PATIENT INFORMATION LEAFLET

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Read all of this leaflet carefully before you start taking PRADAXA

- 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
- PRADAXA 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

SCHEDULING STATUS S4

Pradaxa® 75 mg
Pradaxa® 110 mg
Pradaxa® 150 mg

Capsules
Dabigatran etexilate

1. WHAT PRADAXA CONTAINS

The active substance is: dabigatran etexilate. Each capsule contains 75 mg, 110 mg or 150 mg dabigatran etexilate (as mesilate salt).
The other ingredients are: acacia gum, dimeticone 350, hydroxypropyl cellulose, hypromellose, talc, tartaric acid.
Capsule shell: carrageenan, hypromellose, Indigo Carmin (E132) (PRADAXA 110 and 150 mg only), potassium chloride, titanium dioxide.
Printing ink: ammonia solution, ethanol anhydrous, iron oxide black (E172), isopropyl alcohol, butyl alcohol, potassium hydroxide, propylene glycol, purified water, shellac.
The capsules are sugar free.

2. WHAT PRADAXA IS USED FOR

PRADAXA is used 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

3. BEFORE YOU TAKE PRADAXA

Do not take PRADAXA:

- if you are allergic (hypersensitive) to dabigatran etexilate, dabigatran or any of the other ingredients of PRADAXA
- 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 suffer from a condition that increases your risk of bleeding, 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 any medicines which may affect the blood clotting system (tell your doctor about all the medicines you are taking)
- if you are taking oral ketoconazole, a medicine used to treat fungal infections
- if you have a prosthetic heart valve

Take special care with PRADAXA:
- If you have an increased bleeding risk, or are over 75 years of age, or are taking certain co-medications (including antidepressants called SSRIs or SNRIs), your doctor will observe you for any sign of increased bleeding. Please tell your doctor if you take any medicines (including aspirin) so that he/she can check which ones could additionally affect blood clotting, or 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 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 PRADAXA are not too strong.
- Your kidney function should be assessed before you start with PRADAXA 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 co-medications. If you have severely reduced kidney function or if your kidneys do not function, PRADAXA must not be used. See “Do not take PRADAXA”. 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 you take PRADAXA and need to undergo planned surgery, PRADAXA will need to be stopped temporarily due to an increased bleeding risk during and shortly after an operation. If possible, PRADAXA 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 PRADAXA 2 – 4 days prior to surgery. Your doctor will inform you when you can resume taking PRADAXA after your surgery.
- If you take PRADAXA and need to undergo unplanned surgery, if possible, the surgery should be delayed until at least 12 hours after your last dose of PRADAXA. If surgery cannot be delayed there may be an increased risk of bleeding. Your doctor will take this risk into consideration, together with the urgency of the surgery. Your doctor will inform you when you can resume taking PRADAXA after your surgery.
- If you need emergency surgery or an urgent procedure, your doctor can administer a specific reversal agent, called idarucizumab, to rapidly reverse the effects of PRADAXA.
- You can continue taking PRADAXA during electrical treatment to correct abnormal heart rhythms (cardioversion) or during a procedure called catheter ablation.

- 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.
- 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.

Pregnancy and breastfeeding:
If you are pregnant or breastfeeding your baby please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Driving and using machinery:
No studies on the effects of PRADAXA on the ability to drive and use machines have been performed. Driving or using machines should be avoided for a period of time after orthopaedic surgery.

It is not always possible to predict to what extent PRADAXA 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 PRADAXA affects you.

Taking other medicines with PRADAXA:
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines). The use of PRADAXA with these medicines may cause undesirable interactions. Particularly if you are taking or have taken any medicines which affect the blood clotting system, your doctor may decide to change the medicine or to observe you especially carefully for signs of bleeding. This can also apply to freely available acetylsalicylic acid, also known as aspirin, or other compounds of this class, which you might take e.g. for headaches, rheumatic symptoms or arthritis, or antiplatelet medicines, including aspirin, clopidogrel and ticagrelor, and antidepressants called SSRIs or SNRIs.

PRADAXA can interact with the following medicines:
- Blood thinners (e.g. warfarin, heparin),
- Anti-inflammatory and pain reliever medicines (e.g. aspirin) and NSAIDs
- St. John's wort (Hypericum perforatum), a herbal medicine taken for depression
- Antibiotics such as rifampicin, used for TB, or clarithromycin
- Medicines used to treat abnormal heartbeats (e.g. amiodarone, dronedarone, verapamil, quinidine)
- Medicines used to treat fungal infections (e.g. ketoconazole, itraconazole), unless they are only applied to the skin
- Anti-viral medicines for HIV (e.g. ritonavir)
- Medicines used to treat epilepsy (e.g. carbamazepine)
- A combination product of glecaprevir and pibrentasvir (an antiviral medicine used to treat hepatitis C)

Please consult your doctor, pharmacist or other healthcare professional for advice.

Taking PRADAXA with food and drink:
PRADAXA capsules should be swallowed orally with a glass of water to facilitate delivery to the stomach.
PRADAXA can be taken with or without food. If PRADAXA upsets your stomach you should take it with a meal or your doctor may also recommend that you take it with another medicine called a proton pump inhibitor to help with this.
Do not open the capsule.

4. HOW TO TAKE PRADAXA
Do not share medicines prescribed for you with any other person.

When taking PRADAXA capsules out of the blister pack, please observe the following instructions:
- Tear off one individual blister from the blister card along the perforated line
- Remove the PRADAXA capsules by peeling off the backing foil of the blister card.
- Do not push the PRADAXA capsules through the blister foil.
- Do not peel off the blister backing foil until a PRADAXA capsule is required.

- PRADAXA capsules should be swallowed with a glass of water to facilitate delivery to the stomach. PRADAXA can be taken with or without food. Do not chew the capsules. Do not open the capsules.
- Always take your PRADAXA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Do not take more or less capsules and do not take them more often than recommended.
- Your doctor will tell you how long your treatment with PRADAXA will last. (See "If you stop taking PRADAXA").
- If you have the impression that PRADAXA is too strong or too weak, talk to your doctor or pharmacist.
- PRADAXA capsules are only for adults and should not be taken by children and adolescents under 18 years of age.
- If you have any further questions on the use of PRADAXA, ask your doctor or pharmacist.

Prevention of the formation of blood clots after knee and hip replacement surgery:
You will be given your first dose of one capsule of PRADAXA 110 mg between one to four hours after your operation is over. After that you will take two capsules together 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.

Patients with moderately reduced kidney function:
If you have moderately reduced kidney function you could have an increased risk of bleeding. If necessary, your doctor will have prescribed the lower strength of PRADAXA (75 mg) for you. You will be given your first dose of one capsule of PRADAXA 75 mg between one to four hours after your operation is over. After that you will take two capsules together 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.

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 PRADAXA 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 PRADAXA 220 mg taken as one 110 mg capsule twice daily.

Treating blood clots which are causing blockage in a vein or in the lungs:
The recommended daily dose of PRADAXA is 300 mg taken as one 150 mg capsule twice daily. PRADAXA 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 blockage in a vein or in the lungs due to blood clots:
The recommended daily dose of PRADAXA 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.

Lowering the risk of stroke or other blood vessel blockages caused by formation of blood clots developing after abnormal heart rhythm (atrial fibrillation):
You can continue to take PRADAXA if your heart beat needs to be restored to normal by a procedure called cardioversion or during catheter ablation. Take PRADAXA as your doctor has told you.

If a medical device (stent) has been deployed in a blood vessel to keep it open in a procedure called percutaneous coronary intervention (PCI) with stenting, you can be treated with PRADAXA after your doctor has decided that normal control of blood clotting is achieved. Take PRADAXA as your doctor has told you.

Changing from treatment with PRADAXA 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 PRADAXA to a parenteral 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 PRADAXA.

Treating blood clots which are causing blockage in a vein or in the lungs and prevention of recurrence of blockage due to blood clots:
Do not start treatment with injectable anticoagulant medicines (for example, heparin) until 12 hours after the final dose of PRADAXA.

Changing from anticoagulant treatment given by injection to treatment with PRADAXA:
Start taking PRADAXA within 2 hours before the time you would have had the next injection.

Changing from blood thinners containing warfarin to PRADAXA:
Stop taking the medicine containing warfarin. Your doctor needs to do blood measurements and instruct you when you can start PRADAXA.

Changing from PRADAXA to blood thinners containing warfarin:
The starting time of warfarin will be determined by your doctor depending on your kidney function.

If you take more PRADAXA than you should:
If you take more PRADAXA than you should, you may have an increased risk of bleeding. Your doctor can perform a test to assess the risk of bleeding. Inform your doctor or pharmacist as soon as possible if you take more than the prescribed dose of PRADAXA. If bleeding occurs, surgical treatment or treatment with blood transfusions may be required. If your doctor or pharmacist is not available, seek help at the nearest hospital or poison control centre.

If you forget to take PRADAXA:
Prevention of the formation of blood clots after knee and hip replacement surgery:
If you miss a dose of PRADAXA, take it as soon as you remember on the same day. If you do not take your capsules on that 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 PRADAXA 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 PRADAXA 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.

If you stop taking PRADAXA:
Do not stop taking PRADAXA without first consulting your doctor, since the risk of developing a blood clot in a vein could be higher if you stop treatment early.

5. POSSIBLE SIDE EFFECTS
PRADAXA can have side effects.
Not all side effects reported for PRADAXA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PRADAXA, please consult your doctor, pharmacist, or other healthcare professional for advice.

If any of the following happens, stop taking PRADAXA and tell your doctor immediately or go to the casualty department of your nearest hospital:
- Difficulty in breathing or wheezing

- Difficulty in swallowing
- Sudden signs of allergy including rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body and wheezing
- 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.

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

The possible side effects are listed below grouped according to how likely they are to happen.

Frequent:
- 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
- Nose bleed
- Bleeding into the stomach or bowel
- Belly ache or stomach ache
- Frequent loose or liquid bowel movements
- Heartburn or discomfort in the upper alimentary tract
- Nausea
- Bleeding from penis/vagina or urinary tract
- Blood in the urine that stains the urine pink or red
- Bleeding under the skin
- Unusual laboratory test results on liver function

Less frequent:
- A fall in the number of platelets in the blood
- A fall of haemoglobin, the substance of red cells in the blood
- Bruise formation or bleeding as a result of trauma or injury
- Bleeding into a joint
- Bleeding into the rectum
- Bleeding from piles
- Allergic reaction
- Skin rash notable for dark red, raised, itchy bumps caused by an allergic reaction
- Itching
- Coughing of blood or blood-stained sputum
- Bleeding in the brain
- Gastrointestinal ulcer, including oesophageal ulcer
- Inflammation of the gullet and stomach
- Reflux of gastric juice into the gullet
- Vomiting
- Difficulty in swallowing
- Swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing (angioedema)
- Pinkish, itchy swellings on the skin, also called hives or nettle rash (urticaria)
- Blood-stained discharge from the site of entry of an injection needle
- Blood-stained discharge from the site of entry of a catheter into a vein

- Blood-stained discharge and drainage from wounds (e.g. surgical incision)
- Bleeding from a surgical incision
- Difficulty in breathing or wheezing
- Sudden signs of allergy including rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body and wheezing

Frequency not known:
- Decreases in the number or even lack of white blood cells (which help to fight infections)
- Hair loss

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

6. STORING AND DISPOSING OF PRADAXA
Store at or below 30 °C in the original package in order to protect from moisture. Keep the blisters in the carton until required for use. Do not put the capsules in pill boxes or pill organizers, unless capsules can be maintained in the original blister.
Keep all medicines out of the reach and sight of children.

Do not take PRADAXA after the expiry date stated on the blister strips and carton. The expiry date refers to the last day of that month. Return unused or expired medicines to your pharmacist for safe disposal. Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF PRADAXA
PRADAXA 75 and 110 mg capsules: cartons containing 30 or 60 capsules, packed in aluminium blister strips of 10 capsules per strip.
PRADAXA 150 mg capsules: cartons containing 60 capsules, packed in aluminium blister strips of 10 capsules per strip.

8. IDENTIFICATION OF PRADAXA:
PRADAXA 75 mg capsules: Oblong imprinted capsules (size 2) with a white, opaque cap and a white, opaque body filled with yellowish spherical pellets. The cap is imprinted with the Boehringer Ingelheim company symbol, the body with R75.

PRADAXA 110 mg capsules: Oblong imprinted capsules (size 1) with a light blue, opaque cap and a light blue, opaque body filled with yellowish spherical pellets. The cap is imprinted with the Boehringer Ingelheim company symbol, the body with R110.

PRADAXA 150 mg capsules: Oblong imprinted capsules (size 0) with a light blue, opaque cap and a white, opaque body filled with yellowish spherical pellets. The cap is imprinted with the Boehringer Ingelheim company symbol, the body with R150.

9. REGISTRATION NUMBERS
PRADAXA 75 mg capsules: 42/8.2/0130
PRADAXA 110 mg capsules: 42/8.2/0131
PRADAXA 150 mg capsules: 45/8.2/0162

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET

Dates of registration: 19 March 2010 (75 mg & 110 mg); 14 September 2012 (150 mg)
Revised: 17 August 2022