SCHEDULING STATUS:

S4

DABIGATRAN 75/110/150 DRL Capsules

dabigatran etexilate

Sugar free

Read all of this leaflet carefully before you start taking DABIGATRAN DRL capsules

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- DABIGATRAN DRL 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 is in this leaflet:

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

1. What DABIGATRAN DRL is and what it is used for

DABIGATRAN DRL contains the active substance dabigatran etexilate and belongs to a group of medicines called anticoagulants.

It works by blocking a substance in the body which is involved in blood clot formation.

DABIGATRAN DRL is used to:

- prevent the formation of blood clots in the veins after knee or hip replacement surgery in adults.
- lower the risk of stroke or other blood vessel blockages caused by formation of blood clots developing after abnormal heart rhythm (atrial fibrillation).
- treat and prevent the formation of blood clots in the lungs and rest of the body.

2. What you need to know before you take DABIGATRAN DRL

Do not take DABIGATRAN DRL if you:

- are allergic (hypersensitive) to dabigatran etexilate or any of the other ingredients of DABIGATRAN DRL (see "What DABIGATRAN DRL contains").
- if you have severely reduced kidney function.
- if you are currently bleeding.
- if you have a reduced liver function or liver disease which could possibly cause death.
- 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 inborn, 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 having a venous or arterial line and you get heparin through this line to keep it open or while your heart beat is being restored to normal by a procedure called catheter ablation for atrial fibrillation.

- 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 abnormal heart beat.
- if you are taking a combination product of glecaprevir and pibrentasvir, an antiviral medicine used to treat hepatitis C.
- if you are aware of a previous diagnosis of an infection of parts of your heart (endocarditis).
- if you have received an artificial heart valve.

Warnings and precautions

Special care should be taken with DABIGATRAN DRL.

Tell your doctor immediately if you experience symptoms or if you have to undergo surgery.

Before you start taking DABIGATRAN DRL, tell your doctor if you suffer from any of the following:

- if you have an increased bleeding risk.
- 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) urine).
- if you have a liver disease that is associated with changes in the blood tests. The use of DABIGATRAN DRL is not recommended in this case.

- 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 DABIGATRAN DRL before and after the operation 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 you need to have an operation:
  In this case DABIGATRAN DRL will need to be stopped temporarily due to an increased bleeding risk during and shortly after an operation. It is very important to take DABIGATRAN DRL before and after the operation exactly at the times you have been told by your doctor.
- 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.

Children and adolescents

DABIGATRAN DRL is not for use in children and adolescents below 18 years old.

Other medicines and DABIGATRAN DRL

Always tell your healthcare professional if you are taking any other medicine.
(This includes complementary or traditional medicines).
Taking DABIGATRAN DRL with some medicines may mean the doctor will need to change your dose of DABIGATRAN DRL or the other medicines.

Tell your doctor if you are taking the following:

- medicines to reduce blood clotting (e.g., warfarin, 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 abnormal heart beats (e.g., amiodarone, dronedarone, quinidine, verapamil)
  If you are taking amiodarone, quinidine or verapamil containing medicines, your doctor will tell you to use a reduced dose of DABIGATRAN DRL. See also 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 (two antibiotics)
- anti-viral medicines for AIDS (e.g., ritonavir)
- certain medicines for treatment of epilepsy (e.g., carbamazepine)

These medicines may increase the risk of side effects or reduce the effect of DABIGATRAN DRL. If you get any unusual symptoms taking any of these medicines together with DABIGATRAN DRL you should see your doctor or healthcare provider.

DABIGATRAN DRL with food and drink

DABIGATRAN DRL can be taken with or without food.

Pregnancy and Breastfeeding

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

- DABIGATRAN DRL should not be used during pregnancy unless clearly necessary.
- You should not take DABIGATRAN DRL if you are breastfeeding.
- If you are a woman of child-bearing age, you should avoid becoming pregnant while you are taking DABIGATRAN DRL.

Driving and using machines

No studies on the effects of DABIGATRAN DRL on the ability to drive and use machines have been performed. It is not always possible to predict to what extent DABIGATRAN DRL may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which DABIGATRAN DRL affects you.

DABIGATRAN DRL contains sodium

DABIGATRAN DRL contains sodium which is a type of salt. If you are on a controlled salt diet, contact your doctor before taking DABIGATRAN DRL.

3. How to take DABIGATRAN DRL

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

Always take DABIGATRAN DRL exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

Do not change the dose or stop taking DABIGATRAN DRL without talking with your doctor or pharmacist.

Talk with your doctor about how long you should keep on taking DABIGATRAN DRL.

DABIGATRAN DRL is for oral use.

DABIGATRAN DRL 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. If gastrointestinal symptoms develop it is recommended to take DABIGATRAN DRL with a meal and to contact your healthcare provider.

Prevention of venous thromboembolism (VTE) in patients following hip and knee replacement surgery:

The usual dose is 220 mg once a day (taken as 2 capsules of 110 mg).

VTE prevention following knee replacement surgery:

You should start treatment with DABIGATRAN DRL within 1 to 4 hours after surgery finishes, usually as a single capsule (110 mg). Thereafter two capsules once a day should be taken for a total of 10 days.

VTE prevention following hip replacement surgery:

You should start treatment with DABIGATRAN DRL within 1 to 4 hours after surgery finishes, taking a single capsule (110 mg) as the usual dose. Thereafter two capsules once a day

should be taken for a total of 28 days.

To reduce the risk of stroke and systemic embolism in patients with atrial fibrillation:
The usual daily dose of DABIGATRAN DRL is 300 mg taken orally as 150 mg capsules twice daily. Therapy should be continued life-long.

Treatment of acute deep vein thrombosis (DVT) and/or pulmonary embolism (PE):
The usual daily dose of DABIGATRAN DRL is 300 mg taken orally as 150 mg capsules twice daily following treatment with a parenteral anticoagulant for at least 5 days. Therapy should be continued for up to 6 months.

Prevention of recurrent deep vein thrombosis (DVT) and/or pulmonary embolism (PE):
The usual daily dose of DABIGATRAN DRL is 300 mg taken orally as 150 mg capsules twice daily. Therapy could be continued life-long depending on the individual patient's risk factors.

If you have the impression that the effect of DABIGATRAN DRL is too strong or too weak, talk to your doctor or pharmacist.

If you take more DABIGATRAN DRL than you should
Taking too much DABIGATRAN DRL increases the risk of bleeding. Contact your doctor immediately if you have taken too many DABIGATRAN DRL capsules. Specific treatment options are available.

If you forget to take DABIGATRAN DRL

Continue with your remaining daily doses of DABIGATRAN DRL at the same time of the next day.

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

If you stop taking DABIGATRAN DRL

- Take DABIGATRAN DRL exactly as prescribed. Do not stop taking DABIGATRAN DRL 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 DABIGATRAN DRL.
- If you have any further questions on the use of this product, ask your doctor, pharmacist or other healthcare provider.

4. Possible side effects

DABIGATRAN DRL can have side effects.

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

If any of the following happens, stop taking DABIGATRAN DRL and tell your doctor, pharmacist or healthcare provider immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, mouth, lips, gums, tongue, throat and neck which may cause difficulty in swallowing or breathing.
- throat tightness, shortness of breath and wheezing.

Allergic reactions, including death, can happen in patients taking DABIGATRAN DRL even

after only one dose.

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

DABIGATRAN DRL affects blood clotting, so most side effects are related to signs such as bruising or bleeding.

Major or severe bleeding may occur, these constitute the most serious side effects and, regardless of location, may become disabling, life-threatening or even lead to death. In some cases, these bleedings 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, pharmacist or healthcare provider if you notice any of the following:

Frequent side effects:

- a decrease in the proportion of red cells in the blood (anaemia) which causes a pale complexion, extreme tiredness, flaky nails and shortness of breath when exercising;
- bleeding may happen from the nose;
- bleeding in the stomach and from the rectum, stomach pain, loose stools (diarrhoea), indigestion (dyspepsia), feeling sick (nausea);
- unusual laboratory test results on liver function;
- bleeding under the skin;

- bleeding from the urinary tract (incl. blood in the urine which stains the urine pink or red) or from the penis/vagina.

Less frequent:

- a decrease of platelets - it causes nosebleeds, bleeding gums, blood in urine, heavy menstrual periods, and bruising;
- a decrease in the amount of haemoglobin in the blood (the substance in the red blood cells);
- "hives", rash, itching;
- bleeding may happen in the brain;
- localised bleeding outside of blood vessels (haematoma);
- coughing up blood;
- liver enzymes increased (can be seen in blood tests);
- bleeding in the joints;
- bleeding at an injection site and from the site of entry of a catheter into a vein;
- blood-stained discharge;
- wound secretion (liquid exuding from the surgical wound);
- fluid exiting a wound;
- fluid exiting a wound after an operation.

Side effects with unknown frequencies:

- difficulty in breathing or wheezing;
- decreases in the number or even lack of white blood cells (which help to fight infections);
- severe and life-threatening allergic reaction;

- hair loss.

If you notice any other side effects not on this leaflet, please inform your doctor, pharmacist or other healthcare provider.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or health care professional. You can also report side effects to SAHPRA (South African Health Products Regulatory Authority) via the "6.04 Adverse Drug Reaction 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 DABIGATRAN DRL.

5. How to store DABIGATRAN DRL

Store at or below 25 °C.

Store in the original packaging in order to protect from moisture.

Keep all medicines out of reach and sight of children.

Do not dispose medicines in drains or sewerage systems (e.g., toilets).

Do not store in bathrooms.

Do not use after the expiry date stated on the carton/blister.

6. Contents of the pack and other information

What DABIGATRAN DRL contains

The active substance is dabigatran etexilate.

DABIGATRAN 75 DRL: Each capsule contains 75 mg of dabigatran etexilate (as mesilate

salt).

DABIGATRAN 110 DRL: Each capsule contains 110 mg of dabigatran etexilate (as mesilate salt).

DABIGATRAN 150 DRL: Each capsule contains 150 mg of dabigatran etexilate (as mesilate salt).

The other ingredients are croscarmellose sodium, hydroxypropyl cellulose, hypromellose, magnesium stearate, talc, tartaric acid.

The capsule shell contains hypromellose and titanium dioxide.

The black printing ink contains black iron oxide, butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac, strong ammonia solution.

What DABIGATRAN DRL looks like and contents of the pack

DABIGATRAN 75 DRL: Size "2" capsule with a white opaque cap imprinted "MD" and white opaque body imprinted "75" with black ink, containing a blend of white to light yellow coloured pellets and light yellow coloured granulate.

DABIGATRAN 110 DRL: Size "1" capsule with a white opaque cap imprinted "MD" and white opaque body imprinted "110" with black ink, containing a blend of white to light yellow coloured pellets and light yellow coloured granulate.

DABIGATRAN 150 DRL: Size "0" capsule 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.

DABIGATRAN 75 DRL and DABIGATRAN 110 DRL capsules: cartons containing 30 or 60 capsules, packed in aluminium blister strips of 10 capsules per strip.

DABIGATRAN 150 DRL capsules: cartons containing 30 or 60 capsules, packed in aluminium blister strips of 10 capsules per strip.

This leaflet was last revised in

11 June 2024

Registration numbers

DABIGATRAN 75 DRL: 56/8.2/0695

DABIGATRAN 110 DRL: 56/8.2/0696

DABIGATRAN 150 DRL: 56/8.2/0697

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100

Other sources of information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories website:

http://www.drreddys.co.za