Package leaflet: Information for the patient

Dabigatran etexilaat CF 150 mg, harde capsules
dabigatran etexilate

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

<Product name> contains the active substance dabigatran etexilate and belongs to a group of medicines called anticoagulants. It works by blocking a substance in the body, that is involved in blood clot formation.

<Product name> is used in adults to:
- prevent blood clots in the brain (stroke) and other blood vessels in the body if you have a form of irregular heart rhythm called nonvalvular atrial fibrillation and at least one additional risk factor
- treat blood clots in the veins of your legs and lungs and to prevent blood clots from re-occurring in the vein of your legs and lungs

<Product name> is used in children to:
- treat blood clots and to prevent blood clots from reoccurring

2. What you need to know before you take <Product name>

DO NOT take <Product name>
- if you are allergic to dabigatran etexilate or any of the other ingredients of this medicine (listed in section 6)
- if you have severely reduced kidney function
- if you are currently bleeding
- if you have a disease in an organ of the body that increases the risk of serious bleeding (e.g. stomach ulcer, injury or bleeding in the brain, recent surgery of the brain or eyes)
- if you have an increased tendency to bleed. This may be hereditary, of unknown cause or due to other medicines
- if you are taking medicines to prevent blood clotting (e.g. warfarin, rivaroxaban, apixaban or heparin), except when changing anticoagulant treatment, while receiving heparin to keep a venous or arterial line open or while your heartbeat is being restored to normal by a procedure called catheter ablation for atrial fibrillation

- if you have severely reduced liver function or liver disease which could possibly cause death
- if you are taking oral ketoconazole or itraconazole, medicines to treat fungal infections
- if you are taking oral cyclosporine, a medicine to prevent organ rejection after transplantation
- if you are taking dronedarone, a medicine used to treat an abnormal heartbeat
- if you are taking a combination product of glecaprevir and pibrentasvir, an antiviral medicine used to treat hepatitis C
- if you have received an artificial heart valve which requires permanent blood thinning

Warnings and precautions
Talk to your doctor before taking <Product name>. You may also need to talk to your doctor during treatment with <Product name> if you experience symptoms or if you have to undergo surgery.

Tell your doctor if you have or have had any medical conditions or illnesses, in particular any of those included in the following list:
- if you have an increased bleeding risk, such as:
  - if you have been recently bleeding
  - if you have had a surgical tissue removal (biopsy) in the past month
  - if you have had a serious injury (e.g. a bone fracture, head injury or any injury requiring surgical treatment)
  - if you are suffering from an inflammation of the gullet or stomach
  - if you have problems with reflux of gastric juice into the gullet
  - if you are receiving medicines which could increase the risk of bleeding. See 'Other medicines and <Product name>' below
  - if you are taking anti-inflammatory medicines such as diclofenac, ibuprofen, piroxicam
  - if you are suffering from an infection of the heart (bacterial endocarditis)
  - if you know you have impaired kidney function, or you are suffering from dehydration (symptoms include feeling thirsty and passing reduced amounts of dark-coloured (concentrated) / foaming urine)
  - if you are older than 75 years
  - if you are an adult patient and weigh 50 kg or less
  - only if used for children: if the child has an infection around or within the brain
- if you have had a heart attack or if you have been diagnosed with conditions that increase the risk of developing a heart attack
- if you have a liver disease that is associated with changes in blood tests. The use of this medicine is not recommended in this case

Take special care with <Product name>
- if you need to have an operation:
  In this case, <Product name> will need to be stopped temporarily due to an increased bleeding risk during and shortly after an operation. It is very important to take <Product name> before and after the operation at exactly the times you have been told by your doctor
- if an operation involves a catheter or injection into your spinal column (e.g. for epidural or spinal anaesthesia or pain reduction):
  - it is very important to take <Product name> before and after the operation at exactly the times you have been told by your doctor
  - tell your doctor immediately if you get numbness or weakness of your legs or problems with your bowel or bladder after the anaesthesia wears off, because urgent care is necessary
- if you fall or injure yourself during treatment, especially if you hit your head. Please seek urgent medical attention. You may need to be checked by a doctor, as you may be at increased risk of bleeding
- if you know that you have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk of blood clots), tell your doctor, who will decide if the treatment needs to be changed

Other medicines and <Product name>
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

In particular, you should tell your doctor before taking <Product name>, if you are taking one of the medicines listed below:
- medicines to reduce blood clotting (e.g. warfarin, phenprocoumon, acenocoumarol, heparin, clopidogrel, prasugrel, ticagrelor, rivaroxaban, acetylsalicylic acid)
- medicines to treat fungal infections (e.g. ketoconazole, itraconazole), unless they are only applied to the skin
- medicines to treat an abnormal heartbeat (e.g. amiodarone, dronedarone, quinidine, verapamil).
  If you are taking verapamil-containing medicines, your doctor may tell you to use a reduced dose of <Product name> depending on the condition for which it is prescribed to you. See section 3.
- medicines to prevent organ rejection after transplantation (e.g. tacrolimus, cyclosporine)
- a combination product of glecaprevir and pibrentasvir (an antiviral medicine used to treat hepatitis C)
- anti-inflammatory and pain reliever medicines (e.g. acetylsalicylic acid, ibuprofen, diclofenac)
- St. John´s Wort, a herbal medicine for depression
- antidepressant medicines called selective serotonin re-uptake inhibitors or serotonin-norepinephrine re-uptake inhibitors
- rifampicin or clarithromycin (antibiotics)
- anti-viral medicines for AIDS (e.g. ritonavir)
- certain medicines for the treatment of epilepsy (e.g. carbamazepine, phenytoin)

Pregnancy and breast-feeding
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 this medicine.

The effects of <Product name> on pregnancy and the unborn child are not known. You should not take <Product name> if you are pregnant unless your doctor advises you that it is safe to do so. If you are a woman of childbearing age, you should avoid becoming pregnant while you are taking <Product name>.

You should not breast-feed while you are taking <Product name>.

Driving and using machines
Dabigatran etexilate has no known effects on the ability to drive or use machines.

<Product name> contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially ‘sodium-free’.

3. How to take <Product name>

<Product name> capsules can be used in adults and children aged 8 years or older who are able to swallow the capsules whole. There are other age appropriate dose forms for the treatment of children below 8 years.

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

Take <Product-name> as recommended for the following conditions:

Prevention of brain or body vessel obstruction by blood clot formation developing after abnormal heart beats and Treatment of blood clots in the veins of your legs and lungs including prevention of blood clots from reoccurring in the vein of your legs and lungs

The recommended dose is 300 mg taken as one **150 mg capsule twice a day**.

If you are **80 years or older**, the recommended dose of <Product name> is 220 mg taken as **one 110 mg capsule twice a day**.

If you are taking **verapamil-containing medicines**, you should be treated with a reduced <Product name> dose of 220 mg taken as **one 110 mg capsule twice a day**, because your bleeding risk may be increased.

If you have a **potentially higher risk for bleeding**, your doctor may decide to prescribe a dose of <Product name> 220 mg taken as **one 110 mg capsule twice a day**.

You can continue to take this medicine if your heartbeat needs to be restored to normal by a procedure called cardioversion or by a procedure called catheter ablation for atrial fibrillation. Take <Product name> as your physician has told you.

If a medical device (stent) has been deployed in a blood vessel to keep it open in a procedure called percutaneous coronary intervention with stenting, you can be treated with <Product name> after your physician has decided that normal control of blood coagulation is achieved. Take <Product name> as your physician has told you.

Treatment of blood clots and prevention of blood clots from reoccurring in children

<Product name> should be taken twice daily, one dose in the morning and one dose in the evening, at approximately the same time every day. The dosing interval should be as close to 12 hours as possible.

The recommended dose depends on weight and age. Your doctor will determine the correct dose. Your doctor may adjust the dose as treatment progresses. Keep using all other medicines, unless your doctor tells you to stop using any.

Table 1 shows single and total daily <Product name> doses in milligrams (mg). The doses depend on weight in kilograms (kg) and age in years of the patient.

Table 1: Dosing table for <Product name> capsules

Weight / age combinations		**Single dose in mg**	**Total daily dose in mg**
Weight in kg	**Age in years**		
11 to less than 13 kg	8 to less than 9 years	75	150
13 to less than 16 kg	8 to less than 11 years	110	220
16 to less than 21 kg	8 to less than 14 years	110	220
21 to less than 26 kg	8 to less than 16 years	150	300
26 to less than 31 kg	8 to less than 18 years	150	300
31 to less than 41 kg	8 to less than 18 years	185	370
41 to less than 51 kg	8 to less than 18 years	220	440
51 to less than 61 kg	8 to less than 18 years	260	520

Weight / age combinations		Single dose in mg	Total daily dose in mg
Weight in kg	**Age in years**		
61 to less than 71 kg	8 to less than 18 years	300	600
71 to less than 81 kg	8 to less than 18 years	300	600
81 kg or greater	10 to less than 18 years	300	600

Single doses requiring combinations of more than one capsule:
300 mg: two 150 mg capsules or
four 75 mg capsules
260 mg: one 110 mg plus one 150 mg capsule or
one 110 mg plus two 75 mg capsules
220 mg: as two 110 mg capsules
185 mg: as one 75 mg plus one 110 mg capsule
150 mg: as one 150 mg capsule or
two 75 mg capsules

How to take <Product name>
<Product name> can be taken with or without food. The capsule should be swallowed whole with a glass of water, to ensure delivery to the stomach. Do not break, chew, or empty the pellets from the capsule since this may increase the risk of bleeding.

Instructions for the bottle
- push and turn for opening
- after removing the capsule, place the cap back on the bottle and tightly close the bottle right away after you take your dose

Change of treatment with <Product name>
Without specific guidance from your doctor, do not change your dosage or treatment in any way.

If you take more <Product name> than you should
Taking too much of this medicine increases the risk of bleeding. Contact your doctor immediately if you have taken too many <Product name> capsules. Specific treatment options are available.

If you forget to take <Product name>
A forgotten dose can still be taken up to 6 hours prior to the next due dose.
A missed dose should be skipped if the remaining time is below 6 hours prior to the next due dose. Do not double a dose to make up for a forgotten dose.

If you stop taking <Product name>
Take <Product name> exactly as prescribed. Do not stop taking <Product name> without talking to your doctor first, because the risk of developing a blood clot could be higher if you stop treatment too early. Contact your doctor if you experience indigestion after taking <Product name>.

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.

Serious side effects

<Product name> affects blood clotting, so most side effects are related to symptoms such as bruising or bleeding.
Major or severe bleeding may occur and these constitute the most serious side effects that, regardless of location, may become disabling, life threatening or even lead to death. In some cases, this bleeding may not be obvious.

- If you experience any bleeding event that does not stop by itself or if you experience signs of excessive bleeding (exceptional weakness, tiredness, paleness, dizziness, headache or unexplained swelling) consult your doctor immediately. Your doctor may decide to keep you under closer observation or change your medicine.

- Tell your doctor immediately, if you experience a serious allergic reaction which causes difficulty in breathing or dizziness.

Other side effects

Possible side effects are listed below, grouped by how likely they are to happen.

Prevention of brain or body vessel obstruction by blood clot formation developing after abnormal heartbeats

Common (may affect up to 1 in 10 people):
- bleeding may happen from the nose, into the stomach or bowel, from penis/vagina or urinary tract (incl. blood in the urine that stains the urine pink or red), or under the skin
- a fall in the number of red blood cells
- belly ache or stomach ache
- indigestion
- frequent loose or liquid bowel movements
- feeling sick

Uncommon (may affect up to 1 in 100 people):
- bleeding
- bleeding may happen from piles, from the rectum, or in the brain
- bruising
- coughing up blood or blood stained saliva
- a fall in the number of platelets in the blood
- a fall in the amount of haemoglobin in the blood (the substance in red blood cells)
- allergic reaction
- sudden skin change which affects its colour and appearance
- itching
- ulcer in the stomach or bowel (incl. ulcer in the gullet)
- inflammation of the gullet and stomach
- reflux of gastric juice into the gullet
- vomiting
- difficulty swallowing
- unusual laboratory test results on liver function

Rare (may affect up to 1 in 1 000 people):
- bleeding may happen into a joint, from a surgical incision, from an injury, from the site of entry of an injection or from the site of entry of a catheter into a vein
- serious allergic reaction which causes difficulty breathing or dizziness
- serious allergic reaction which causes swelling of the face or throat
- skin rash notable for dark red, raised, itchy bumps caused by an allergic reaction
- a decrease in the proportion of red blood cells
- increased liver enzymes

- yellowing of the skin or whites of the eyes, caused by liver or blood problems

Not known (frequency cannot be estimated from the available data):
- difficulty breathing, wheezing
- decrease in the number or even lack of white blood cells (which help to fight infections)
- hair loss

In a clinical trial, the rate of heart attacks with dabigatran etexilate was numerically higher than with warfarin. The overall occurrence was low.

Treatment of blood clots in the veins of your legs and lungs including prevention of blood clots from reoccurring in the veins of your legs and/or lungs

Common (may affect up to 1 in 10 people):
- bleeding may happen from the nose, into the stomach or bowel, from the rectum, from penis/vagina or urinary tract (incl. blood in the urine that stains the urine pink or red), or under the skin
- indigestion

Uncommon (may affect up to 1 in 100 people):
- bleeding
- bleeding into a joint or from an injury
- bleeding from piles
- a fall in the number of red blood cells
- bruising
- coughing of blood or blood stained saliva
- allergic reaction
- sudden skin change which affects its colour and appearance
- itching
- ulcer in the stomach or bowel
- inflammation of the gullet and stomach
- reflux of gastric juice into the gullet
- feeling sick
- vomiting
- belly ache or stomach ache
- frequent loose or liquid bowel movements
- unusual laboratory test results on liver function
- increased liver enzymes

Rare (may affect up to 1 in 1 000 people):
- bleeding may happen from a surgical incision, or from the site of entry of an injection or from the site of entry of a catheter into a vein or from the brain
- a fall in the number of platelets in the blood
- serious allergic reaction which causes difficulty in breathing or dizziness
- serious allergic reaction which causes swelling of the face or throat
- skin rash notable for dark red, raised, itchy bumps caused by an allergic reaction
- difficulty swallowing

Not known (frequency cannot be estimated from the available data):
- difficulty breathing, wheezing
- a fall in the amount of haemoglobin in the blood (the substance in red blood cells)
- a fall in the number of red blood cells
- decrease in the number or even lack of white blood cells (which help to fight infections)
- yellowing of the skin or whites of the eyes, caused by liver or blood problems
- hair loss

In the trial program, the rate of heart attacks with dabigatran etexilate was higher than with warfarin. The overall occurrence was low. No imbalance in the rate of heart attacks was observed in patients treated with dabigatran etexilate versus patients treated with a placebo.

Treatment of blood clots and prevention of blood clots from reoccurring in children

Common (may affect up to 1 in 10 people):
- a fall in the number of red blood cells
- a fall in the number of platelets in the blood
- skin rash notable for dark red, raised, itchy bumps caused by an allergic reaction
- sudden skin change which affects its colour and appearance
- haematoma formation
- nosebleed
- reflux of gastric juice into the gullet
- vomiting
- feeling sick
- frequent loose or liquid bowel movements
- indigestion
- hair loss
- increased liver enzymes

Uncommon (may affect up to 1 in 100 people):
- decrease in the number of white blood cells (which help to fight infections)
- bleeding may happen into the stomach or bowel, from the brain, from the rectum, from penis/vagina or urinary tract (incl. blood in the urine that stains the urine pink or red), or under the skin
- a fall in the amount of haemoglobin in the blood (the substance in the red blood cells)
- a decrease in the proportion of blood cells
- itching
- coughing up blood or blood stained saliva
- belly ache or stomach ache
- inflammation of the gullet and stomach
- allergic reaction
- difficulty swallowing
- yellowing of the skin or whites of the eyes, caused by liver or blood problems

Not known (frequency cannot be estimated from the available data):
- lack of white blood cells (which help to fight infections)
- serious allergic reaction which causes difficulty in breathing or dizziness
- serious allergic reaction which causes swelling of the face or throat
- difficulty breathing, wheezing
- bleeding
- bleeding may happen into a joint or from an injury, from a surgical incision, or from the site of entry of an injection or from the site of entry of a catheter into a vein
- bleeding may happen from piles
- ulcer in the stomach or bowel (incl. ulcer in the gullet)
- unusual laboratory test results on liver function

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 carton, blister or bottle after "EXP". The expiry date refers to the last day of that month.

Blister: Store below 30 °C.

Bottle: Store below 30 °C. Store in the original package in order to protect from moisture. Once opened, the medicine must be used within 60 days.

When taking a hard capsule out of the bottle, the following instructions should be observed:

- The cap opens by pushing and turning.
- After taking the capsule out, the cap should be returned on the bottle right away and the bottle should be tightly closed.

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 protect the environment.

6. Contents of the pack and other information

What <Product name> contains

- The active substance is dabigatran. Each hard capsule contains dabigatran etexilate mesylate equivalent to 150 mg dabigatran etexilate.
- The other ingredients are tartaric acid (E334), hypromellose, talc, hydroxypropylcellulose (E463), croscarmellose sodium and magnesium stearate (E470b).
  Capsule shell: titanium dioxide (E171) and hypromellose.
  Black printing ink: shellac (E904), propylene glycol (E1520), black iron oxide (E172) and potassium hydroxide (E525).

What <Product name> looks like and contents of the pack

<Product name> 150 mg are hard capsules in size "0" (21.50 ± 0.40 mm) with a white opaque cap imprinted "MD" and white opaque body imprinted "150" with black ink, containing a blend of white to light yellow coloured pellets and light yellow coloured granulate.

<Product name> is available in OPA/Alu/desiccant PE-Alu/PE blisters containing 10, 30, 60 or 180 hard capsules

<Product name> 150 mg hard capsules are also available in 120 ml and 150 ml polypropylene bottles with child-resistant polypropylene closure and a desiccant containing 60 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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

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

Fabrikant:
Pharmadox Healthcare Ltd
KW20A Kordin Industrial Park
Paola, PLA3000
Malta

STADA Arzneimittel AG
Stadastrasse 2-18
61118 Bad Vilbel
Duitsland

STADA Arzneimittel GmbH
Muthgasse 36
1190 Wenen
Oostenrijk

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

Clonmel Healthcare Ltd.
Waterford Road
Clonmel, Co. Tipperary
Ierland

In het register ingeschreven onder
Dabigatran etexilaat CF 150 mg, harde capsules RVG 127268

Dit medicijn is geregistreerd in lidstaten van de Europese Economische Ruimte onder de volgende namen:

België	Dabigatran etexilate Eurogenerics 150 mg harde capsules
Denemarken	Dabigatran etexilate STADA
Duitsland	Dabigatranetexilat AL 150 mg Hartkapseln
Finland	Dabigatran etexilate STADA 150 mg kapseli, kova
Frankrijk	DABIGATRAN ETEXILATE EG 150 mg, gélule
Griekenland	Dabigatran etexilate / Stada
Hongarije	Dabigatrán-etexilát Stada 150 mg kemény kapszula
Ierland	Dabigatran etexilate Clonmel 150 mg hard capsules
IJsland	Dabigatran etexilate STADA 150 mg hörð hylki
Italië	Dabigatrano etexilato EG
Luxemburg	Dabigatran etexilate Eurogenerics 150 mg gélules
Nederland	Dabigatran etexilaat CF 150 mg, harde capsules
Oostenrijk	Dabigatranetexilat STADA Arzneimittel 150 mg Hartkapseln
Portugal	Dabigatrano etexilato Ciclum
Slowakije	Dabigatrán etexilát STADA 150 mg tvrdé kapsuly
Spanje	Dabigatrán Etexilato STADA 150 mg cápsulas duras EFG
Zweden	Dabigatran etexilate STADA 150 mg hårda kapslar

Deze bijsluiter is voor het laatst goedgekeurd in november 2023.