PRADAXA® Hard Capsule

Consumer Medication Information Leaflet (RiMUP)

Dabigatran etexilate (75 mg, 110 mg, 150 mg)

What is in this leaflet

1. What PRADAXA is used for

75 mg/ 110 mg: PRADAXA is used to prevent the formation of blood clots in the veins after knee or hip replacement surgery in adults.

110 mg/ 150 mg: PRADAXA is a medicine which is used to reduce the risk of brain or body vessel obstruction by blood clot formation in adult patients with an abnormal heart beat (atrial fibrillation) and additional risk factors. PRADAXA is a blood thinner medicine that lowers the risk of blood clot formation. PRADAXA is used to treat blood clots in the veins of your legs and lungs and to prevent blood clots from reoccurring in the vein of your legs and lungs.

2. How PRADAXA works

PRADAXA is a medicine which contains the active substance dabigatran etexilate. It works by blocking a substance in the body which is involved in blood clot formation.

3. Before you use PRADAXA

- *When you must not use it*
  - if you are allergic to dabigatran etexilate or any of the other ingredients of this medicine (listed in section 8).
  - if you have severely reduced kidney function.
  - if you are currently bleeding.
  - if you have a disease in an organ of the body that increases the risk of serious bleeding.
  - if you have an increased tendency to bleed. This may be inborn, of unknown cause or due to other medicines.
  - if you have a severely reduced liver function or liver disease which could possibly cause death.
  - 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 medicines to prevent blood clotting (eg. warfarin, rivaroxaban, apixaban or heparin), except when changing anticoagulant treatment or 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 a combination product of glecaprevir and pibrentasvir, an antiviral medicine used to treat hepatitis C.
  - if you have received an artificial heart valve which requires permanent blood thinning.

Paediatic population
PRADAXA is not indicated in children and adolescents below 18 years old.

Pregnancy and breast-feeding
The effects of PRADAXA on pregnancy and the unborn child are not known. You should not take PRADAXA if you are pregnant unless your doctor advises you that it is safe to do so. If you are a woman of child-bearing age, you should avoid becoming pregnant while you are taking PRADAXA.

You should not breast-feed while you are taking PRADAXA.

- *Before you start use it*
  Talk to your doctor before taking PRADAXA. You may also need to talk to your doctor during treatment with PRADAXA if you experience symptoms or if you have to undergo surgery.

  Tell your doctor if you have or have had any medical conditions or illnesses, in particular any of those included in the following list:

  - if you have a liver disease that is associated with changes in the blood tests, the use of PRADAXA is not recommended.

  - if you have an increased bleeding risk, as could be the case in the following situations:
    - if you have been recently bleeding.
    - if you have had a surgical tissue removal (biopsy) in the past month.
    - if you have had a serious injury (e.g. a bone fracture, head injury or any injury requiring surgical treatment).
    - if you are suffering from an inflammation of the gullet or stomach.
    - if you have problems with reflux of gastric juice into the gullet.
    - if you are receiving medicines which could increase the risk of bleeding. See 'Taking other medicines' below.
    - if you are taking anti-inflammatory medicines such as diclofenac, ibuprofen, piroxicam.
    - if you are suffering from an infection of the heart (bacterial endocarditis).
    - if you know you have decreased kidney function, or you are suffering from dehydration (symptoms include feeling thirsty and passing reduced amounts of dark-coloured (concentrated) / foaming urine).

- if you are older than 75 years.
- if you weigh 50 kg or less.

- if you have had a heart attack or if you have been diagnosed with conditions that increase the risk to develop a heart attack.

- 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 need to have an operation: PRADAXA will need to be stopped temporarily due to an increased bleeding risk during and shortly after an operation.

- 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 Pradaxa 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 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.

- *Taking other medicines*
  Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular you should tell your doctor before taking Pradaxa, if you are taking one of the medicines listed below:
  - Medicines to reduce blood clotting (e.g. warfarin, phenprocoumon, heparin, clopidogrel, prasugrel, ticagrelor, rivaroxaban, acetylsalicylic acid)
  - 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)
  - Medicines to treat abnormal heart beats (e.g. Amiodarone, dronedarone, quinidine, verapamil). If you are taking amiodarone, quinidine or verapamil containing medicines, your doctor may tell you to use a reduced dose of Pradaxa depending on the condition for which Pradaxa is prescribed to you.
  - Medicines to treat fungal infections (e.g. ketoconazole, itraconazole), unless they are only applied to the skin
  - 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-viral medicines for AIDS (e.g. ritonavir)
  - Medicines for treatment of epilepsy (e.g. carbamazepine, phenytoin)

4. How to use PRADAXA

- *How much to use*
  Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

  Take PRADAXA as recommended for the following conditions:

  Prevention of blood clot formation after knee or hip replacement surgery
  The recommended dose is 220 mg once a day (taken as 2 capsules of 110 mg).

  If your kidney function is decreased by more than half or if you are 75 years of age or older, the recommended dose is 150 mg once a day (taken as 2 capsules of 75 mg).

  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).

  If you are taking verapamil containing medicines and your kidney function is decreased by more than half, you should be treated with a reduced dose of 75 mg PRADAXA because your bleeding risk may be increased.

  After knee replacement surgery
  You should start treatment with PRADAXA within 1-4 hours after surgery finishes, taking a single capsule (110 mg). Thereafter two capsules once a day should be taken for a total of 10 days.

  After hip replacement surgery
  You should start treatment with PRADAXA within 1-4 hours after surgery finishes, taking a single capsule (110 mg). Thereafter two capsules once a day should be taken for a total of 28-35 days.

  For both surgery types, treatment should not be started if there is bleeding from the site of operation. If the treatment cannot be started until the day after surgery, dosing should be started with 2 capsules once daily.

  Prevention of brain or body vessel obstruction by blood clot formation developing after abnormal heart beats and Treatment of blood clots in the veins of your legs and lungs including prevention of blood clots from re-occuring in the vein of your legs and lungs
  The recommended dose is 300 mg taken as one 150 mg capsule twice a day.

  If you are 80 years or older, the recommended dose of PRADAXA is

220 mg taken as one 110 mg capsule twice a day.

If you are taking verapamil-containing medicines, you should be treated with a reduced PRADAXA dose of 220 mg taken as one 110 mg capsule twice a day, because your bleeding risk may be increased.

If you have a potentially higher risk for bleeding, your doctor may decide to prescribe a dose of PRADAXA 220 mg taken as one 110 mg capsule twice a day.

You can continue to take this medicine if your heartbeat needs to be restored to normal by a procedure called cardioversion. Take PRADAXA as your physician 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 with stenting, you can be treated with PRADAXA after your physician has decided that normal control of blood coagulation is achieved. Take PRADAXA as your physician has told you.

PRADAXA 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.

Change of anticoagulant treatment
Without specific guidance from your doctor do not change your anticoagulant treatment.

- *When to use it*
  Use as directed by your doctor or pharmacist.

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

- *How long to use it*
  Continue taking PRADAXA for as long as your doctor recommends.

- *If you forget to use it*
  Prevention of blood clot formation after knee or hip replacement surgery
  Continue with your remaining daily doses of PRADAXA at the same time of the next day.
  Do not take a double dose to make up for missed doses.

  Prevention of brain or body vessel obstruction by blood clot formation developing after abnormal heart beats and treatment of blood clots in the veins of your legs and lungs including prevention of blood clots from re-occuring in the vein of your legs and lungs
  A forgotten 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 doses.

- *If you use too much (overdose)*
  Taking too much PRADAXA increases risk of bleeding. Inform your doctor immediately, if you take more than the prescribed dose of PRADAXA. Specific treatment options are available.

5. While you are using it

- *Things you must do*
  Take your medicine exactly as your doctor has told you.

  Tell all the doctors, dentists and pharmacists treating you that you are taking PRADAXA.

  Tell your doctor immediately if you become pregnant while taking this medication.

- *Things you must not do*
  Take PRADAXA exactly as prescribed. Do not stop taking PRADAXA without first consulting your doctor 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 PRADAXA.

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

- *Things to be careful of*
  Driving and using machines
  PRADAXA has no known effects on the ability to drive or use machines.

6. Side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

PRADAXA 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.

- Bleeding into the kidney (which may be evident by the appearance of blood in the urine) may lead to worsening of kidney function (which may manifest as reduced urine output).
- Bleeding into muscles can cause compartment syndrome due to increased pressure within muscles of the legs or arms, causing pain, swelling, altered sensation or paralysis.

Your doctor may decide to keep you under closer observation or change your medicine.

Tell your doctor immediately, if you experience a serious allergic reaction which causes difficulty in breathing or dizziness.

The common side effects (may affect up to 1 in 10 people) are listed below.

Prevention of blood clot formation after knee or hip replacement surgery
- A fall in the amount of haemoglobin in the blood (the substance in the red blood cells)
- Unusual laboratory test results on liver function

Prevention of brain or body vessel obstruction by blood clot formation developing after abnormal heart beats
- Bleeding may happen from the nose, into the stomach or bowel, from penis/vagina or urinary tract (incl. blood in the urine that stains the urine pink or red), or under the skin
- A fall in the number of red cells in the blood
- Belly ache or stomach ache
- Indigestion
- Frequent loose or liquid bowel movements
- Feeling sick

Treatment of blood clots in the veins of your legs and lungs including prevention of blood clots from re-occuring in the veins of your legs and/or lungs
- Bleeding may happen from the nose, into stomach or bowel, into the rectum, from penis/vagina or urinary tract (incl. blood in urine that stains the urine pink or red), or under the skin
- Indigestion

Reporting of side effects
You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my (Consumers→ Reporting Side Effects to Medicines (ConSERF or Vaccines (AEFI)).

7. Storage and Disposal of PRADAXA
- *Storage*
  Store below 30°C.
  Store in original package in order to protect from moisture.
  Please refer to the packaging for information on shelf-life.
  Keep this medicine out of sight and reach of children.

- *Disposal*
  Medicines should not be disposed of via wastewater or household waste.
  Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

8. Product Description
- *What it looks like*
  75 mg: Consist of an imprinted hydroxypropylmethylcellulose (HPMC) capsule with white opaque cap andwhite opaque body of size 2 filled with yellowish pellets. The cap is imprinted with the Boehringer Ingelheim company symbol, the body with "R75". The colour of the imprint is black.

  110 mg: Consist of an imprinted hydroxypropylmethylcellulose (HPMC) capsule with light blue opaque cap and light blue opaque body of size 1 filled with yellowish pellets. The cap is imprinted with the Boehringer Ingelheim company symbol, the body with "R110". The colour of the imprint is black.

  150 mg: Consist of an imprinted hydroxypropylmethylcellulose (HPMC) capsule with light blue opaque cap and white opaque body of size 0 filled with yellowish pellets. The cap is imprinted with the Boehringer Ingelheim company symbol, the body with "R150". The colour of the imprint is black.

- *Ingredients*
  - Active ingredient(s)
    One hard capsule contains 75 mg, 110 mg or 150 mg dabigatran (as etexilate).
  - Inactive ingredients
    - The other ingredients are tartaric acid, acacia, hypromellose, dimeticone 350, talc, and hydroxypropylcellulose.
    - The capsule shell contains carrageenan, potassium chloride, titanium dioxide, indigo carmine, hypromellose and purified water.
    - The black printing ink contains shellac, N-butyl alcohol, isopropyl alcohol, industrial methylated spirit, iron oxide black, purified water and propylene glycol.

- *MAL number(s):*
  PRADAXA 75 mg Hard Capsule - MAL20091868AZ
  PRADAXA 110 mg Hard Capsule - MAL20091869AZ
  PRADAXA 150 mg Hard Capsule – MAL20112114AZ

9. Manufacturer
Manufactured by
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