PART III: CONSUMER INFORMATION

Pr Pradaxa®
Dabigatran Etexilate Capsules

Read this carefully before you start taking PRADAXA and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your doctor, nurse, or pharmacist about your medical condition and treatment and ask if there is any new information about PRADAXA.

ABOUT THIS MEDICATION

What the medication is used for:
PRADAXA is a blood thinner (prevents blood clots from forming).

PRADAXA is prescribed:
- After knee or hip replacement surgery to prevent the formation of blood clots in the vein of your leg(s) or in your lung(s).

- To treat blood clots and prevent them from re-occurring in the veins of your legs and/or lungs. If blood clots form in the veins of your legs you are at risk of a blood clot dislodging and traveling to the lungs causing serious health risks.

- To people who have irregular heartbeats (*atrial fibrillation*) to prevent a stroke (damage to part of the brain caused by an interruption of its blood supply), or sudden blocking of a blood vessel by a blood clot. People with atrial fibrillation have a part of their heart that does not beat the way it should. This can lead to formation of blood clots which increases the risk of stroke.

What it does:
PRADAXA helps prevent the formation of blood clots by blocking the activity of a protein called thrombin.

When it should not be used:
Do not take PRADAXA if you:
- Have severely reduced kidney function or your kidneys do not function.
- Have active bleeding or bleed excessively.
- Have a disease that increases your chances of bleeding, or bleeding in the brain (stroke) within the last 6 months or recent bleeding of a stomach ulcer.
- Have an epidural or spinal catheter in place or within the first two hours after its removal. Your doctor will know what precautionary measures are required. PRADAXA is not recommended for patients receiving epidural pain control after surgery.
- Are taking oral ketoconazole, used to treat fungus infection.
- Are already taking another blood thinner, including apixaban (ELIQUIS), bivalirudin, dalteparin, enoxaparin, fondaparinux, rivaroxaban (XARELTO), unfractionated heparin, warfarin (COUMADIN), unless your physician has decided to switch you to or from PRADAXA.
- Have an artificial heart valve.
- Are breastfeeding. It is possible that PRADAXA passes into breast milk.
- Are allergic to dabigatran etexilate, dabigatran, or any other ingredient in the formulation.

What the medicinal ingredient is:
Dabigatran etexilate, as dabigatran etexilate mesilate.

What the non-medicinal ingredients are:
acacia, carragenan, dimethicone, hydroxypropyl cellulose, hypromellose, indigocarmin (150 mg, 110 mg only), iron oxide black, potassium chloride, potassium hydroxide, propylene glycol, shellac, talc, tartaric acid, titanium dioxide.

What dosage forms it comes in:
Capsules: 75 mg, 110 mg and 150 mg.

WARNINGS AND PRECAUTIONS

Stopping early any blood thinner, including PRADAXA, increases the risk of having a sudden blocking of a blood vessel by a blood clot. This can lead to death or severe injury. If you need to stop PRADAXA, your doctor may give you another blood thinner.

You may bleed very seriously or severely in any part of your body while you are taking PRADAXA.

In order to help prevent serious bleeding with PRADAXA, it is important to take PRADAXA exactly as prescribed by your doctor.

In rare occasions, where you need emergency surgery or other urgent procedure or have obvious

or hidden uncontrolled bleeding, you may have to discontinue taking PRADAXA. In these situations, PRAXBIND (idarucizumab), a specific antidote for reversing the effect of PRADAXA, can be used to immediately and completely reverse the blood-thinning effect of PRADAXA.

Your doctor will tell you when it is appropriate for you to resume taking PRADAXA.

BEFORE you use PRADAXA talk to your doctor, nurse, or pharmacist if you:

- Have moderately reduced kidney function.
- Are dehydrated.
- Have a disease or have had an operation recently that increases your risk of bleeding. Examples are a blood clotting disease, a stomach ulcer, a biopsy, a very serious injury, or an inflammation of parts of your heart caused by bacteria.
- Are older than 75 years old.
- Have severe or life-threatening liver disease, or high liver enzymes.
- Are going to have a surgery, including a surgery on your brain, back, eye or other invasive or dental procedure. Your doctor may ask you to stop PRADAXA temporarily for a few days before the surgery.
- Are pregnant or plan to become pregnant. The effects of PRADAXA on pregnancy and the unborn child are not known.
- Are about to give birth.
- Are less than 18 years old.
- Weigh less than 50 kg.

INTERACTIONS WITH THIS MEDICATION

As with most medicines, interactions with other drugs are possible. Tell your doctor, nurse, or pharmacist about all medicines you take, including drugs prescribed by other doctors, vitamins, minerals, natural supplements, or alternative medicines.

The following may interact with PRADAXA:

- Antacids, used to treat heartburns. If you need to take an antacid, take it at least two hours after taking PRADAXA.
- Antibiotics, including rifampicin and clarithromycin.
- Antidepressants, in particular selective serotonin re-uptake inhibitors (SSRIs) or selective serotonin norepinephrine re-uptake inhibitors (SNRIs).
- Antifungal drugs, including oral itraconazole and posaconazole.
- Antiretroviral drugs, used to treat HIV, including nelfinavir, ritonavir, saquinavir, and tipranavir.
- Blood thinners, including clopidogrel, prasugrel (EFFIENT) or ticagrelor (BRILINTA).
- Drugs used to prevent organ rejection after transplantation, including cyclosporine and tacrolimus.
- Drugs used to treat epilepsy, including carbamazepine
- Drugs used to treat irregular heartbeats, including amiodarone (CORDARONE), dronedarone (MULTAQ) and quinidine.
- Nonsteroidal anti-inflammatory drugs (NSAIDs), used to reduce pain and swelling. Examples include aspirin (ASA), diclofenac, ibuprofen and naproxen.
- Proton pump inhibitors, used to treat heartburns.
- St. John's Wort, a herbal medicine.
- Verapamil, used to lower blood pressure.

Know the medicines you take. Keep a list of them and show it to your doctor, dentist and pharmacist when you get a new medicine or whenever you seek medical treatment.

PROPER USE OF THIS MEDICATION

Before you start taking PRADAXA and regularly after, your doctor will test your kidney function.

Take PRADAXA exactly as prescribed.

PRADAXA should be taken with a full glass of water and can be taken with or without food. If PRADAXA upsets your stomach, take it with meals or within 30 minutes after meals. If PRADAXA still upsets your stomach, consult your physician or pharmacist. It is important to continue taking PRADAXA as prescribed.

Swallow the capsule(s) whole. Do not chew or open the capsule. Do not sprinkle the pellets on food or mix with liquids.

Usual Adult dose:

If your doctor has given you PRADAXA to take **twice a day**, it is important to take it regularly at the same time each day at approximately 12 hour

intervals.

- **After knee or hip replacement surgery:** 220 mg once daily, taken as two (2) capsules of 110 mg at the same time.

Depending on your kidney function or other drugs you may be taking, your doctor may prescribe a lower dose of 150 mg once daily (taken as two capsules of 75 mg at the same time).

Take PRADAXA for as long as the doctor tells you.

- **To treat blood clots and prevent them from re-occurring in the veins of your leg(s) or in your lung(s):** 300 mg a day, taken as one (1) capsule of 150 mg twice daily.

You will start taking PRADAXA following 5 to 10 days treatment with an injectable blood thinner.

The doctor will determine how long you should take PRADAXA so take it until your doctor tells you to stop.

If you are 80 years and older and/or the doctor thinks you are more likely to bleed: 220 mg a day, taken as one (1) capsule of 110 mg, twice daily.

- **For patients who have irregular heartbeats (*atrial fibrillation*):** 300 mg a day, taken as one (1) capsule of 150 mg, twice daily.

If you are 80 years and older and/or the doctor thinks you are more likely to bleed: 220 mg a day, taken as one (1) capsule of 110 mg, twice daily.

Switching to PRADAXA:
If you are currently taking the blood thinner warfarin or receive a blood thinner given by injection, and your doctor has decided PRADAXA is appropriate for you, make sure you ask your doctor when and how best to switch and start taking PRADAXA.

Overdose:

If you think you have taken too much PRADAXA, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

If you take more than the recommended dose of PRADAXA, you may have an increased risk of bleeding. Your doctor can perform a blood test to assess the risk of bleeding.

For situations when rapid reversal of the blood-thinning effect of PRADAXA is required, PRAXBIND (idarucizumab), a specific antidote for reversing the effect of PRADAXA, can be available in hospitals and emergency rooms.

Missed Dose:

For all treatments, if you forget to take PRADAXA, do not take a double dose to make up for the missed dose.

- **After knee or hip replacement surgery:** Take your next dose at the same time next day.

- **To treat blood clots and prevent them from re-occurring in the veins of your leg(s) or in your lung(s):**Take it as soon as you remember, but if it is almost time for your next dose (less than 6 hours before your next dose), take your next dose when you are supposed to.

- **For patients who have irregular heartbeats (*atrial fibrillation*)**: Take it as soon as you remember, but if it is almost time for your next dose (less than 6 hours before your next dose), take your next dose when you are supposed to.

If you had knee or hip replacement surgery or are receiving treatment for prevention of blood clots in the veins of your legs and lungs and stop taking PRADAXA before your doctor told you to, you are at risk of developing a blood clot in a vein of your leg or in the lungs, which can be life-threatening.

If you have atrial fibrillation and stop taking PRADAXA without talking to your doctor, you are at risk of suffering from a stroke or other complications due to blood clot formation, which can be fatal or lead to severe disability.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

You should be aware that prescription medicines carry some risks and that all possible risks may not be known at this stage.

As PRADAXA acts on the blood clotting system, most side effects are related to signs of bruising or bleeding.

Although rare, PRADAXA can cause very serious or severe bleeding that can occur in any part of your body. These bleedings may reduce your physical abilities or even lead to death.

If you fall or injure yourself while taking PRADAXA, 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.

Patients treated with PRADAXA may experience the following side effects:

- abdominal pain, diarrhea, heartburn, nausea, reflux of gastric juice, upset stomach, vomiting;
- difficulty swallowing;
- bruising;
- hives, itching, rash.

PRADAXA can cause abnormal blood test results for kidney and liver function, number of platelets and number of red blood cells (anemia). Your doctor will ask for blood tests and will interpret the results.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM				
Symptom / effect		**Talk with your doctor or pharmacist**		**Stop taking drug and seek immediate emergency medical attention**
		Only if severe	**In all cases**	
Common	**Anemia:** feeling tired and weak, pale skin, cold hands and feet		✓	
	Bleeding from penis/vagina		✓	
	Blood in the urine that stains it pink or red		✓	
	Bleeding in the stomach or bowel: darker stool (like tar), bright red blood in your toilet or toilet tissue, vomiting blood		✓	
	Bruising or bleeding due to injury or after operation	✓		
	After surgery: Severe bleeding from the surgical wound, an injury or other procedures			✓
	After surgery: Liquid oozing from the surgical wound		✓	
	Nose bleed	✓		
	Bleeding under the skin	✓		
Uncommon	**Allergic reaction, including angioedema:** rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
	Decreased platelets: bruising, bleeding, fatigue and weakness		✓	
	Coughing blood or blood stained sputum		✓	
	Bleeding into a joint: pain, swelling at a single spot on the knee, ankle or shoulder		✓	
	Bleeding into the rectum or from haemorrhoids		✓	
	Bleeding from site of catheter	✓		

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM			
Symptom / effect	**Talk with your doctor or pharmacist**		**Stop taking drug and seek immediate emergency medical attention**
	Only if severe	**In all cases**	
entry into vein			
Bleeding into the brain: headache, difficulty seeing or speaking, lack of balance and coordination, weakness on one side, numbness			✓
Inflammation of the stomach, esophagus (food pipe): difficult and/or painful swallowing, heartburn, mouth sores, feeling of something being stuck in the throat, nausea, vomiting		✓	
Liver disorder - symptoms include nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark urine			✓

This is not a complete list of side effects. For any unexpected effects while taking PRADAXA, contact your doctor, nurse, or pharmacist immediately.

HOW TO STORE IT

Keep out of the reach and sight of children and pets. Do not use PRADAXA after the expiry date printed on the carton or blister.

Blister: Store between 15-30°C. Store in the original package to protect from moisture.

When removing a capsule from the blister, please note the following instructions:
- Tear off one individual blister from the blister card along the perforated line;
- Peel off the backing foil and remove the capsule;
- The capsule should not be pushed through the blister foil;
- Do not peel the blister foil until a capsule is required.

Bottle: Store between 15-30° C. Once opened, the product must be used within 4 months. Keep the bottle tightly closed. Store in the original package in order to protect from moisture.

When taking a capsule out of the bottle, please note the following instructions:
- The cap opens by pushing and turning.
- After removing the capsule, place the cap back on the bottle and tightly close the bottle right away.

Do not put the capsules in pill boxes or pill organizers, unless capsules can be maintained in the original package.

Any unused product or waste material should be disposed in accordance with local requirements.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

• Report online at www.healthcanada.gc.ca/medeffect
• Call toll-free at 1-866-234-2345
• Complete a Canada Vigilance Reporting Form and:
- Fax toll-free to: 1-866-678-6789, or
- Mail to: Canada Vigilance Program
Health Canada
Postal Locator 0701E
Ottawa, Ontario
K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: http://www.boehringer-ingelheim.ca or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 84633.

Please check our website to see if more up-to-date information has been posted.

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