soon, have a higher risk of getting a blood clot in the stent, having a heart attack, or dying. If you stop ticagrelor tablets because of bleeding, or for other reasons, your risk of a heart attack or stroke may increase.

Your healthcare provider may instruct you to stop taking ticagrelor tablets 5 days before surgery. This will help to decrease your risk of bleeding with your surgery or procedure. Your healthcare provider should tell you when to start taking ticagrelor tablets again, as soon as possible after surgery.

Taking ticagrelor tablets with aspirin

Ticagrelor tablet is taken with aspirin, unless your healthcare provider specifically tells you otherwise. Talk to your healthcare provider about the dose of aspirin that you should take with ticagrelor tablets. In most cases, you should not take a dose of aspirin higher than 100 mg daily. Do not take doses of aspirin higher than what your healthcare provider tells you to take. Tell your healthcare provider if you take other medicines that contain aspirin, and do not take new over-the-counter medicines with aspirin in them.

What is ticagrelor tablet?

Ticagrelor tablet is a prescription medicine used to:

- decrease your risk of death, heart attack, and stroke in people with a blockage of blood flow to the heart (acute coronary syndrome or ACS) or a history of a heart attack. Ticagrelor tablets can also decrease your risk of blood clots in your stent in people who have received stents for the treatment of ACS.
- decrease your risk of a first heart attack or stroke in people who have a condition where the blood flow to the heart is decreased (coronary artery disease or CAD) who are at high risk for having a heart attack or stroke.
- decrease your risk of stroke in people who are having a stroke (acute ischemic stroke) or mini-stroke (transient ischemic attack or TIA).

It is not known if ticagrelor tablet is safe and effective in children.

Do not take ticagrelor tablets if you:

- have a history of bleeding in the brain
- are bleeding now
- are allergic to ticagrelor or any of the ingredients in ticagrelor tablets. See the end of this Medication Guide for a complete list of ingredients in ticagrelor tablets.

Before taking ticagrelor tablets, tell your healthcare provider about all of your medical conditions, if you:

- have had bleeding problems in the past
- have had any recent serious injury or surgery
- plan to have surgery or a dental procedure. See **"What is the most important information I should know about ticagrelor tablets?"**
- have a history of stomach ulcers or colon polyps
- have lung or breathing problems, such as COPD or asthma
- have liver problems
- have a history of stroke
- are pregnant or plan to become pregnant. It is not known if ticagrelor tablets will harm your unborn baby. You and your healthcare provider should decide if you will take ticagrelor tablets.
- are breastfeeding or plan to breastfeed. It is not known if ticagrelor passes into your breast milk. You should not breastfeed during treatment with ticagrelor tablets. Talk to your healthcare provider about the best way to feed your baby during treatment with ticagrelor tablets.

Tell all of your healthcare providers and dentists that you are taking ticagrelor tablets. They should talk to the healthcare provider who prescribed ticagrelor tablets for you before you have any surgery or procedure.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. **Ticagrelor tablets may affect the way other** medicines work, and other medicines may affect how ticagrelor tablet works. Certain medicines may increase your risk of bleeding.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take ticagrelor tablets?

- Take ticagrelor tablets exactly as prescribed by your healthcare provider.
- Your healthcare provider will tell you how many ticagrelor tablets to take and when to take them.
- Take ticagrelor tablets with aspirin, unless your healthcare provider specifically tells you otherwise. See **"What is the most important information I should know about ticagrelor tablets?"**
- You may take ticagrelor tablets with or without food.
- Take ticagrelor tablets two times each day, around the same times each day.
- If you miss your scheduled dose of ticagrelor tablets, take your next dose at its scheduled time. Do not take 2 doses at the same time unless your healthcare provider tells you to.
- If you take too much ticagrelor tablets, call your healthcare provider or local poison control center or go to the nearest emergency room right away.
- **If you are unable to swallow the tablet(s) whole**, you may crush the ticagrelor tablet(s) and mix it with water. Drink all the water right away. Refill the glass with water, stir, and drink all the water.

Ticagrelor tablets may also be given through certain nasogastric (NG) tubes. Ask your healthcare provider for instructions on how to take ticagrelor tablets through a NG tube.

What are the possible side effects of ticagrelor tablets?

Ticagrelor tablets can cause serious side effects, including:

- **See "What is the most important information I should know about ticagrelor tablets?"**

Shortness of breath. Tell your healthcare provider if you have new, worsening or unexpected shortness of breath when you are at rest, at night, or when you are doing any activity.

Slow or irregular heartbeat.

Irregular breathing. Tell your healthcare provider if you develop irregular breathing patterns when asleep or awake such as speeding up, slowing down or short pauses in breathing. Your healthcare provider will decide if you need further evaluation.

These are not all of the possible side effects of ticagrelor tablets.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ticagrelor tablets?

- Store ticagrelor tablets at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F) [see USP Controlled Room Temperature].
- Bottle of 30's count, 60's count and 100's count of ticagrelor tablets 90 mg and bottle of 60's count of ticagrelor tablets 60 mg comes in a child-resistant package.

Keep ticagrelor tablets and all medicines out of the reach of children.

General information about the safe and effective use of ticagrelor tablets.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ticagrelor tablets for a condition for which it was not prescribed. Do not give ticagrelor tablets to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about ticagrelor tablets that is written for health professionals.

What are the ingredients in ticagrelor tablets?

Active ingredient: ticagrelor

90 mg tablets:

Inactive ingredients: dibasic calcium phosphate, magnesium stearate, mannitol, povidone K30 and sodium starch glycolate. The film coating material contains hypromellose, iron oxide yellow, polyethylene glycol 400, talc and titanium dioxide.

60 mg tablets:

Inactive ingredients: dibasic calcium phosphate, magnesium stearate, mannitol, povidone K30 and sodium starch glycolate. The film coating material contains hypromellose, iron oxide black, iron oxide red, polyethylene glycol 400 and titanium dioxide.

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