PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

PRODUCT NAME, STRENGTH AND PHARMACEUTICAL FORM

EMBIRIV 10 (FILM COATED TABLETS)

Read all of this leaflet carefully before you start taking EMBIRIV 10

- 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.
- **EMBIRIV 10** 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

1. WHAT EMBIRIV 10 IS AND WHAT IT IS USED FOR:

- **EMBIRIV 10** belong to a group of medicines called antithrombotic medicines. It works by blocking a blood clotting factor (Factor Xa) and thus reduces the tendency of the blood to clot.
- **EMBIRIV 10** prevents blood clots in the veins after a hip or knee replacement operation. Your doctor has prescribed this medicine for you because after an operation you are at an increased risk of getting blood clots.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE

Sign:

Do not take EMBIRIV 10

- If you are allergic (hypersensitive) to Rivaroxaban or to any ingredients of **EMBIRIV 10,** (listed in section 6)
- If you have a bleeding disorder that you have inherited or bleeding excessively
- 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 taking medicines to prevent blood clotting (e.g. warfarin or heparin), except when changing anticoagulant treatment or while getting heparin through a venous or arterial line to keep it open
- If you have a liver disease which leads to an increased risk of bleeding
- If you are pregnant or breastfeeding

EMBIRIV 10 should not be used in children and adolescents**,** under 18 years of age.

Warnings and precautions

EMBIRIV 10 should not be used in combination with certain other medicines which reduce blood clotting such as prasugrel or ticagrelor other than acetylsalicylic acid and clopidogrel/ticlopidine.

Take Special Care with **EMBIRIV 10**:

- If you suffer from moderate or severe kidney disease
- If you suffer from 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, diseases of your stomach or bowel that might result in bleeding, e.g. inflammation of the bowels or stomach, or

inflammation of the oesophagus (gullet), e.g. due to gastroesophageal reflux disease (disease where stomach acid goes upwards into the oesophagus
    - a problem with the blood vessels in the back of your eyes (retinopathy)
    - recent bleeding in your brain (intracranial 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.
- 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 may need to be changed.
- If your doctor determines that your blood pressure is unstable or another treatment or surgical procedure to remove the blood clot from your lungs is planned.

If you need to have an operation:

- it is very important to take **EMBIRIV 10** 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 **EMBIRIV 10** 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.

Sign: 

Other medicines and EMBIRIV 10

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

If you are taking:

- some medicine for fungal infections (e.g. ketoconazole, itraconazole, voriconazole), 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)
- anti-inflammatory and pain-relieving medicines (e.g. naproxen or acetylsalicylic acid)
- some medicine for treatment of epilepsy (phenytoin, carbamazepine, phenobarbitone)
- St John's Wort, a herbal product used for depression
- some medicines to treat depression (selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs)
- rifampicin**,** an antibiotic
- dronedarone, a medicine to treat abnormal heartbeat

EMBIRIV 10 with food and drink and alcohol

EMBIRIV 10 must be taken with or without food.

Pregnancy and breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other health care provider for advice before taking this medicine.

Do not take **EMBIRIV 10** if you are pregnant or breast-feeding. If there is a chance that you could become pregnant, use a reliable contraceptive while you are taking **EMBIRIV 10**.

Sign:

Driving and using machines

EMBIRIV 10 may cause dizziness or fainting (see section 4," Possible side effects"). You should not drive or use machines if you are affected by these symptoms.

It is not always possible to predict to what extent **EMBIRIV 10** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **EMBIRIV 10** affects them.

EMBIRIV 10 contains:

EMBIRIV 10 contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **EMBIRIV 10**.

3. HOW TO TAKE EMBIRIV 10

Do not share medicines prescribed for you with any other person.

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

How much to take

To prevent blood clots in the veins after a hip or knee replacement operation

The recommended dose is one tablet **EMBIRIV 10** mg once a day.

Your doctor has prescribed you **EMBIRIV 10** mg once a day.

When to take EMBIRIV 10

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

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.

Sign: 

To prevent blood clots in the veins after a hip or knee replacement operation:

Take the first tablet 6 - 10 hours after your operation.

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.

If you take more EMBIRIV 10 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison center**.**

Taking too much **EMBIRIV 10** increases the risk of bleeding.

If you forget to take EMBIRIV 10

Do not take a double dose to make up for forgotten individual doses. 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.

If you stop taking EMBIRIV 10

Do not stop taking **EMBIRIV 10** without talking to your doctor first, because **EMBIRIV 10** treats and prevents serious conditions.

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

4. POSSIBLE SIDE EFFECTS

EMBIRIV 10 can have side-effects.

*Not all side effects reported for **EMBIRIV 10** are included in this leaflet. Should your health worsen or if you experience any untoward effects while taking **EMBIRIV 10**, please consult your doctor, pharmacist or other health care professional for advice.*

Sign: 

If any of the following happens, stop taking **EMBIRIV 10** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the face, lips, mouth, tongue or throat; difficulty swallowing; hives and breathing difficulties(angioedema); sudden drop in blood pressure.
- anaphylactic reactions, including anaphylactic shock
- allergic oedema

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- long or excessive bleeding
- exceptional weakness, tiredness, paleness, dizziness, headache, unexplained swelling, breathlessness, chest pain or angina pectoris, which may be signs of bleeding.
- spreading intense skin rash, blisters or mucosal lesions, e.g. in the mouth or eyes (Stevens-Johnson syndrome/toxic epidermal necrolysis).
- a medicine reaction that causes rash, fever, inflammation of internal organs, hematologic abnormalities and systemic illness (DRESS syndrome).

These are all serious side effects. You may need urgent medical attention.

These are all very serious side effects. If you have them, you may have had a serious reaction to **EMBIRIV 10.** You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- reduction in red blood cells which can make the skin pale and cause weakness or breathlessness
- bleeding in the stomach or bowel, urogenital bleeding (including blood in the urine and heavy menstrual bleeding), nosebleed, bleeding in the gum
- bleeding into the eye (including bleeding from the whites of the eyes)

Sign:

- bleeding into tissue or a cavity of the body (haematoma, bruising)
- coughing up blood
- bleeding from the skin or under the skin
- bleeding following an operation
- oozing of blood or fluid from surgical wound
- swelling in the limbs
- pain in the limbs
- impaired function of the kidneys (may be seen in tests performed by your doctor)
- fever
- stomach-ache, indigestion, feeling or being sick, constipation, diarrhoea
- low blood pressure (symptoms may be feeling dizzy or fainting when standing up)
- decreased general strength and energy (weakness, tiredness), headache, dizziness
- rash, itchy skin
- blood tests may show an increase in some liver enzymes

Less Frequent side effects:

- bleeding into the brain or inside the skull
- bleeding into a joint causing pain and swelling
- thrombocytopenia (low number of platelets, which are cells that help blood to clot)
- allergic reactions, including allergic skin reactions
- impaired function of the liver (may be seen in tests performed by your doctor)
- blood tests may show an increase in bilirubin, some pancreatic or liver enzymes or in the number of platelets
- fainting
- feeling unwell
- faster heartbeat
- dry mouth

Sign: 

- hives
- bleeding into a muscle
- cholestasis (decreased bile flow), hepatitis incl. hepatocellular injury (inflamed liver incl. liver injury)
- yellowing of the skin and eye (jaundice)
- localised swelling
- collection of blood (haematoma) in the groin as a complication of the cardiac procedure where a catheter is inserted in your leg artery (pseudoaneurysm)

Frequency not known:

- kidney failure after a severe bleeding
- 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)

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. You can also report side effects to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **EMBIRIV 10**

Sign:

5. HOW TO STORE EMBIRIV 10

KEEP OUT OF REACH OF CHILDREN

Any unused medicine or waste material should be returned to the pharmacy for destruction. Do not dispose of unused medicine in drains or sewerage systems (e.g toilets).

Store at or below 30 °C in original container, protect from moisture and light.

Do not remove blister card from the carton until required for use.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What EMBIRIV 10 contains:

The active substance is Rivaroxaban

Excipients:

EMBIRIV 10 – Lactose monohydrate, croscarmellose sodium, hypromellose, sodium lauryl sulphate, colloidal silicon dioxide, magnesium stearate, opadry pink, titanium dioxide, macrogol / peg, iron oxide red.

What EMBIRIV 10 looks like and contents of the pack

EMBIRIV 10 round pink, biconvex film coated tablets, debossed with “L” on one side and “10” on other side.

EMBIRIV 10 (rivaroxaban) film-coated tablets are available as follows: A carton containing aluminium foil and transparent PVC/PVDC blister strips containing 10 tablets each and 3 blister strips per pack.

Sign:

Holder of Certificate of Registration

Ranbaxy Pharmaceuticals (Pty) Ltd.

14 Lautre Road, Stormill, Ext.1

Roodepoort, 1724

South Africa

This leaflet was revised in

Registration number

EMBIRIV 10 mg: 55/8.2/0317

Sign:

Date: July 2024

PASIËNTINLIGTINGSPAMFLET

SKEDULERINGSTATUS

S4

PRODUKNAAM, STERKTE EN FARMASEUTIESE VORM

EMBIRIV 10 (FILMBEDEKTE TABLETTE)

Lees die hele pamflet deeglik deur voordat jy begin om EMBIRIV te neem.

- Hou hierdie pamflet. Dit is moontlik dat jy dit weer sal wil lees.
- Indien jy verdere vrae het, vra gerus jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **EMBIRIV 10** is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander persone deel nie. Dit kan skadelik vir hulle wees, selfs al het hulle dieselfde simptome as jy.

1. WAT EMBIRIV IS EN WAARVOOR DIT GEBRUIK WORD:

- **EMBIRIV 10** 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.
- **EMBIRIV 10** voorkom bloedklonte in die are ná ’n heup- of knievervangingsoperasie. Jou dokter het hierdie medisyne vir jou voorgeskryf omdat jy ná ’n operasie ’n verhoogde risiko het om bloedklonte te kry.

2. WAT JY MOET WEET VOORDAT JY EMBIRIV GEBRUIK

Moet nie EMBIRIV 10 neem nie:

Sign:

- As jy allergies (hipersensitief) is vir rivaroksaban of vir enige bestanddeel van **EMBIRIV 10**.
- As jy ’n bloedingsversteuring het wat jy oorgeërf het, of as jy buitensporig bloei.
- As jy 'n siekte of toestand in 'n orgaan van jou liggaam het wat die risiko van ernstige bloeding verhoog (bv. ’n maagsweer, besering of bloeding in die brein, of ’n onlangse operasie aan die brein of oë).
- As jy medisyne gebruik om bloedstolling te voorkom (bv. warfarien of heparien), behalwe wanneer jy van antistollingsbehandeling verander, of terwyl jy heparien deur ’n veneuse of arteriële lyn ontvang om die lyn oop te hou.
- As jy ’n lewersiekte het wat tot ’n verhoogde risiko van bloeding lei.
- As jy swanger is of borsvoed.

EMBIRIV 10 moet nie by kinders en adolessente onder die ouderdom van 18 jaar gebruik word nie.

Waarskuwings en voorsorgmaatreëls

EMBIRIV 10 moet nie in kombinasie met sekere ander medisyne gebruik word wat bloedstolling verminder nie, soos prasugrel of tikagrelor (behalwe saam met asetielsalisielsuur en klopidogrel/tiklopidien).

Wees versigtig met **EMBIRIV 10**:

- As jy aan matige of ernstige niersiekte ly.
- As jy aan matige lewersiekte ly.
- As jy ’n verhoogde risiko van bloeding het, byvoorbeeld:
    - bloedingsversteurings
    - baie hoë bloeddruk wat nie deur mediese behandeling beheer word nie
    - ’n aktiewe ulkus of ’n onlangse ulkus van jou maag of derm, siektes van jou maag of derm wat tot bloeding kan lei, bv. ontsteking van die derm of maag, of

ontsteking van die slukderm (esofagus), bv. as gevolg van gastro-esofageale reflukssiekte (’n toestand waar maagsuur opbeweeg in die slukderm)

- ’n probleem met die bloedvate aan die agterkant van jou oë (retinopatie)
- ’n onlangse bloeding in jou brein (intrakraniale bloeding)
- probleme met die bloedvate in jou brein of werwelkolom
- ’n onlangse operasie van jou brein, ruggraat of oë
- ’n longsiekte waar jou brongi verwyd is en met etter gevul is (brongiëktase), of as jy voorheen bloeding uit jou long gehad het.

- As jy ’n kunsmatige hartklep het.
- As jy weet dat jy ’n siekte genaamd antifosfolipied-sindroom het (’n immuunstelseltoestand wat die risiko van bloedklonte verhoog), stel jou dokter in kennis — jou dokter sal besluit of die behandeling verander moet word.
- As jou dokter bepaal dat jou bloeddruk onstabiel is, of as ’n ander behandeling of chirurgiese prosedure beplan word om die bloedklont uit jou longe te verwyder.

As jy ’n operasie moet ondergaan:

- Dit is baie belangrik om **EMBIRIV 10** voor én ná die operasie presies op die tye in te neem wat jou dokter aangedui het.
- As jou operasie ’n kateter of inspuiting in jou ruggraat behels (bv. vir epidurale of spinale narkose of pynbeheer):
  - Dit is baie belangrik om **EMBIRIV 10** voor én ná die inspuiting of verwydering van die kateter presies op die tye in te neem wat jou dokter aangedui het.
  - Stel jou dokter onmiddellik in kennis indien jy gevoelloosheid of swakheid in jou bene ervaar of probleme met jou derm of blaas ná die narkose opmerk, want dringende mediese sorg is nodig.

Ander medisyne en EMBIRIV 10

Sign:

Vertel altyd vir jou gesondheidsorgverskaffer as jy enige ander medisyne gebruik. (Dit sluit *komplementêre* of *tradisionele* medisyne in.)

As jy enige van die volgende medisyne neem:

- sekere medisyne vir swaminfeksies (bv. ketokonasool, itrakonasool, vorikonasool), tensy dit slegs op die vel toegedien word
- sekere anti-retrovirale medisyne vir MIV/VIGS (bv. ritonavir)
- ander medisyne wat bloedstolling verminder (bv. enoksaparien of klopidogrel, of vitamien-K antagoniste soos warfarin)
- anti-inflammatoriese en pynstillende medisyne (bv. naprokseen of asetielsalisielsuur)
- sekere medisyne vir die behandeling van epilepsie (fenitoïen, karbamasepien, fenobarbital)
- Sint-Janskruid, ’n kruieproduk wat vir depressie gebruik word
- sekere medisyne om depressie te behandel (selektiewe serotonienheropname-inhibeerders of serotonien-noradrenalienheropname-inhibeerders, d.w.s. SSRI’s of SNRI’s)
- rifampisien, ’n antibiotikum
- dronedaroon, ’n medisyne om ’n abnormale hartklop te behandel

EMBIRIV 10 saam met kos, drank en alkohol

EMBIRIV 10 kan saam kos of sonder kos geneem word.

Swangerskap, borsvoeding en vrugbaarheid

As jy swanger is of borsvoed, dink dat jy swanger is of beplan om ’n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne neem.

Moet nie **EMBIRIV 10** neem indien jy swanger is of borsvoed nie. As daar ’n kans is dat jy swanger kan raak, gebruik ’n betroubare voorbehoedmiddel terwyl jy **EMBIRIV 10** neem.

Sign:

Bestuur en gebruik van masjiene

EMBIRIV 10 kan duiseligheid of floute veroorsaak (sien afdeling 4, **"Moontlike newe-effekte"**). Jy moet nie bestuur of masjiene gebruik indien jy deur hierdie simptome geaffekteer word nie.

Dit is nie altyd moontlik om vooraf te weet in watter mate **EMBIRIV 10** jou daaglikse aktiwiteite kan beïnvloed nie, totdat jy bewus is van hoe dit jou raak.

EMBIRIV 10 bevat:

EMBIRIV 10 bevat laktose. As jou dokter vir jou gesê het dat jy 'n intoleransie vir sekere suikers het, raadpleeg jou dokter voordat jy **EMBIRIV 10** neem.

3. HOE OM EMBIRIV 10 TE NEEM

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem hierdie medisyne altyd presies soos jou dokter of apteker vir jou gesê het. Raadpleeg jou dokter of apteker indien jy nie seker is nie.

Hoeveel EMBIRIV 10 om te neem

Om bloedklonte in jou are te voorkom ná 'n heup- of knievervangingsoperasie

Die voordestelde dosis is een tablet **EMBIRIV 10** een keer per dag.

Jou dokter het vir jou **EMBIRIV 10** mg voorgeskryf om een keer elke dag te neem.

Wanneer om EMBIRIV 10 te neem

Neem die tablet(te) elke dag totdat jou dokter jou laat weet om op te hou. Probeer om die tablet(te) elke dag op dieselfde tyd te neem, sodat jy dit makliker kan onthou. Jou dokter sal besluit hoe lank jy met die behandeling moet voortgaan.

Om bloedklonte in jou are te voorkom ná 'n heup- of knievervangingsoperasie:

Neem die eerste tablet 6 tot 10 uur ná jou operasie.

Sign:

As jy ’n groot heupoperasie gehad het, sal jy gewoonlik die tablette vir 5 weke gebruik.

As jy ’n groot knie-operasie gehad het, sal jy gewoonlik die tablette vir 2 weke neem.

As jy meer EMBIRIV 10 geneem as wat jy moet

In die geval van oordosering, raadpleeg jou dokter of apteker dadelik. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum. Om te veel **EMBIRIV 10** te neem verhoog die risiko van bloeding.

As jy vergeet om EMBIRIV 10 te neem

Moet nie ‘n dubbele dosis neem om op te maak vir die een dosis wat jy vergeet het nie.

Neem dit sodra jy daaraan dink. Neem die volgende tablet die dag daarna en gaan dan aan soos gewoonlik – een tablet per dag.

As jy ophou om EMBIRIV 10 te neem

Moenie ophou om **EMBIRIV 10** te neem sonder om eers met jou dokter te praat nie, want **EMBIRIV 10** behandel en voorkom ernstige toestande.

Indien jy enige verdere vrae het oor die gebruik van hierdie medisyne, vra jou dokter of apteker.

4. MOONTLIKE NEWE-EFFEKTE

EMBIRIV 10 kan newe-effekte hê.

Nie alle newe-effekte wat vir **EMBIRIV 10** gerapporteer is, is in hierdie pamflet gelys nie. As jou gesondheid versleg of as jy enige ongewenste effekte ervaar terwyl jy **EMBIRIV 10** neem, raadpleeg asseblief jou dokter, apteker of ’n ander gesondheidsorgverskaffer vir advies.

Indien een van die volgende gebeur, staak die gebruik van **EMBIRIV 10** en stel jou dokter onmiddellik in kennis of gaan na die ongevalle-afdeling van jou naaste hospitaal:

- swelling van die gesig, lippe, mond, tong of keel; slukprobleme; uitslag en asemhalingsprobleme (angio-edeem); skielike daling in bloeddruk

Sign:

- anafilaktiese reaksies, insluitend anafilaktiese skok
- allergiese edeem

Laat weet jou dokter dadelik, of gaan na die noodafdeling van jou naaste hospitaal as jy een van die volgende dinge opmerk:

- langdurige of oormatige bloeding
- uitsonderlike swakheid, moegheid, bleekheid, duiseligheid, hoofpyn, onverklaarbare swelling, kortasemigheid, borspyn of angina pectoris – dit kan tekens van bloeding wees
- wydverspreide, erge veluitslag; blase of letsels op slymvliese (bv. in die mond of oë) – bekend as Stevens-Johnson-sindroom / toksiese epidermale nekrolose
- 'n medisyne-reaksie wat uitslag, koors, ontsteking van interne organe, bloedafwykings en sistemiese siekte veroorsaak (*DRESS*-sindroom)

Dit is alles baie ernstige newe-effekte. Jy mag dalk dadelik mediese hulp nodig hê.
Hierdie is baie ernstige newe-effekte. As jy enige van bogenoemde ervaar, kan jy 'n ernstige reaksie op **EMBIRIV 10** hê en moontlik dringende mediese aandag of hospitalisasie benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:

Gereelde newe-effekte:

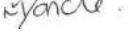
- vermindering in rooibloedselle, wat jou vel bleek kan maak en swakheid of kortasemigheid kan veroorsaak
- bloeding in die maag of ingewande; bloeding in die urineweg (insluitend bloed in die urine en swaar menstruasie); neusbloeding; bloeding van die tandvleis
- bloeding in die oog (insluitend bloeding in die wit deel van die oog)
- bloeding in weefsel of 'n liggaamsholte (hematome, kneusings)
- ophoes van bloed
- bloeding op die vel of onder die vel

Sign:

- bloeding ná ’n operasie
- afskeiding van bloed of vloeistof vanuit ’n chirurgiese wond
- swelling in die ledemate
- pyn in die ledemate
- verminderde nierfunksie (word dikwels slegs opgemerk in toetse wat jou dokter uitvoer)
- koors
- maagpyn, slegte spysvertering, naarheid of braking, hardlywigheid, diarree
- lae bloeddruk (simptome hiervan kan insluit duiseligheid of floute wanneer jy opstaan)
- verminderde algemene krag en energie (swakheid, moegheid); hoofpyn; duiseligheid
- veluitslag, jeukerige vel
- bloedtoetse kan ’n verhoging in sekere lewerensieme wys

Minder algemene newe-effekte:

- bloeding in die brein of binne-in die skedel
- bloeding in ’n gewrig wat pyn en swelling veroorsaak
- trombositopenie (lae aantal bloedplaatjies, die selle wat help met bloedstolling)
- allergiese reaksies, insluitend allergiese velreaksies
- verminderde lewerfunksie (kan gesien word in toetse wat deur jou dokter uitgevoer word)
- bloedtoetse kan ’n verhoging in bilirubien wys, of ’n toename in sekere pankreas- of lewerensieme, of in die getal bloedplaatjies
- floute
- ’n gevoel van ongesteldheid (gevoel dat jy siek/naar is)
- vinniger hartklop
- droë mond
- korwe (urtikarie)
- bloeding in ’n spier

Sign: 

- cholestase (verminderde galvloei); hepatitis, insluitend hepatosellulêre skade (ontsteking van die lewer, insluitend lewerskade)
- geel verkleuring van die vel en oë (geelsug)
- plaaslike swelling
- versameling van bloed (hematoom) in die lies as ’n komplikasie van ’n hartprosedure waar ’n kateter in jou beenarterie geplaas word (*pseudo*-aneurisme)

Frekwensie onbekend:

- nierversaking ná ’n ernstige bloeding
- verhoogde druk binne-in die spiere van die bene of arms ná bloeding, wat pyn, swelling, veranderde gevoel, gevoelloosheid of verlamming veroorsaak (*kompartement-sindroom* na bloeding)

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

Aanmelding van newe-effekte

As jy newe-effekte ervaar, praat met jou dokter, apteker of verpleegkundige. Jy kan newe-effekte ook aan SAHPRA rapporteer via die Med Safety App (Medsafety X SAHPRA) en die eReporting-platform (who-umc.org) wat op SAHPRA se webwerf beskikbaar is. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van **EMBIRIV 10** te verskaf.

5. HOE OM EMBIRIV 10 TE BEWAAR

HOU BUITE BEREIK VAN KINDERS.

Enige ongebruikte medisyne of afvalmateriaal moet vir vernietiging aan die apteek terugbesorg word. Moenie ongebruikte medisyne in dreine of in die rioolstelsel (bv. in die toilet) weggooi nie.

Bêre by of onder 30 °C in die oorspronklike houer, en beskerm teen vog en lig.

Moenie die stulpverpakking uit die karton verwyder voordat dit benodig word vir gebruik nie.

Sign:

6. INHOUD VAN DIE VERPAKKING EN ANDER INLIGTING

Wat EMBIRIV 10 bevat:

Die aktiewe bestanddeel is rivaroksaban.

Hulpstowwe:

EMBIRIV 10 – laktosemonohidraat, natriumkroskarmellose, hipromellose, natriumlaurielsulfaat, kolloïdale silikondioksied, magnesiumstearaat, Opadry pienk, titaniumdioksied, makrogol/PEG, ysteroksied rooi.

Hoe EMBIRIV 10 lyk en inhoud van die verpakking:

EMBIRIV 10 ronde pienk, bikonvekse filmbedekte tablette, met “L” aan die een kant en “10” aan die ander kant.

EMBIRIV 10 (rivaroksaban) filmbedekte tablette is beskikbaar as volg: ’n karton met aluminiumfoelie- en deursigtige PVC/PVDC-stulpstroke wat elk 10 tablette bevat en 3 stulpstroke per pak.

Houer van Registrasiesertifikaat:

Ranbaxy Pharmaceuticals (Pty) Ltd.

Lautre Road 14, Stormill Ext. 1

Roodepoort, 1724

Suid-Afrika

Hierdie pamflet is hersien in:

27 November 2024

Registrasienommer:

EMBIRIV 10 mg: 55/8.2/0317

Sign: 