Front Side

400 mm

335 mm

XABRIVA
10/15/20 mg
(film-coated tablet)
PM04335162

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

WARNING: (A) PREMATURE DISCONTINUATION OF XABRIVA INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HAEMATOMA

A. Premature discontinuation of XABRIVA increase the risk of thrombotic events:
Premature discontinuation of any oral anticoagulant, including XABRIVA, increases the risk of thrombotic events. If anticoagulation with XABRIVA is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant *[see Posology and method of administration (4.2), Special Warnings and Precautions (4.4), and Clinical Studies (5.1 & 5.2)].*

B. Spinal/epidural haematoma:
Epidural or spinal haematomas have occurred in patients treated with XABRIVA who are receiving neuraxial anaesthesia or undergoing spinal puncture. These haematomas may result in long term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures.
Factors that can increase the risk of developing epidural or spinal haematomas in these patients include:
- **Use of indwelling epidural catheters**
- **Concomitant use of other medicines that affect haemostasis, such as nonsteroidal anti-inflammatory medicines (NSAIDs), platelet inhibitors, other anticoagulants.**
- **History of traumatic or repeated epidural spinal punctures**
- **History of spinal deformity or spinal surgery**
- **Optimal timing between the administration of XABRIVA and neuraxial procedure is not known *(see Special Warnings and Precautions (4.4) and Undesirabe effects (4.8)***

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary *[see Special Warnings and Precautions (4.4)].*
Consider the benefits and risks before neuraxial intervention n patients anticoagulated or to be anticoagulated for thromboprophylaxis *(See Special Warnings and precautions (4.4)*

XABRIVA 10 mg film-coated tablets
Contains rivaroxaban 10 mg
Contains sugar (17 mg of lactose monohydrate)

XABRIVA 15 mg film-coated tablets
Contains rivaroxaban 15 mg
Contains sugar (25.5 mg of lactose monohydrate)

XABRIVA 20 mg film-coated tablets
Contains rivaroxaban 20 mg
Contains sugar (34 mg of lactose monohydrate)

Read all of this leaflet carefully before you start taking XABRIVA
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **XABRIVA** have 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.are the same as yours.

What is in this leaflet

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

1. What XABRIVA is and what it is used for

XABRIVA 10 mg film-coated tablets
XABRIVA 10 mg is used to prevent blood clots in your veins after a major operation on your legs. For example this could be an operation on your hip or knee. Your doctor has prescribed **XABRIVA 10 mg** for you because after an operation you are at an increased risk of getting blood clots. The active substance is rivaroxaban. It belongs to a group of medicines called antithrombotic agents. It works by inhibiting blood clotting Factor Xa.

XABRIVA 15 mg film-coated tablets
XABRIVA 20 mg film-coated tablets
XABRIVA 15 mg and **XABRIVA 20 mg** 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).

XABRIVA 15 mg and **XABRIVA 20 mg** 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.

2. What you need to know before you take XABRIVA

Do not take XABRIVA if:
- If you are allergic (hypersensitive) to rivaroxaban or any of the other ingredients of **XABRIVA**
- if you are bleeding excessively or have an inherited bleeding disorder
- If you have a disease or condition 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 are on any other anti-clotting medicine e.g. warfarin
- If you have severe liver disease which leads to an increased risk of bleeding
- If you are pregnant or breast feeding

If you think any of these apply to you, tell your doctor.

Warnings and precautions
Talk to your doctor or pharmacist before taking **XABRIVA**
- If you have moderate or severe kidney 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)
  - 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 **XABRIVA**, if any of these apply to you. Your doctor may decide to keep you under closer observation. 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 **XABRIVA** 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.

If any of the above applies to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking **XABRIVA**.
If you need to have an operation
- It is very important to take **XABRIVA** before and after the operation exactly at the times you have been told by your doctor.
- 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 **XABRIVA** 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.

Use in children and adolescents
XABRIVA should not be given to children and patients below 18 years of age.

Other medicines and XABRIVA
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Tell your doctor or pharmacist if you (or your child) are taking any of the following:
- Some medicines for fungal infections (e.g. ketoconazole), unless they are only applied to the skin
- Anti-viral medicines for HIV / AIDS (e.g. ritonavir)
- Other medicines to reduce blood clotting (e.g. enoxaparin or clopidogrel)
- Anti-inflammatory and pain relieving medicines (e.g. naproxen or acetylsalicylic acid)

Tell your doctor before taking **XABRIVA**, because its effect may be increased. Your doctor will decide if you should be treated with **XABRIVA** 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 **XABRIVA**, because its effect may be reduced.

XABRIVA with food and drink:
Swallow the tablet preferably with water. **XABRIVA** can be taken with or without food.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding don't take **XABRIVA.** If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking **XABRIVA.** If you become pregnant while you are taking **XABRIVA**, immediately tell your doctor who will decide how you should be treated.

Driving and using machines
XABRIVA 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.

XABRIVA contains lactose
Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **XABRIVA**
This medicine contains less than 1 mmol sodium per tablet, that is to say essentially 'sodium-free'

3. How to take XABRIVA

Do not share medicines prescribed for you with any other person.
Always take **XABRIVA** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
Take **XABRIVA** by mouth. Take or give **XABRIVA** with or without food. Do not chew, cut, or crush **XABRIVA.**

XABRIVA 10 mg film-coated tablets
The usual dose is:
The usual dose is one **XABRIVA 10 mg** tablet (10 mg) once a day. Swallow the tablet preferably with water. **XABRIVA 10 mg** tablet can be taken with or without food. When to take **XABRIVA 10 mg:** Take the first tablet 6 - 10 hours after your operation. Then take a tablet every day until your doctor tells you to stop. Try to take the tablet at the same time every day to help you to remember it. If you have had a major hip operation you will usually take the tablets for 5 weeks. If you have had a major knee operation you will usually take the tablets for 2 weeks. Children and adolescents up to 18 years of age: Don't give **XABRIVA 10 mg** tablets to people under 18 years of age. There is not enough information on its use in children and adolescents.

XABRIVA 15 mg & 20 mg film-coated tablets
The usual dose is:
- To prevent blood clots in the brain (stroke) and other blood vessels in your body: The usual dose is one **XABRIVA 20 mg** tablet once a day.

If your kidneys are not working properly, the dose may be reduced to one **XABRIVA 15 mg** 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 **XABRIVA 15 mg** tablet twice a day for the first 3 weeks. For treatment after 3 weeks, the usual dose is one **XABRIVA 20 mg** 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 **XABRIVA 15 mg** tablet twice a day for the first 3 weeks. For treatment after 3 weeks, the usual dose is one **XABRIVA 20 mg** tablet once a day.
Swallow the tablet preferably with water.
XABRIVA 15 mg and **XABRIVA 20 mg** have to be taken with food.

If you take more XABRIVA than you should
In the event of an overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center.
If you (or your child) take too many tablets of **XABRIVA** contact your doctor or pharmacist for advice. If possible, show them the **XABRIVA** pack. Taking too much **XABRIVA 15 mg** or **XABRIVA 20 mg** increases the risk of bleeding.

If you forget to take XABRIVA:
It is important to take your **XABRIVA** regularly at the same time each day. If you have missed a dose, take it as soon as you remember. Take the next tablet on the following day and then carry on taking a tablet once a day as normal. Do not take a double dose to make up for a forgotten tablet.

If you stop taking XABRIVA:
Don't stop taking **XABRIVA** without talking to your doctor first, because **XABRIVA** prevents the development of a serious condition. If you have any further questions on the use of **XABRIVA**, ask your doctor or pharmacist.

4. Possible side effects

XABRIVA can have side effects.
Not all side effects reported for **XABRIVA** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking **XABRIVA** and tell your doctor immediately or go to the casualty department at your nearest hospital.
These are serious side effects and you may need urgent medical attention:
- Allergic reactions :If you notice signs such as: skin rash, a high temperature (fever), lack of energy (fatigue), swelling, sometimes of the face or mouth (angioedema), difficulty in breathing, muscle or joint aches, see a doctor straight away.

XABRIVA 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. Your doctor may decide to carry out tests on your liver, kidneys or blood, and may tell you to stop taking **XABRIVA**

Check with your doctor If any of the following side effects worry you:
Frequent side effects may include:
- Anaemia (reduction in the quantity of oxygen-carrying material (haemoglobin) in the blood)
- Headache and dizziness
- bleeding into the eye (including bleeding from the whites of the eyes)
- Low blood pressure and bleeding into tissue or a cavity of the body (haematoma, bruising)
- Nose bleed and coughing of blood
- Bleeding gums, bleeding stomach and intestines, stomach pains, acid reflux, nausea, constipation, vomiting, diarrhoea
- Blood tests may show an increase in some liver enzymes
- Itchy skin, rash, bleeding from the skin surface and underneath the skin
- Pain in the limbs
- urogenital bleeding (including blood in the urine and heavy menstrual bleeding)
- Impaired function of the kidneys (may be seen in tests performed by your doctor)
- fever, swelling in the limbs, decrease in general strength and energy
- bleeding following an operation, oozing of blood or fluid from surgical wound

Less frequent side effects
- thrombocytopenia (low number of platelets, which are cells that help blood to clot)
- Allergic reactions, including allergic skin reactions
- bleeding into the brain or inside the skull (see above, signs of bleeding), fainting
- Irregular and fast heartbeat
- dry mouth
- Impaired function of the liver (may be seen in tests performed by your doctor)
- Hives
- Feeling unwell, localised swelling
- Vascular pseudoaneurysm - Blood vessel wall is injured and the leaking blood collects in the surrounding tissue.

Frequency unknown
- Severe allergic reactions and shock
- Spreading intense skin rash, blisters or mucosal lesions, e.g. in the mouth or eyes (Stevens-Johnson syndrome/toxic epidermal necrolysis).
- a drug reaction that causes rash, fever, inflammation of internal organs, blood abnormalities and systemic illness (DRESS syndrome).
- 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 severe bleeding

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reactions & Quality Problem Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8
By reporting side effects, you can help provide more information on the safety of **XABRIVA.**

5. How to store XABRIVA

Store at or below 30 °C (room temperature). Protect from light.
Keep the blisters in the carton until required for use.
Store in the original package in order to protect from light and moisture.
KEEP OUT OF THE REACH OF CHILDREN.
Do not store in a bathroom.
Do not use after the expiry date stated on the bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What XABRIVA contains
XABRIVA 10 mg film-coated tablets
Each film-coated tablet contains rivaroxaban 10 mg
Contains sugar (Lactose monohydrate 17 mg).

XABRIVA 15 mg film-coated tablets
Each film-coated tablet contains rivaroxaban 15 mg
Contains sugar (Lactose monohydrate 25.5 mg).

XABRIVA 20 mg film-coated tablets
Each film-coated tablet contains rivaroxaban 20 mg
Contains sugar (Lactose monohydrate 34 mg).

Other ingredients include:
Colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl methylcellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate.
Film coating contains [HPMC 2910 / Hypromellose 6 cPs, polyethylene glycol 400, polyethylene glycol 6000, titanium dioxide (C.I. No. 77891), red iron oxide (C.I. No. 77491)].

What XABRIVA looks like and contents of the pack
XABRIVA 10 mg film-coated tablets
Pink colour, circular, biconvex, film coated tablets debossed with "J 8" on one side and plain on the other side.
XABRIVA 15 mg film-coated tablets
Light red colour, circular, biconvex, film coated tablets debossed with "J 9" on one side and plain on the other side.
XABRIVA 20 mg film-coated tablets
Red colour, triangular shape, film coated tablets debossed with "J 10" on one side and plain on the other side.

Blister pack
Tablets are packed in a white Opaque film PVC/PE/PVdC film 250/25/90, 250 µ PVC film coated with 90 GSM PVDC and lidded with plain 25 µ Aluminium foil/ 6-8 gsm heat seal lacquer coating.
Pack sizes include:
XABRIVA 10 mg: 5s, 10s, 28s, 30s, 42s 100s
XABRIVA 15 mg and 20 mg: 14s, 28s, 30s, 42s, 98s, 100s
Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

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31 October 2023.

Registration number
XABRIVA 10 mg: 56/8.2/0741
XABRIVA 15 mg: 56/8.2/0742
XABRIVA 20 mg: 56/8.2/0743

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169.

Back Side

400 mm

335 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

WAARSKUWING: (A) VROEË STAKING VAN XABRIVA VERHOOG DIE RISIKO VAN TROMBOTIESE GEBEURE, (B) SPINALE/EPIDURALE HEMATOOM

A. Vroeë staking van XABRIVA verhoog die risiko van trombotiese gebeure:
Vroeë staking van enige orale antikoagulant, insluitend XABRIVA, verhoog die risiko van trombotiese gebeure. Indien antikoagulasie met XABRIVA gestaak word vir 'n rede anders as patologiese bloeding of voltooiing van 'n behandelingskursus, oorweeg dekking met 'n ander antikoagulant *[sien Posologie en metode van toediening (4.2), Spesiale Waarskuwings en Voorsorgmaatreëls (4.4) en Kliniese Studies (5.1 & 5.2)].*

B. Spinale/epidurale hematoom:
Epidurale of spinale hematome het voorgekom in pasiënte wat met XABRIVA behandel is, wat neuraksiale narkose ontvang of ruggraatpunktuur ondergaan. Hierdie hematome kan langtermyn of permanente verlamming tot gevolg hê. Oorweeg hierdie risiko's wanneer pasiënte vir spinale prosedures geskeduleer word.
Faktore wat die risiko vir die ontwikkeling van epidurale- of spinale hematome in hierdie pasiënte kan verhoog, sluit in:
- **Gebruik van epidurale kateters binne jou liggaam**
- **Gelyktydige gebruik van ander medisyne wat hemostase beïnvloed, soos nie-steroïdale anti-inflammatoriese medisyne (NSAIM's), bloedplaatjie-inhibeerders, ander antikoagulante.**
- **Geskiedenis van traumatiese of herhaalde epidurale/spinale punktuur**
- **Geskiedenis van spinale misvorming of spinale chirurgie**
- **Optimale tydsberekening tussen die toediening van XABRIVA en neuraksiale prosedure is nie bekend nie *(sien Spesiale Waarskuwings en Voorsorgmaatreëls (4.4) en Ongewenste-effekte (4.8)***

Monitor pasiënte gereeld vir tekens en simptome van neurologiese inkorting. Indien neurologiese beklemming opgemerk word, is dringende behandeling nodig *[sien Spesiale Waarskuwings en Voorsorgmaatreëls (4.4)]*. Oorweeg die voordele en risiko's voor neuraksiale ingryping in antikoagulerende pasiënte of wat geantikoaguleer gaan word vir trombo-voorkoming *(sien Spesiale Waarskuwings en Voorsorgmaatreëls (4.4))*.

XABRIVA 10 mg filmbedekte tablette
Bevat rivaroksabaan 10 mg
Bevat suiker: (17 mg van laktosemonohidraat)

XABRIVA 15 mg filmbedekte tablette
Bevat rivaroksabaan 15 mg
Bevat suiker: (25,5 mg van laktosemonohidraat)

XABRIVA 20 mg filmbedekte tablette
Bevat rivaroksabaan 20 mg
Bevat suiker: (34 mg van laktosemonohidraat)

Lees hierdie inligtingstuk sorgvuldig deur voordat jy XABRIVA begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees om dit weer te lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer
- **XABRIVA** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

1. Wat **XABRIVA** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **XABRIVA** neem
3. Hoe om **XABRIVA** te neem
4. Moontlike newe-effekte
5. Hoe om **XABRIVA** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat XABRIVA is en waarvoor dit gebruik word

XABRIVA 10 mg filmbedekte tablette
XABRIVA 10 mg word gebruik om bloedklonte in jou are te voorkom na 'n groot operasie op jou bene. Dit kan byvoorbeeld 'n operasie op jou heup of knie wees. Jou dokter het **XABRIVA 10 mg** vir jou voorgeskryf, omdat jy na 'n operasie 'n verhoogde risiko het om bloedklonte te kry. Die aktiewe bestanddeel is rivaroksabaan. Dit behoort aan 'n groep medisyne wat antitrombotiese middels genoem word. Dit werk deur die inhibering van bloedstollingsfaktor Xa.

XABRIVA 15 mg filmbedekte tablette
XABRIVA 20 mg filmbedekte tablette
XABRIVA 15 mg en XABRIVA 20 mg tablette word gebruik om:
- bloedklonte in die brein (beroerte) en ander bloedvate in jou liggaam te voorkom, indien jy 'n vorm van onreëlmatige hartritme het wat nie-klep atriale fibrillasie genoem word.
- bloedklonte in die are van jou bene te behandel (diep veneuse trombose) en om te verhoed dat bloedklonte weer in die are van jou bene en/of longe voorkom (pulmonale embolisme).
- bloedklonte in die bloedvate van jou longe te behandel (pulmonale embolisme) en om te verhoed dat bloedklonte weer in die bloedvate van jou longe en/of bene voorkom (diep veneuse trombose).

XABRIVA 15 mg en XABRIVA 20 mg behoort aan 'n groep medisyne wat antitrombotiese middels genoem word. Dit werk deur 'n bloedstollingsfaktor (Faktor Xa) te blokkeer en verminder dus die neiging van die bloed om te stol.

2. Wat jy behoort te weet voordat jy XABRIVA gebruik

Moet nie XABRIVA neem nie:
- indien jy allergies (hipersensitief) vir rivaroksabaan of enige van die ander bestanddele van **XABRIVA is.**
- indien jy oormatig bloei of 'n oorerflike bloedingsversteuring het
- indien jy 'n siekte of toestand in 'n orgaan van die liggaam het wat die risiko van ernstige bloeding verhoog (bv. maagulkus, besering of bloeding in die brein, onlangse chirurgie van die brein of oë).
- indien jy enige ander anti-stollingsmedisyne gebruik, bv. warfarien
- indien jy ernstige lewersiekte het wat lei tot 'n verhoogde bloedingsrisiko
- indien jy swanger is of borsvoed

Indien jy dink dat enige van hierdie op jou van toepassing is, vertel dit vir jou dokter.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter of apteker voordat jy **XABRIVA** neem
- Indien jy matige of ernstige niersiekte het
- Indien jy 'n verhoogde risiko van bloeding het soos:
  - bloedingsversteurings
  - Baie hoë bloeddruk, nie beheer deur mediese behandeling nie
  - Aktiewe ulkus of 'n onlangse ulkus van jou maag of derm
  - 'n Probleem met die bloedvate agter in jou oë (retinopatie)
  - Onlangse bloeding in jou brein (intrakraniale of intraserebrale bloeding)
  - 'n Onlangse operasie op jou brein, spinale kolom of oog
  - 'n Longsiekte waar jou brongi verwyd en gevul is met etter (bronggiektase), of vorige bloeding vanuit jou long.
- Indien jy 'n kunsmatige hartklep het.

Vertel jou dokter voordat jy **XABRIVA** neem, indien enige van hierdie op jou van toepassing is. Jou dokter kan besluit om jou onder nadere waarneming te hou. Indien jou operasie 'n kateter of inspuiting in jou werwelkolom behels (bv. vir epidurale of spinale narkose of pynvermindering):
- Dit is baie belangrik om **XABRIVA** voor en na die inspuiting of verwydering van die kateter te neem op die presiese tye wat jou dokter vir jou gesê het.
- Vertel onmiddellik jou dokter indien jy na die einde van narkose, gevoelloosheid of swakheid van jou bene, of probleme met jou derm of blaas ondervind, want dringende sorg is nodig.

Indien enige van die bogenoemde op jou van toepassing is (of jy is nie seker nie), praat met jou dokter, apteker of verpleegkundige voordat jy **XABRIVA** neem.
Indien jy 'n operasie moet kry
- dit is baie belangrik om **XABRIVA** voor en na die operasie te neem op die presiese tye wat jou dokter vir jou gesê het.
- Indien jou operasie 'n kateter of inspuiting in jou werwelkolom behels (bv. vir epidurale of spinale narkose of pynvermindering):
- dit is baie belangrik om **XABRIVA** voor en na die inspuiting of verwydering van die kateter te neem op die presiese tye wat jou dokter vir jou gesê het.
- vertel onmiddellik jou dokter indien jy gevoelloosheid of swakheid van jou bene, of probleme met jou derm of blaas, na die einde van narkose kry, want dringende sorg is nodig.

Gebruik in kinders en adolessente
XABRIVA moet nie aan kinders en pasiënte jonger as 18 jarige ouderdom gegee word nie.

Ander medisyne en XABRIVA
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Vertel jou dokter of apteker indien jy (of jou kind) enige van die volgende gebruik:
- Sommige medisyne vir swaminfeksies (bv. ketokonasool), tensy dit slegs op die vel toegedien word
- Anti-virale medisyne vir MIV / VIGS (bv. ritonavir)
- Ander medisyne om bloedstolling te verminder (bv. enoksaparien of klopidogrel)
- Anti-inflammatoriese en pynverligtende medisyne (bv. naproksen of asetielsalisielsuur)

Vertel jou dokter voordat jy **XABRIVA** neem, omdat die effek daarvan kan verhoog word. Jou dokter sal besluit of jy met **XABRIVA** behandel moet word en of jy onder nadere waarneming gehou moet word.
Indien jou dokter dink dat jy 'n groter risiko het om 'n ulkus van jou maag of derm te ontwikkel, kan hy / sy ook 'n voorkomende ulkusbehandeling gebruik.

Indien jy die volgende neem:
- sommige medisyne vir behandeling van epilepsie (fenitolen, karbamasepien, fenobarbital)
- St Johannes kruid, 'n kruieproduk wat gebruik word vir depressie
- rifampisien, 'n antibiotika.

Vertel jou dokter voordat jy **XABRIVA** neem, omdat die effek daarvan kan verminder word.

XABRIVA met voedsel en drank:
Sluk die tablet verkieslik met water. **XABRIVA** kan met of sonder kos geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of borsvoed, moet jy nie **XABRIVA** neem nie. Gebruik 'n betroubare voorbehoedmiddel indien daar 'n moontlikheid is dat jy swanger kan raak, terwyl jy **XABRIVA** gebruik. Vertel onmiddellik jou dokter as jy swanger raak terwyl jy **XABRIVA** gebruik, wat dan sal besluit hoe jy behandel moet word.

Bestuur en gebruik van masjinerie
XABRIVA kan newe-effekte soos duiseligheid of floute veroorsaak (sien "Moontlike newe-effekte"). Jy moet nie bestuur of masjiene gebruik indien jy deur hierdie simptome geaffekteer word nie.

XABRIVA bevat laktose
Pasiënte met die seldsame oorerflike toestande van laktose of galaktose-intoleransie moet nie **XABRIVA** neem nie
Hierdie medisyne bevat minder as 1 mmol natrium per tablet, dit wil sê in wese 'natriumvry'

3. Hoe om XABRIVA te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie
Neem altyd **XABRIVA** presies soos jou dokter vir jou voorgeskryf het. Jy behoort met jou dokter of apteker te bevestig indien jy onseker is.
Neem **XABRIVA** per mond. Neem of gee **XABRIVA** met of sonder kos. Moet nie **XABRIVA** kou, sny, of fyn druk nie.

XABRIVA 10 mg filmbedekte tablette
Die gewone dosis is:
Die gewone dosis is een **XABRIVA 10 mg** tablet (10 mg) een keer per dag. Sluk die tablet verkieslik met water. **XABRIVA 10 mg** tablet kan met of sonder kos geneem word. Wanneer om **XABRIVA 10 mg** te neem: Neem die eerste tablet 6 - 10 ure na jou operasie. Neem dan elke dag 'n tablet totdat jou dokter vir jou sê om op te hou. Om jou te help om dit te onthou, probeer om die tablet elke dag op dieselfde tyd te neem. Indien jy 'n groot knie-operasie gehad het, sal jy gewoonlik die tablette vir 2 weke neem.
Kinders en adolessente tot 18 jarige ouderdom: Moet nie **XABRIVA 10 mg** tablette aan mense jonger as 18 jarige ouderdom gee nie. Daar is nie genoeg inligting oor die gebruik daarvan in kinders en adolessente nie.
XABRIVA 15 mg & 20 mg filmbedekte tablette
Die gewone dosis is:
- Om bloedklonte in die brein (beroerte) en ander bloedvate in jou liggaam te verhoed: Die gewone dosis is een **XABRIVA 20 mg** tablet een keer per dag.

Indien jou niere nie behoorlik werk nie, kan die dosis tot een **XABRIVA 15 mg** tablet, een keer per dag verminder word.
- Om bloedklonte in die are van jou bene te behandel en om te verhoed dat bloedkolle weer voorkom:

Die gewone dosis is een **XABRIVA 15 mg** tablet twee keer per dag vir die eerste 3 weke. Vir behandeling na die 3 weke is die gewone dosis een **XABRIVA 20 mg** tablet een keer per dag.
- Om bloedklonte in die bloedvate van jou longe te behandel en om te verhoed dat bloedklonte weer voorkom:

Die gewone dosis is een **XABRIVA 15 mg** tablet twee keer per dag vir die eerste 3 weke. Vir behandeling na 3 weke is die gewone dosis een **XABRIVA 20 mg** tablet een keer per dag.
Sluk verkieslik die tablet met water.
XABRIVA 15 mg en XABRIVA 20 mg moet saam met kos geneem word.

Indien jy meer XABRIVA neem as wat jy behoort te neem
In die geval van 'n oordosering, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, soek hulp by die naaste hospitaal of gifbeheersentrum.
Indien jy (of jou kind) te veel **XABRIVA** tablette neem, kontak jou dokter of apteker vir advies. Indien moontlik, wys vir hulle die **XABRIVA** pak. Die neem van te veel **XABRIVA 15 mg** of **XABRIVA 20 mg**, verhoog die risiko van bloeding.

Indien jy vergeet om XABRIVA te neem:
Dit is belangrik om jou **XABRIVA** gereeld, elke dag op dieselfde tyd, te neem. Indien jy 'n dosis vergeet het, neem dit sodra jy daarvan onthou. Neem die volgende tablet op die volgende dag en gaan dan aan om 'n tablet een keer per dag te neem, soos normaal. Moet nie 'n dubbele dosis neem om vir 'n vergete tablet op te maak nie.

Indien jy ophou om XABRIVA te neem:
Moet nie ophou om **XABRIVA** te neem sonder om eers met jou dokter te praat nie, want **XABRIVA** voorkom die ontwikkeling van 'n ernstige toestand. Indien jy enige verdere vrae het oor die gebruik van **XABRIVA**, vra jou dokter of apteker.

4. Moontlike newe-effekte

XABRIVA kan newe-effekte hê.
Nie al die newe-effekte wat vir **XABRIVA** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid egteruitgaan of indien jy enige ongewenste effekte ervaar terwyl jy hierdie medisyne gebruik, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, hou op om **XABRIVA** te neem en kontak onmiddellik jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal.
Hierdie is ernstige newe-effekte en jy mag dringende mediese aandag benodig:
- Allergiese reaksies Indien jy tekens opmerk soos: veluitslag, 'n hoë temperatuur (koors), 'n gebrek aan energie (moegheid), swelling, soms in die gesig of mond (angioedeem), asemhalingsprobleme, spier- of gewrigspyne, moet jy onmiddellik 'n dokter gaan sien.

XABRIVA kan bloeding veroorsaak wat moontlik lewensgevaarlik kan wees. Oormatige bloeding kan lei tot skielike daling in bloeddruk (skok). In sommige gevalle mag hierdie bloeding nie voor die hand liggend wees nie.
Vertel onmiddellik jou dokter, indien jy enige van die volgende newe-effekte ervaar:
- Lang of oormatige bloeding
- Uitsonderlike swakheid, moegheid, bleekheid, duiseligheid, hoofpyn, onverklaarbare swelling, asemloosheid, borskaspyn (angina pectoris). Hierdie kan tekens van bloeding wees.

Jou dokter kan besluit om jou onder nadere waarneming of verandering te hou. Jou dokter kan besluit om toetse op jou lewer, niere of bloed uit te voer, en kan jou aansê om op te hou om **XABRIVA** te neem.

Gesels met jou dokter indien enige van die volgende newe-effekte jou bekommerd maak:
Gereelde newe-effekte kan insluit:
- Anemie (vermindering in die hoeveelheid suurstofdraende materiaal (hemoglobien) in die bloed)
- Hoofpyn en duiseligheid
- bloeding in die oog (insluitend bloeding vanuit die wit van die oë)
- Lae bloeddruk en bloeding in weefsel of 'n holte van die liggaam (hematoom, kneusplekke)
- Neusbloeding en hoes van bloed
- Bloeiende tandvleis, bloeiende maag en ingewande, maagpyn, suur reflukse, naarheid, hardlywigheid, braking, diarree
- Bloedtoetse kan 'n toename in sommige lewerensieme toon
- Jeukerige vel, uitslag, bloeding vanuit die veloppervlak en onder die vel
- Pyn in die ledemate
- urogenitale bloeding (insluitend bloed in die urine en swaar menstruele bloeding)
- ingekorte funksie van die niere (kan gesien word in toetse wat deur jou dokter uitgevoer word)
- koors, swelling in die ledemate, afname in algemene krag en energie
- bloeding na 'n operasie, bloed of vloeistof wat uit chirurgiese wond vloei

Minder gereelde newe-effekte
- trombositopenie (lae aantal bloedplaatjies, wat selle is wat bloed help stol)
- Allergiese reaksies, insluitend allergiese velreaksies
- bloeding in die brein of binne-in die skedel (sien hierbo, tekens van bloeding), floutes
- onreëlmatige en vinnige hartklop
- droë mond
- Ingekorte funksie van die lewer (kan gesien word in toetse wat deur jou dokter uitgevoer word)
- Galbulte
- Ongesteld voel, gelokaliseerde swelling
- Vaskulêre pseudo-aneurisme - Bloedvatwand is beseer en die lekkende bloed versamel in die omliggende weefsel.

Frekwensie onbekend
- Erge allergiese reaksies en skok
- Verspreiding van intense veluitslag, blase of mukosale letsels, bv. in die mond of oë (Stevens-Johnson-sindroom / toksiese epidermale nekrolise).
- 'n geneesmiddelreaksie wat uitslag, koors, ontsteking van interne organe, bloedabnormaliteite en sistemiese siekte (DRESS-sindroom) veroorsaak.
- verhoogde druk binne in spiere van die bene of arms na bloeding, wat lei tot pyn, swelling, veranderde sensasie, gevoelloosheid of verlamming (kompartement sindroom na bloeding)
- nierversaking na ernstige bloeding

Indien jy enige newe-effekte ervaar wat nie in hierdie inligtingstuk genoem word nie, stel asseblief jou dokter of apteker in kennis.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk genoem word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction & Quality Problem Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8
Deur newe-effekte aan te meld kan jy help om meer inligting te verskaf aangaande die veiligheid van **XABRIVA.**

5. Hoe om XABRIVA te bewaar

Bewaar by of benede 30°C (kamertemperatuur). Beskerm teen lig.
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Bewaar in die oorspronklike verpakking om sodoende teen lig en vog te beskerm.
BEWAAR BUITE DIE BEREIK VAN KINDERS
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat op die bottel aangedui word nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat XABRIVA bevat
XABRIVA 10 mg filmbedekte tablette
Elke filmbedekte tablet bevat rivaroksabaan 10 mg
Bevat suiker (Laktosemonohidraat 17 mg).

XABRIVA 15 mg filmbedekte tablette
Elke filmbedekte tablet bevat rivaroksabaan 15 mg
Bevat suiker (Laktosemonohidraat 25,5 mg).

XABRIVA 20 mg filmbedekte tablette
Elke filmbedekte tablet bevat rivaroksabaan 20 mg
Bevat suiker (Laktosemonohidraat 34 mg).

Ander bestanddele sluit in:
Kolloïdale silikondioksied, natriumkroskarmellose, hidroksipropielmetielsellulose, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, natriumlaurielsulfaat.
Filmbedekking bevat [HPMC 2910 / Hipromellose 6 cPs, poliëtileenglikol 400, poliëtileenglikol 6 000, titaandioksied (C.I. No. 77891), rooi ysteroksied (C.I. No. 77491)].

Hoe XABRIVA lyk en inhoud van die pak
XABRIVA 10 mg filmbedekte tablette
Pienk kleur, sirkelvormige, bikonvekse, filmbedekte tablette bedruk met "J 8" op die een kant en glad aan die ander kant.
XABRIVA 15 mg filmbedekte tablette
Ligte rooi kleur, sirkelvormige, bikonvekse, filmbedekte tablette bedruk met "J 9" op die een kant en glad aan die ander kant.
XABRIVA 20 mg filmbedekte tablette
Rooi kleur, driehoekige vorm, filmbedekte tablette bedruk met "J 10" op die een kant en glad aan die ander kant.

Stulpverpakking
Tablette is verpak in 'n wit Ondeursigtige film PVC/PE/PVdC film 250/25/90, 250 µ PVC film bedek met 90 GSM PVDC en bedek met gewone 25 µ Aluminium foelie/ 6-8 gsm hittе seëllak laag.
Pakgroottes sluit in:
XABRIVA 10 mg: 5s, 10s, 28s, 30s, 42s 100s
XABRIVA 15 mg en 20 mg: 14s, 28s, 30s, 42s, 98s, 100s
Nie alle verpakkings en pakgroottes word noodwendig bemark nie.

Houer van die Sertifikaat van Registrasie en Vervaardiger
MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos).
Cussonia-rylaan 1, Bassonia Rock, Uitbr 12.
Alberton, Suid-Afrika

Hierdie inligtingstuk was laas hersien in
31 Oktober 2023.

Registrasienommer
XABRIVA 10 mg: 56/8.2/0741
XABRIVA 15 mg: 56/8.2/0742
XABRIVA 20 mg: 56/8.2/0743

Toegang tot die oorsenstemmende Professionele Inligting
Die oorsenstemmende professionele inligting kan verkry word by http://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 11t/3.

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MACLEODS

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: XABRIVA 10/15/20 mg (Rivaroxaban Tablets 10/15/20 mg)	
2. Country: South Africa (Private Market)	3. Packaging component: Patient Information Leaflet
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	8. Dimensions: 400 (L) x 335 (W) mm
9. Design / Style: Booklet type	10. Item code No.: PM04335152
11. Artwork has been made: Actual Size	12. Pharma code No.: 33803 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: NA
15. Revision no: 00	16. A/W File name: Z:\RIVAROXABAN\SA Private Market\01\Rivaroxaban Tablets PIL - PM04335152.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
07/06/2024	Vanita Rajool	10/06/24	14/06/24	17/6/24	19/06/24

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa - Private Market	PM04335152		

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