

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

PROPRIETARY NAME AND PHARMACEUTICAL FORM:

XARELTO® 15 Film-coated tablets

XARELTO® 20 Film-coated tablets

Read all of this leaflet carefully before you start taking XARELTO 15 or XARELTO 20.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- XARELTO 15 or XARELTO 20 has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

WHAT XARELTO 15 AND XARELTO 20 CONTAIN:

The active substance is rivaroxaban. Each tablet contains 15 mg (XARELTO 15) or 20 mg (XARELTO 20) of rivaroxaban.

The other ingredients are:

Tablet core: cellulose microcrystalline, croscarmellose sodium, hypromellose 5 cP, lactose monohydrate, magnesium stearate, sodium lauryl sulphate.

Film-coat: ferric oxide red E172, hypromellose 15 cP, macrogol 3350, titanium dioxide E171.

WHAT XARELTO 15 AND XARELTO 20 IS AND WHAT IT IS USED FOR:

XARELTO 15 and XARELTO 20 tablets are used to:

- **prevent blood clots in the brain (stroke) and other blood vessels in your body** if you have a form of irregular heart rhythm called non-valvular atrial fibrillation
- **treat blood clots** in the veins of your legs (deep vein thrombosis) and to **prevent blood clots** from re-occurring in the veins of your legs and/or lungs (pulmonary embolism)
- **treat blood clots** in the blood vessels of your lungs (pulmonary embolism) and to **prevent blood clots** from re-occurring in the blood vessels of your lungs and/or legs (deep vein thrombosis).

XARELTO 15 and XARELTO 20 belong to a group of medicines called antithrombotic agents. It works by blocking a blood clotting factor (Factor Xa) and thus reduces the tendency of the blood to clot.

BEFORE YOU TAKE XARELTO 15 OR XARELTO 20:

Do not take XARELTO 15 or XARELTO 20 and tell your doctor if any of the following apply to you:

- **if you are allergic** (hypersensitive) to rivaroxaban or any of the other ingredients of XARELTO 15 and XARELTO 20
- **if you have an inherited bleeding disorder**
- **if you have a liver disease** which leads to an increased risk of bleeding
- **if you are pregnant or breastfeeding.**

Take special care with XARELTO 15 and XARELTO 20:

- if you have **moderate or severe kidney disease**

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- if you have **moderate liver disease**
- if you have **an increased risk of bleeding** such as:
 - **bleeding disorders**
 - **very high blood pressure**, not controlled by medical treatment
 - **active ulcer or a recent ulcer** of your stomach or bowel
 - **a problem with the blood vessels in the back of your eyes** (retinopathy)
 - **recent bleeding in your brain** (intracranial or intracerebral bleeding)
 - **problems with your blood vessels in your brain or spinal column**
 - **a recent operation on your brain, spinal column or eye**
 - **a lung disease where your bronchi are widened and filled with pus** (bronchiectasis), or **previous bleeding from your lung**.
- if you have **an artificial heart valve**.

Tell your doctor before you take XARELTO 15 or XARELTO 20, if any of these apply to you. Your doctor may decide if you should be treated with XARELTO 15 or XARELTO 20 or if you should be kept under closer observation.

In children and adolescents, XARELTO 15 and XARELTO 20 are **not recommended for people under 18 years of age**. There is not enough information on its use in children and adolescents.

If you need to have an operation:

- it is very important to take XARELTO 15 or XARELTO 20 before and after the operation exactly at the times you have been told by your doctor. Inform your doctor that you are taking XARELTO 15 or XARELTO 20.

If your 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 XARELTO 15 or XARELTO 20 before and after the injection or removal of the catheter exactly at 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 end of anaesthesia, because urgent care is necessary.

Taking XARELTO 15 or XARELTO 20 with food and drink:

XARELTO 15 and XARELTO 20 have to be taken with food.

Pregnancy and breastfeeding:

- **If you are pregnant or breastfeeding** do not take XARELTO 15 or XARELTO 20. If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking XARELTO 15 or XARELTO 20. If you become pregnant while you are taking XARELTO 15 or XARELTO 20, immediately tell your doctor, who will decide how you should be treated.

Driving and using machines:

- XARELTO 15 and XARELTO 20 may cause side effects such as dizziness or fainting (see "Possible side effects"). You should not drive or use machines if you are affected by these symptoms.

Important information about some of the ingredients of XARELTO 15 and XARELTO 20:

Lactose intolerance:

- XARELTO contains lactose. Patients with rare hereditary problems of lactose or galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, who are on a lactose-free diet, should take this into consideration.

Taking other medicines with XARELTO 15 or XARELTO 20:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of XARELTO 15 or XARELTO 20 with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

If you are taking:

- some **medicines for fungal infections** (e.g. ketoconazole, itraconazole, voriconazole, posaconazole), unless they are only applied to the skin
- some **anti-retroviral medicines for HIV/AIDS** (e.g. ritonavir)
- other medicines to **reduce blood clotting** (e.g. enoxaparin or clopidogrel or Vitamin K antagonists such as warfarin and acenocoumarol)
- **anti-inflammatory and pain relieving medicines** (e.g. naproxen or acetylsalicylic acid).

Tell your doctor before taking XARELTO 15 or XARELTO 20, because its effect may be increased. Your doctor will decide if you should be treated with XARELTO 15 or XARELTO 20 and if you should be kept under closer observation.

If your doctor thinks that you are at an increased risk to develop an ulcer of your stomach or bowel, he/she may also use a preventative ulcer treatment.

If you are taking:

- some **medicines for treatment of epilepsy** (phenytoin, carbamazepine, phenobarbital)
- **St John's Wort**, a herbal product used for depression
- **rifampicin**, an antibiotic.

Tell your doctor before taking XARELTO 15 or XARELTO 20, because its effect may be reduced. Your doctor will decide if you should be treated with XARELTO 15 or XARELTO 20 and if you should be kept under closer observation.

HOW TO TAKE XARELTO 15 OR XARELTO 20:

Do not share medicines prescribed for you with others.

Always take XARELTO 15 or XARELTO 20 exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

How much to take:

- **To prevent blood clots in the brain (*stroke*) and other blood vessels in your body:**
The usual dose is one XARELTO 20 tablet once a day.
If your kidneys are not working properly, the dose may be reduced to one XARELTO 15 tablet once a day.
- **To treat blood clots in the veins of your legs and for preventing blood clots from re-occurring:**
The usual dose is one XARELTO 15 tablet twice a day for the first 3 weeks. For treatment after 3 weeks, the usual dose is one XARELTO 20 tablet once a day.
- **To treat blood clots in the blood vessels of your lungs and for preventing blood clots from re-occurring:**
The usual dose is one XARELTO 15 tablet twice a day for the first 3 weeks. For treatment after 3 weeks, the usual dose is one XARELTO 20 tablet once a day.

Swallow the tablet preferably with water.

XARELTO 15 and XARELTO 20 have to be taken with food.

When to take XARELTO 15 or XARELTO 20:

Take the tablet(s) every day until your doctor tells you to stop.

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Try to take the tablet(s) at the same time every day to help you to remember it. Your doctor will decide how long you must continue treatment for.

If you take more XARELTO 15 or XARELTO 20 than you should:

Contact your doctor immediately if you have taken too many XARELTO 15 or XARELTO 20 tablets. Taking too much XARELTO 15 or XARELTO 20 increases the risk of bleeding.

Please consult your doctor or pharmacist in the case of accidental overdose. If neither is available, rush the patient to the nearest hospital.

If you forget to take XARELTO 15 or XARELTO 20:

- **If you are taking one XARELTO 20 tablet or one XARELTO 15 tablet once a day** and have missed a dose, take it as soon as you remember. Do not take more than one tablet in a single day to make up for a forgotten dose. Take the next tablet on the following day and then carry on taking one tablet once a day.
- **If you are taking one XARELTO 15 tablet twice a day** and have missed a dose, take it as soon as you remember. Do not take more than two XARELTO 15 tablets in a single day. If you forget to take a dose you can take two XARELTO 15 tablets at the same time to get a total of two tablets (30 mg) on one day. On the following day you should carry on taking one XARELTO 15 tablet twice a day.

If you stop taking XARELTO 15 or XARELTO 20:

Don't stop taking XARELTO 15 or XARELTO 20 without talking to your doctor first, because XARELTO 15 and XARELTO 20 treats and prevents serious conditions.

If you have any further questions on the use of XARELTO 15 or XARELTO 20, ask your doctor or pharmacist.

POSSIBLE SIDE EFFECTS:

XARELTO 15 and XARELTO 20 can have side effects.

Not all side effects reported for XARELTO 15 and XARELTO 20 are included in this leaflet. Should your general health worsen while taking XARELTO 15 or XARELTO 20, please consult your doctor, pharmacist or other healthcare professional for advice.

XARELTO 15 and XARELTO 20 may cause bleedings which may potentially be life threatening. Excessive bleeding may lead to sudden drop in blood pressure (shock). In some cases these bleedings may not be obvious.

Tell your doctor immediately, if you experience any of the following side effects:

- long or excessive bleeding
- exceptional weakness, tiredness, paleness, dizziness, headache, unexplained swelling, breathlessness, chest pain (angina pectoris). These may be signs of bleeding.

Your doctor may decide to keep you under closer observation or change how you should be treated.

It has been reported for XARELTO 15 and XARELTO 20 that the following side effects can occur:

Frequent side effects:

- bleeding in the stomach or bowel, urogenital bleeding (including blood in the urine and heavy menstrual bleeding), nose bleed, bleeding in the gum
- bleeding into the eye (including bleeding from the whites of the eyes)
- bleeding into tissue or a cavity of the body (haematoma, bruising)
- bleeding following an operation
- swelling in the limbs

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- pain in the limbs
- fever
- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- stomach ache, indigestion, feeling or being sick, constipation, diarrhoea
- low blood pressure
- decreased general strength and energy (weakness, tiredness), headache, dizziness
- rash, itchy skin
- blood tests may show an increase in some liver enzymes
- impaired function of the kidneys
- bleeding from the skin or under the skin
- coughing up blood.

Less frequent side effects:

- bleeding into the brain or inside the skull
- bleeding into a joint causing pain and swelling
- oozing of blood or fluid from surgical wound
- feeling unwell
- dry mouth
- allergic reactions, including allergic skin reactions
- hives
- impaired function of the liver
- blood tests may show an increase in bilirubin, some pancreatic or liver enzymes or in the number of platelets
- raised heartbeat
- fainting
- bleeding into a muscle
- collection of blood (haematoma) following complication in a cardiac procedure where a catheter is inserted to treat narrowed coronary arteries (pseudoaneurysm)
- localised swelling
- yellowing of the skin and eye (jaundice).

Side effects where frequency is not known:

(frequency cannot be estimated from the available data)

- increased pressure within muscles of the legs or arms after a bleeding, which leads to pain, swelling, altered sensation, numbness or paralysis (compartment syndrome after a bleeding)
- kidney failure after a severe bleeding.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

IDENTIFICATION OF XARELTO 15 AND XARELTO 20:

XARELTO 15: Round, biconvex, red film-coated tablets, 6 mm in diameter, 9 mm radius of curvature, debossed with a triangle over "15" on the top side and the BAYER cross on the bottom side of the tablet.

XARELTO 20: Round, biconvex, brown red film-coated tablets, 6 mm in diameter, 9 mm radius of curvature, debossed with a triangle over "20" on the top side and the BAYER cross on the bottom side of the tablet.

PRESENTATION OF XARELTO 15 AND XARELTO 20:

XARELTO 15 film-coated tablets are packed in colourless, transparent PP (polypropylene)/aluminium blister strips or colourless, transparent PVC/PVDC/aluminium blister strips. Pack sizes: 14 tablets, 28 tablets, 42 tablets, 98 tablets or 100 tablets.

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XARELTO 20 film-coated tablets are packed in colourless, transparent PP (polypropylene)/aluminium blister strips or colourless, transparent PVC/PVDC/aluminium blister strips. Pack sizes: 14 tablets, 28 tablets, 42 tablets, 98 tablets or 100 tablets.

STORING AND DISPOSING OF XARELTO 15 AND XARELTO 20:

Store at or below 30 °C. Keep blister strips in the original carton until use.

Do not use XARELTO 15 or XARELTO 20 after the expiry date which is stated on the carton and on each blister.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

REGISTRATION NUMBERS:

XARELTO 15: 46/8.2/0111

XARELTO 20: 46/8.2/0112

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Bayer (Pty) Ltd
Reg. No.: 1968/011192/07
27 Wrench Road
ISANDO
1609

DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

5 December 2013