

**Package leaflet: Information for the user****Ticagrelor CF 60 mg, filmomhulde tabletten**  
**Ticagrelor CF 90 mg, filmomhulde tabletten**

ticagrelor

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- 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 only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What [Product name] is and what it is used for
2. What you need to know before you take [Product name]
3. How to take [Product name]
4. Possible side effects
5. How to store [Product name]
6. Contents of the pack and other information

**1. What [Product name] is and what it is used for****What [Product name] is**

[Product name] contains an active substance called ticagrelor. This belongs to a group of medicines called antiplatelets.

**What [Product name] is used for****[60 mg:]**

[Product name] in combination with acetylsalicylic acid (another antiplatelet agent) is to be used in adults only. You have been given this medicine because you have had

- a heart attack, over a year ago

**[90 mg:]**

[Product name] in combination with acetylsalicylic acid (another antiplatelet agent) is to be used in adults only. You have been given this medicine because you have had

- a heart attack
- unstable angina (angina or chest pain that is not well controlled)

It reduces the chance of you having another heart attack, stroke, or dying from a condition related to your heart or blood vessels.

**How [Product name] works**

[Product name] affects cells called 'platelets' (also called thrombocytes). These blood cells are very small and help stop bleeding by clumping together to plug tiny holes in blood vessels that are cut or damaged.

However, platelets can also form clots inside diseased blood vessels in the heart and brain. This can be very dangerous because

- the clot can cut off the blood supply completely, causing a heart attack (myocardial infarction) or stroke
- the clot can partly block the blood vessels to the heart, reducing the blood flow to the heart and causing chest pain which comes and goes (called 'unstable angina')

[Product name] helps stop the clumping of platelets. This reduces the chance of a blood clot forming that can reduce blood flow.

## 2. What you need to know before you take [Product name]

### **DO NOT take [Product name] if you**

- are allergic to ticagrelor or any of the other ingredients of this medicine (listed in section 6)
- are bleeding
- have had a stroke caused by bleeding in the brain
- have severe liver disease
- are taking any of the following medicines:
  - ketoconazole (used to treat fungal infections)
  - clarithromycin (used to treat bacterial infections)
  - nefazodone (an antidepressant)
  - ritonavir and atazanavir (used to treat HIV infection and AIDS)

Do not take [Product name] if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking [Product name] if:

- you have an increased risk of bleeding because of
  - a recent serious injury
  - recent surgery (including dental work, ask your dentist about this)
  - you have a condition that affects blood clotting
  - recent bleeding from your stomach or gut (such as a stomach ulcer or colon 'polyps')
- you are due to have surgery (including dental work) at any time while taking [Product name]. This is because of the increased risk of bleeding. Your doctor may want you to stop taking this medicine 5 days prior to surgery
- your heart rate is abnormally low (usually lower than 60 beats per minute) and you do not already have in place a device that regulates your heart (pacemaker)
- you have asthma or other lung problems or breathing difficulties
- you develop irregular breathing patterns such as speeding up, slowing down or short pauses in breathing. Your doctor will decide if you need further evaluation.
- you have had any problems with your liver or have previously had any disease which may have affected your liver
- you have had a blood test that showed more than the usual amount of uric acid

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking this medicine.

If you are taking both [Product name] and heparin:

- Your doctor may require a sample of your blood for diagnostic tests if they suspect a rare platelet disorder caused by heparin. It is important that you inform your doctor that you are taking both [Product name] and heparin, as [Product name] may affect the diagnostic test.

### **Children and adolescents**

[Product name] is not recommended for children and adolescents under 18 years.

### **Other medicines and [Product name]**

Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is because [Product name] can affect the way some medicines work and some medicines can have an effect on [Product name].

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Rosuvastatin, or more than 40 mg daily of either simvastatin or lovastatin (to treat high cholesterol)

- rifampicin (an antibiotic)
- phenytoin, carbamazepine and phenobarbital (to control seizures)
- digoxin (to treat heart failure)
- cyclosporine (to prevent organ rejection)
- quinidine and diltiazem (to treat abnormal heart rhythms)
- beta blockers and verapamil (to treat high blood pressure)
- morphine and other opioids (used to treat severe pain)

In particular, tell your doctor or pharmacist if you are taking any of the following medicines that increase your risk of bleeding

- blood thinners (oral anticoagulants) including warfarin
- painkillers such as ibuprofen and naproxen (Non-Steroidal Anti-Inflammatory Drugs or NSAIDs)
- antidepressants such as paroxetine, sertraline and citalopram (Selective Serotonin Reuptake Inhibitors or SSRIs)
- medicines such as cisapride (to treat heartburn) or ergot alkaloids (to treat migraine and headache)
- medicines such as ketoconazole (to treat fungal infections), clarithromycin (to treat bacterial infections), nefazodone (an antidepressant), ritonavir and atazanavir (to treat HIV infection and AIDS). These **must not** be taken together with [Product name] (see also section 2 “DO NOT take [Product name] if you”)

If your doctor gives you fibrinolytics, often called ‘clot dissolvers’ (e.g. streptokinase or alteplase) you may have an increased risk of bleeding while taking [Product name]. Talk to your doctor about this.

### **Pregnancy and breast-feeding**

[Product name] is not recommended if you are pregnant or may become pregnant. Women should use appropriate contraceptive measures to avoid pregnancy while taking this medicine.

Talk to your doctor before taking this medicine if you are breast-feeding. Your doctor will discuss with you the benefits and risks of taking [Product name] during this time.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking any medicine.

### **Driving and using machines**

[Product name] is not likely to affect your ability to drive or use machines. If you feel dizzy or confused while taking this medicine, be careful while driving or using machines.

## **3. How to take [Product name]**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

### **Dosage**

[60 mg:]

- The usual dose is one 60 mg tablet twice a day. Continue taking this medicine as long as your doctor tells you to.

[90 mg:]

- The starting dose is two 90 mg tablets at the same time (loading dose of 180 mg). This dose will usually be given to you in the hospital.
- After this starting dose, the usual dose is one 90 mg tablet twice a day for up to 12 months unless your doctor tells you differently.
- Take this medicine around the same time every day (for example, one tablet in the morning

and one in the evening).

**Taking [Product name] with other medicines for blood clotting**

Your doctor will usually tell you to take acetylsalicylic acid as well. This is a substance present in many medicines used to prevent blood clotting. Your doctor will tell you how much to take (usually between 75-150 mg daily).

**How to take [Product name]**

- You can take the tablet with or without food.

**If you have trouble swallowing the tablet**

If you have trouble swallowing the tablet you can crush it and mix with water as follows:

- crush the tablet to a fine powder
- pour the powder into half a glass of water
- stir and drink immediately
- to make sure there is no medicine left, rinse the empty glass with another half a glass of water and drink it

If you are in hospital you may be given this tablet mixed with some water and delivered through a tube via your nose (nasogastric tube).

Medicinal products sold in pharmacies / for patients only – to be deleted if not applicable:

**Instructions to open the bottle**

Press downward on the cap and turn it counter-clockwise.

**If you take more [Product name] than you should**

If you take more [Product name] than you should, talk to a doctor or go to hospital straight away. Take the medicine pack with you. You may be at increased risk of bleeding.

**If you forget to take [Product name]**

- If you forget to take a dose, just take your next dose as normal.
- Do not take a double dose (two doses at the same time) to make up for the forgotten dose.

**If you stop taking [Product name]**

Do not stop taking [Product name] without talking to your doctor. Take this medicine on a regular basis and for as long as your doctor keeps prescribing it. If you stop taking [Product name], it may increase your chance of having another heart attack or stroke or dying from a condition related to your heart or blood vessels.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

[Product name] affects blood clotting, so most side effects are related to bleeding. Bleeding may occur in any part of the body. Some bleeding is common (like bruising and nosebleeds). Severe bleeding is uncommon, but can be life threatening.

**See a doctor straight away if you notice any of the following – you may need urgent medical treatment**

- **bleeding into the brain or inside the skull is an uncommon side effect, and may cause signs of a stroke such as:**
  - sudden numbness or weakness of your arm, leg or face, especially if only on one side of the body
  - sudden confusion, difficulty speaking or understanding others

- sudden difficulty in walking or loss of balance or co-ordination
- suddenly feeling dizzy or sudden severe headache with no known cause
- **signs of bleeding such as**
  - bleeding that is severe or that you cannot control
  - unexpected bleeding or bleeding that lasts a long time
  - pink, red, or brown urine
  - vomiting red blood or your vomit looking like coffee grounds
  - red or black stools (resembling tar)
  - coughing up or vomiting blood clots
- **fainting (syncope)**
  - a temporary loss of consciousness due to sudden drop in blood flow to the brain (common)
- **signs of a blood clotting problem called Thrombotic Thrombocytopenic Purpura (TTP) such as:**
  - fever and purplish spots (called purpura) on the skin or in the mouth, with or without yellowing of the skin or eyes (jaundice), unexplained extreme tiredness or confusion

**Discuss with your doctor if you notice any of the following**

- Feeling short of breath - this is very common. It might be due to your heart disease or another cause, or it might be a side effect of [Product name]. [Product name]-related breathlessness is generally mild and characterised as a sudden, unexpected need for air usually occurring at rest. This may appear in the first weeks of therapy and for many will disappear. If your breathlessness gets worse or lasts a long time, tell your doctor. Your doctor will decide if it needs treatment or further investigation.

**Other possible side effects**

**Very common** (may affect more than 1 in 10 people)

- high level of uric acid in your blood (as seen in tests)
- bleeding caused by blood disorders

**Common** (may affect up to 1 in 10 people)

- bruising
- headache
- feeling dizzy or like the room is spinning
- diarrhoea or indigestion
- feeling sick (nausea)
- constipation
- rash
- itching
- severe pain and swelling in your joints – these are signs of gout
- feeling dizzy or light-headed, or having blurred vision – these are signs of low blood pressure
- nosebleed
- bleeding after surgery or from cuts and wounds (for example while shaving) more than is normal
- bleeding from your stomach lining (ulcer)
- bleeding gums

**Uncommon** (may affect up to 1 in 100 people)

- allergic reaction – signs may include a rash, itching, or a swollen face, lips/tongue
- confusion
- visual problems caused by blood in your eye

- vaginal bleeding that is heavier, or happens at different times, than your normal period (menstrual) bleeding
- bleeding into your joints and muscles causing painful swelling
- blood in your ear
- internal bleeding, this may cause dizziness or light-headedness

#### **Not known (frequency cannot be estimated from the available data)**

- Abnormally low heart rate (usually lower than 60 beats per minute)

#### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

### **5. How to store [Product name]**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton after EXP.

The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater <or household waste>. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

### **6. Contents of the pack and other information**

#### **What [Product name] contains**

[60 mg:]

- The active substance is ticagrelor. Each film-coated tablet contains 60 mg of ticagrelor.

[90 mg:]

- The active substance is ticagrelor. Each film-coated tablet contains 90 mg of ticagrelor.
- The other ingredients are

Tablet core: mannitol, calcium hydrogen phosphate dihydrate, hydroxypropyl cellulose, carmellose calcium, magnesium stearate

[60 mg:]

Tablet film-coating: hypromellose (E464), titanium dioxide (E171), iron oxide red (E172), macrogol (E1521)

[90 mg:]

Tablet film-coating: hypromellose (E464), titanium dioxide (E171), talc (E553b), iron oxide yellow (E172), macrogol (E1521)

#### **What [Product name] looks like and contents of the pack**

[60 mg:]

Round, biconvex, pink film-coated tablets, diameter approximately 8 mm.

[90 mg:]

Round, biconvex, yellow film-coated tablets, diameter approximately 9 mm.

[60 mg:]

[Product name] is available in standard & unit dose blisters in cartons of 14, 56, 60, 100, 168 tablets.

[90 mg:]

[Product name] is available in standard & unit dose blisters in cartons of 14, 56, 60, 100, 168 tablets.

Medicinal products sold for hospital / professional use only – to be deleted if not applicable:  
HDPE bottles with a plastic (PP) cap containing 100 tablets.

Medicinal products sold in pharmacies / for patients only – to be deleted if not applicable:  
HDPE bottles with a child-resistant plastic (PP) cap containing 100 tablets.

Not all pack sizes may be marketed.

## Houder van de vergunning voor het in de handel brengen en fabrikant

### Houder van de vergunning voor het in de handel brengen:

Centrafarm B.V.  
Van de Reijtstraat 31-E  
4814 NE Breda  
Nederland

### Fabrikant:

STADA Arzneimittel AG  
Stadastrasse 2-18  
61118 Bad Vilbel  
Duitsland

STADA Arzneimittel GmbH  
Muthgasse 36/2  
1190 Wenen  
Oostenrijk

Centrafarm Services B.V.  
Nieuwe Donk 9  
4879 AC Etten-Leur  
Netherlands

### **In het register ingeschreven onder**

Ticagrelor CF 60 mg, filmomhulde tabletten, RVG 124344  
Ticagrelor CF 90 mg, filmomhulde tabletten, RVG 124346

### **Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:**

België	Ticagrelor EG 60 mg filmomhulde tabletten Ticagrelor EG 90 mg filmomhulde tabletten
Denemarken	Ticagrelor STADA
Duitsland	Ticagrelor AL 60 mg Filmtabletten Ticagrelor AL 90 mg Filmtabletten
Finland	Ticagrelor STADA 60 mg kalvopäällysteinen tabletti Ticagrelor STADA 90 mg kalvopäällysteinen tabletti
Frankrijk	Ticagrelor EG 90 mg, comprimé pelliculé
IJsland	Ticagrelor STADA
Italië	Ticagrelor EG
Luxemburg	Ticagrelor EG 60 mg comprimé pelliculés Ticagrelor EG 90 mg comprimé pelliculés
Nederland	Ticagrelor CF 60 mg, filmomhulde tabletten Ticagrelor CF 90 mg, filmomhulde tabletten
Oostenrijk	Ticagrelor STADA 60 mg Filmtabletten Ticagrelor STADA 90 mg Filmtabletten
Portugal	Ticagrelor Ciclum
Roemenië	Ticagrelor STADA 90 mg comprimate filmate
Slovenië	Ticagrelor STADA 90 mg filmsko obložene tablete
Slowakije	Ticagrelor STADA 90 mg filmom obalené tablety

Spanje	Ticagrelor STADA 60 mg comprimidos recubiertos con película EFG
	Ticagrelor STADA 90 mg comprimidos recubiertos con película EFG
Tsjechië	Ticagrelor STADA
Zweden	Ticagrelor STADA 60 mg filmdragerade tabletter
	Ticagrelor STADA 90 mg filmdragerade tabletter

**Deze bijsluiter is voor het laatst goedgekeurd in januari 2023.**