APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S4

DABIKLOT 75 mg hard capsules

DABIKLOT 110 mg hard capsules

DABIKLOT 150 mg hard capsules

Dabigatran etexilate (as mesilate salt)

DABIKLOT is sugar-free

Read all of this leaflet carefully before you start taking DABIKLOT

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- DABIKLOT 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 DABIKLOT is and what it is used for

DABIKLOT 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.

DABIKLOT is used in adults to:

- prevent the formation of blood clots after hip and knee replacement surgery
- 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 recurrence of blood clots which are causing blockage in a vein or in the lungs.

2. What you need to know before you take DABIKLOT

Do not take DABIKLOT:

- if you are hypersensitive (allergic) to dabigatran etexilate, or to any of the ingredients of DABIKLOT
- if you have severely reduced kidney function (your doctor will know how to determine your kidney function)
- if you are currently bleeding
- if you are aware of an increased tendency of bleeding complications, be it present at birth, spontaneous or caused by other medicines
- if you have moderately to severely reduced liver function (your doctor will know how to

determine your liver function)

- 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), including stroke caused by brain bleeding within the last 6 months
- if specific catheters are used in your back and during the first hour after their removal (your doctor will be informed about the kind of catheters and precautionary measures)
- if you are taking medicines to prevent blood clotting (e.g. warfarin, heparin, clopidogrel, ticlopidine, ticagrelor)
- if you are administered a dextran “”drip” in hospital
- if you are taking sulfinpyrazone (to treat gout)
- if you are taking oral ketoconazole or itraconazole, medicines to treat fungal infections
- if you are taking oral ciclosporin, a medicine to prevent organ rejection after transplantation
- if you are taking dronedarone, a medicine used to treat abnormal heartbeat
- if you are taking a combination product of glecaprevir and pibrentasvir, an antiviral medicine used to treat hepatitis C
- if you have an infection in the heart valves (infective endocarditis)
- if you have received an artificial heart valve which requires permanent blood thinning.

Warnings and precautions

Take special care with DABIKLOT:

- If you have an increased bleeding risk, or are taking certain other medicines at the same time as DABIKLOT, your doctor will observe you for any sign of increased bleeding

- if you are over 75 years of age or if you take any medicines (including aspirin, clopidogrel to prevent heart attack or stroke, or NSAIDs for pain and inflammation) so that your doctor can check which ones could additionally affect blood clotting
- if you are bleeding, your doctor may consider it necessary to perform some tests to see how long it takes your blood to clot in order to make sure that the effects of DABIKLOT are not too strong
- your doctor will assess your kidney function before starting your treatment, and at least once a year thereafter. This is especially important if you are over 75 years old as kidney function declines with age. Your doctor may decide to assess your kidney function more frequently if it is suspected that you may become dehydrated or take certain other medicines at the same time as DABIKLOT. If you have severely reduced kidney function or if your kidneys do not function, DABIKLOT must not be used. A dose adjustment may be needed if you have moderately reduced kidney function. No dose adjustment is needed if you have mildly reduced kidney function. Your doctor is informed about how to determine your kidney function
- 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 DABIKLOT before and after the operation exactly at the times you have been told to 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 are taking DABIKLOT and need to undergo surgery, DABIKLOT will need to be stopped temporarily due to an increased bleeding risk during and shortly after an

operation. If possible, it should be stopped at least 24 hours before an operation. In some cases (if you have a higher risk of bleeding or if you have impaired kidney function) your doctor may require that you stop taking DABIKLOT 2 - 4 days prior to surgery. Your doctor will inform you when you can resume taking DABIKLOT again after your surgery

- if you are taking DABIKLOT and you need to undergo unplanned surgery, if at all possible, the surgery should be delayed until at least 12 hours after your last dose. If surgery cannot be delayed there may be an increased risk of bleeding and your doctor will take this risk into consideration, when weighing up the urgency of the surgery. Your doctor will inform you when you can resume taking DABIKLOT after your surgery
- you can continue taking DABIKLOT during electrical treatment to correct abnormal heart rhythms (cardioversion)
- if you are taking dronedarone to treat an irregular heartbeat
- if you are taking antidepressants called SSRIs (e.g. citalopram, escitaloptam, fluoxetine, paroxetine, sertraline) or SNRIs (e.g. duloxetine, venlafaxine, desvenlafaxine) as there an increased risk of bleeding
- if you have any disease known to have an increased risk of bleeding (e.g. blood clotting disorders), previous bleeding in your stomach, a recent tissue sampling (biopsy), major physical trauma or a recent stroke due to brain bleeding
- if you are aware of a previous diagnosis of an infection of parts of your heart (endocarditis), please tell your doctor
- if you are taking rifampicin (to prevent and treat tuberculosis and other infections), St. John’s Wort (a herbal medicine) or carbamazepine (used in the treatment of epilepsy) as these medicines may affect the way DABIKLOT works

- 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 you fall or injure yourself during treatment, especially if you hit your head, please seek urgent medical attention. You may need to be checked by a doctor, as you may be at increased risk of bleeding.

Other medicines and DABIKLOT

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

- if you are taking medicines to reduce blood clotting (e.g. warfarin, phenprocoumon, acenocoumarol, heparin, clopidogrel, prasugrel, ticagrelor, rivaroxaban, acetylsalicylic acid)

The following medicines are contraindicated when taken with DABIKLOT:

- medicines to treat fungal infections (e.g. ketoconazole, itraconazole), unless they are only applied to the skin
- dronedarone to treat abnormal heart beats
- ciclosporin to prevent organ rejection after transplantation
- glecaprevir/pibrentasvir to treat certain types of chronic (long-term) hepatitis C infection.

The following medicines are not recommended for use with DABIKLOT:

- tacrolimus - an ointment which is used to treat the symptoms of eczema
- anti-viral medicines for AIDS (e.g. ritonavir)

- St. John's Wort, a herbal medicine for depression
- certain medicines for treatment of epilepsy (e.g. carbamazepine, phenytoin)
- rifampicin, used in the treatment of TB
- acetylsalicylic acid (aspirin) used for pain and reduction of blood clotting
- NSAIDs used for pain and inflammation
- clopidogrel used to reduce blood clotting
- enoxaparin used to prevent blood clots

The following medicines are to be used with caution when taking at the same time as DABIKLOT:

- verapamil, quinidine to treat abnormal heart beats
- amiodarone used to restore and maintain normal heart rhythm
- Clarithromycin, an antibiotic
- ticagrelor used to prevent a serious or life-threatening heart attack or stroke
- posaconazole used to treat yeast infections
- antidepressants called SSRIs, e.g. citalopram, escitaloptam, fluoxetine, paroxetine, sertraline, and SNRIs, e.g. duloxetine, venlafaxine, desvenlafaxine.

DABIKLOT with food and drink

DABIKLOT can be taken with or without food and capsules should be swallowed with a glass of water to facilitate delivery to the stomach. Do not open the capsule.

Pregnancy, 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 healthcare professional for advice before using DABIKLOT.

Women of childbearing potential should avoid pregnancy during treatment with DABIKLOT.

Do not take DABIKLOT if you are pregnant or breastfeeding your baby.

Driving and using machines

DABIKLOT has no or negligible influence on the ability to drive and use machines. No studies of the effects on the ability to drive and use machines have been performed.
It is not always possible to predict to what extent DABIKLOT 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 DABIKLOT affects them.

3. How to take DABIKLOT

Do not share medicines prescribed for you with any other person. Always use DABIKLOT exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

DABIKLOT capsules are only for adults and should not be taken by children and adolescents under 18 years of age.

Prevention of the formation of blood clots after knee and hip replacement surgery:
You will be given your first dose of one capsule of DABIKLOT 110 mg within 1 - 4 hours after your operation. After that you will take two capsules once per day for another nine days (if you had knee replacement surgery) or twenty-seven days (if you had hip replacement surgery).

If your doctor notices any signs that you are still bleeding within the first four hours after the knee or hip replacement operation, he/she may decide to start treatment only the next day (with two capsules taken together once per day). You should follow the advice of your doctor.

If you are taking amiodarone, quinidine or verapamil containing medicines the recommended dose is 150 mg once a day (taken as 2 capsules of 75 mg).

Patients with moderately reduced kidney function:
If you have moderately reduced kidney function, there may be an increased risk of bleeding, therefore, your doctor will prescribe a lower strength of DABIKLOT (75 mg) for you. In this

case the recommended dose is two capsules (75 mg) swallowed together once per day (i.e. 150 mg per day).

Lowering the risk of stroke or other blood vessel blockages caused by formation of blood clots developing after abnormal heart rhythm (atrial fibrillation):

The recommended daily dose of DABIKLOT is 300 mg taken as one 150 mg capsule twice daily. Treatment is life-long.

If you are over 80 years of age, or have a potentially higher risk for major bleeding, your doctor may decide to prescribe a daily dose of DABIKLOT 220 mg taken as one 110 mg capsule twice daily.

Treatment of blood clots which are causing blockage in a vein or in the lungs:

The recommended daily dose of DABIKLOT is 300 mg taken as one 150 mg capsule twice daily. DABIKLOT treatment is started after you have received 5 days of treatment with an injected anticoagulant. Treatment is continued for up to 6 months.

Preventing recurrence of a blockage in a vein or in the lungs due to blood clots:

The recommended daily dose of DABIKLOT is 300 mg taken as one 150 mg capsule twice daily. The duration of treatment will be decided by your doctor and could be life-long.

Changing from treatment with DABIKLOT to anticoagulant treatment given by injection:

Prevention of the formation of blood clots after knee and hip replacement surgery:

Wait 24 hours after the last dose before switching from DABIKLOT to an injectable anticoagulant.

Lowering the risk of stroke or other blood vessel blockages caused by formation of blood clots developing after abnormal heart rhythm (atrial fibrillation):

Do not start treatment with injectable anticoagulant medicines (for example, heparin) until 12 hours after the final dose of DABIKLOT.

Treating blood clots which are causing blockage in a vein or in the lungs and prevention of recurrence of blockage due to blood clots:

Injectable anticoagulant medicines (for example, heparin) should not be started for at least 12 hours after the final dose of DABIKLOT.

Changing from anticoagulant treatment given by injection to treatment with DABIKLOT:

DABIKLOT should be started within 2 hours before the time you would have had the next injection.

Changing from blood thinner medicine, warfarin to DABIKLOT:

Stop taking the warfarin. Your doctor needs to do blood measurements and instruct you when you can start DABIKLOT.

Changing from DABIKLOT to blood thinner medicine, warfarin:

The starting time of warfarin will be determined by your doctor depending on your kidney

function.

Prevention of brain or body vessel obstruction by blood clot formation developing in patients with abnormal heart beats:

You can continue to take DABIKLOT if your heartbeat needs to be restored to normal by a procedure called cardioversion. Take DABIKLOT as your doctor has prescribed.

Your doctor will tell you how long your treatment with DABIKLOT will last. Do not stop treatment early without specific guidance from your doctor.

If you have the impression that the effect of DABIKLOT is too strong or too weak, tell your doctor or pharmacist.

If you take more DABIKLOT than you should

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

Symptoms of overdose may include:

- you may have an increased risk of bleeding

If you forget to take DABIKLOT

Prevention of the formation of blood clots after knee and hip replacement surgery:

If you miss a dose of DABIKLOT, take it as soon as you remember on the same day. If you do not take your capsules on the same day, take your normal dose on the next day. Do not double the dose to make up for forgotten individual doses.

Lowering the risk of stroke or other blood vessel blockages caused by formation of blood clots developing after abnormal heart rhythm (atrial fibrillation):

A forgotten DABIKLOT dose can still be taken up to 6 hours prior to the next due dose. A missed dose should be omitted if the remaining time is below 6 hours prior to the next due dose. Do not take a double dose to make up for missed individual doses.

Treating blood clots which are causing blockage in a vein or in the lungs and prevention of recurrence of blockage due to blood clots:

A forgotten DABIKLOT dose can still be taken up to 6 hours prior to the next due dose. A missed dose should be omitted if the remaining time is below 6 hours prior to the next dose. Do not take a double dose to make up for missed individual doses.

If you stop taking DABIKLOT

Do not stop taking DABIKLOT without first consulting your doctor, as the risk of developing a blood clot in a vein could be increased when treatment is stopped early.

4. Possible side effects

DABIKLOT can have side effects.

Not all side effects reported for DABIKLOT are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using DABIKLOT, please consult your healthcare provider for advice.

If any of the following happens, stop using DABIKLOT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- suddenly feeling wheezy, short of breath or coughing (bronchospasm)
- rash or itching

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

As DABIKLOT acts on the blood clotting system, most side effects are related to bruising or bleeding. Major or severe bleeding may occur.

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

- signs of brain bleeding including headache, numbness on one side of the body, visual problems or difficulty speaking
- stabbing abdominal pain, vomiting blood and bloody or tar-coloured stools
- yellowing of the skin or whites of the eyes, caused by liver or blood problems.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- anaemia
- bleeding from the nose (blood nose)

- abdominal pain, diarrhoea, indigestion, nausea
- blood in urine, bleeding from penis/vagina or urinary tract

Less frequent side effects:

- abnormal blood test results, bleeding into the tissues, bruising, and slow blood clotting after injury (thrombocytopenia)
- reduced or increased number of white or red blood cells or platelets
- haematoma (bleeding under the skin), coughing of blood or blood-stained sputum, excessive bleeding
- difficulty or discomfort in swallowing
- gastrointestinal ulcer, including oesophageal ulcer
- inflammation of the gullet and stomach, acid reflux (reflux of gastric juice into the gullet), vomiting, bleeding from piles
- abnormal liver function test results, liver enzymes increased
- bruising under the skin, rash, skin rash, severe itching of the skin, rash of round, red welts on the skin that itch intensely sometimes with swelling
- bleeding into a joint cavity
- bleeding may happen, from the site of entry of an injection or from the site of entry of a catheter into a vein
- bleeding or discharge or secretion may happen from the incision, after surgery a fall in the number of red cells in the blood (anaemia)
- bleeding or drainage may happen, from an injury or wound
- bleeding may happen, from a wound
- blood-stained discharge and drainage from wounds (e.g. surgical incision).

The following side effects have been reported but the frequency for them to occur is not known:

- signs of infection such as sore throat, fever and chills (agranulocytosis)
- abnormally low concentration of neutrophils (a type of white blood cell) in the blood
- hair loss.

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. You can also report side effects to SAHPRA via the 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 CREVAS.

You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store DABIKLOT

Store all medicines out of reach of children.

Store at or below 25 °C, protect from light and moisture.

Do not use after the expiry date stated on the carton. Return all unused medicine to your pharmacist.

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

6. Contents of the pack and other information

What DABIKLOT contains:

DABIKLOT 75 mg: Each capsule contains 75 mg dabigatran etexilate (as mesilate salt).

DABIKLOT 110 mg: Each capsule contains 110 mg dabigatran etexilate (as mesilate salt).

DABIKLOT 150 mg: Each capsule contains 150 mg dabigatran etexilate (as mesilate salt).

The other ingredients are:

Capsule content:

Croscarmellose sodium, hydroxypropyl cellulose, hydroxypropyl methylcellulose, magnesium stearate, talc, tartaric acid pellets (pH-adjustment).

Hard capsules:

Hypromellose, titanium dioxide

Black Printing ink:

Black iron oxide

What DABIKLOT looks like and contents of the pack

DABIKLOT 75 mg: Size “2” capsules with a white opaque cap and body, containing white to light yellow coloured pellets. The white opaque cap is imprinted "MD" and the white opaque body imprinted "75", both with black ink.

DABIKLOT 110 mg: Size “1” capsules with a white opaque cap and body, containing white to light yellow coloured pellets. The white opaque cap is imprinted "MD" and the white opaque body imprinted "110", both with black ink.

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DABIKLOT 150 mg: Size “0” capsules with a white opaque cap and body, containing white to light yellow coloured pellets. The white opaque cap is imprinted "MD" and the white opaque body imprinted "150", both with black ink.

DABIKLOT capsules are available aluminium-LDPE-nitrocellulose/aluminium blisters. 30 or 60 tablets are packed in an outer carton.

Holder of Certificate of Registration

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DABIKLOT 110 mg: A55/8.2/0326

DABIKLOT 150 mg: A55/8.2/0327