

PART III: CONSUMER INFORMATION

Pr PRADAX™

Dabigatran Etexilate Capsules

This leaflet is part III of a three-part "Product Monograph" published when PRADAX was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about PRADAX. Contact your doctor or pharmacist if you have any questions about the drug.

ABOUT THIS MEDICATION

What the medication is used for:

PRADAX is an anticoagulant agent (prevents blood clots from forming). PRADAX is prescribed to you to prevent the formation of blood clots in the vein of your leg(s) or in your lung after major elective orthopaedic surgery (total hip or knee replacement).

What it does:

PRADAX helps prevent the formation of blood clots by blocking the activity of a protein called thrombin.

When it should not be used:

- You are aware of body lesions at risk of bleeding, including bleeding in the brain (stroke) within the last 6 months.
- You have severely reduced kidney function. Your doctor will know how to determine your kidney function.
- While epidural or spinal catheters are in place or within the first two hours after their removal. Your doctor will know what precautionary measures are required. PRADAX is not recommended for patients receiving epidural pain control after surgery.
- PRADAX should not be used during pregnancy, since its effects on pregnancy and the unborn child are not known.
- If you are allergic to dabigatran etexilate, dabigatran or any other ingredients of PRADAX (see **What the important nonmedicinal ingredients are**).
- PRADAX is not recommended in children younger than 18 years old.
- PRADAX is not recommended in patients with liver disease.

What the medicinal ingredient is:

Dabigatran etexilate, as dabigatran etexilate mesilate.

What the important nonmedicinal ingredients are:

acacia, carragenan, dimeticone, hydroxypropyl cellulose, hypromellose, indigocarmin, iron oxide black, potassium chloride, propylene glycol, shellac, sunset yellow, talc, tartaric acid, titanium dioxide.

What dosage forms it comes in:

HPMC Capsules (hard capsules) – 75 mg and 110 mg.

WARNINGS AND PRECAUTIONS

BEFORE you use PRADAX talk to your doctor or pharmacist if:

- You have an increased bleeding risk. Your doctor will observe you for any sign of increased bleeding during and after orthopaedic surgery. Prior to orthopaedic surgery, please tell your doctor if you have any disease known to cause an increased risk of bleeding (e.g. blood clotting disorders), a recent tissue sampling (biopsy), major trauma or recent brain bleeding, stomach ulcer or a previous diagnosis of inflammation of parts of your heart (endocarditis).
- You have severely reduced kidney function or if your kidneys do not function, PRADAX must not be used. If you have moderately reduced kidney function, your doctor will adjust the dose of PRADAX. No dose adjustment is needed if you have mildly reduced kidney function. Your doctor will be able to determine your kidney function. If during treatment with PRADAX you stop producing urine, inform your doctor immediately.
- You should avoid pregnancy during treatment with PRADAX.
- You are nursing. Breast-feeding should be stopped during treatment with PRADAX as a general precaution.
- You have reduced liver function, life-threatening liver disease or increased liver enzymes. Your doctor may decide to use an alternative medication.
- You have allergic reactions to any component of the drug.

INTERACTIONS WITH THIS MEDICATION

If you are taking or have taken any medications that affect the blood clotting system, please inform your doctor, (e.g.: heparin, and related compounds, such as low molecular weight heparin (LMWH), fondaparinux, bivalirudin, clopidogrel, ticlopidine, sulfapyrazone, warfarin (Coumadin)).

Please tell your doctor or pharmacist if you are taking or have recently taken any other medications, including medications obtained without a prescription. This also applies to acetylsalicylic acid, also known as Aspirin, or other medications you might take for headache, inflammation or arthritis.

If you are taking amiodarone, verapamil or quinidine, medications used to treat arrhythmias (abnormal rhythm of the heart), be sure to tell your doctor before you start taking PRADAX.

If you are taking clarithromycin (an antibiotic drug) be sure to tell your doctor when concomitantly taking PRADAX.

PROPER USE OF THIS MEDICATION

Usual dose:

Always take PRADAX exactly as your doctor has told you. This medication is started after orthopaedic surgery and should be taken for the duration specified by your doctor.

PRADAX can be taken with food, or on an empty stomach with water. Do not chew the capsule(s).

The recommended dose of PRADAX is 220 mg once daily, taken as 2 capsules of 110 mg, for most patients. Your doctor may prescribe a lower dose of 150 mg once daily, taken as 2 capsules of 75 mg, depending on your kidney function or other drugs you may be taking.

Overdose:

Inform your doctor or contact the regional Poison Control Centre as soon as possible if you take more than the prescribed dose of PRADAX.

Missed Dose:

If you forget to take PRADAX, do not take a double dose to make up for the missed dose. If you are not sure what your dose is, ask your doctor or pharmacist.

If you stop the treatment 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

As this medicine acts on the blood clotting system, most side effects are related to signs of bruising (haematoma) or bleeding (haemorrhages).

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 call your doctor or pharmacist
		Only if severe	In all cases	
Common	Severe bleeding from the surgical wound, an injury or other procedures			✓
	Liquid oozing from the surgical wound		✓	
	Bruising or bleeding due to injury or after operation	✓		
Un-common	Bleeding into a joint (stiff, sore, hot or painful joint)			✓
	Nose bleed	✓		
	Bleeding into the rectum or from hemorrhoids			✓
	Blood in stools		✓	
	Blood in urine (pink/red tinge to urine)		✓	
	Bleeding from site of catheter entry into vein	✓		
Very rare	Liver disorder - symptoms include nausea, vomiting, loss of appetite combined with itching, yellowing of the skin or eyes, dark urine		✓	

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

Do not be alarmed by this list of possible side effects. You may not experience any of them.

If you think you have an allergic reaction to PRADAX (symptoms such as red and lumpy skin, rash, hives, swelling, trouble breathing), it is important that you seek medical advice from your doctor straight away.

This is not a complete list of side effects. For any unexpected effects while taking PRADAX, contact your doctor or pharmacist immediately, so that these effects may be properly addressed.

HOW TO STORE IT

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

Blister: Store between 15 - 25°C. Store in the original package to protect from moisture. Take the hard capsules out by peeling off the backing foil of the blister card. Do not push the hard capsule through the blister foil. Do not peel the blister foil until a hard capsule is required.

Bottles: Store between 15 - 30°C. Once opened, PRADAX capsules should be used within 30 days. Keep the bottle tightly closed. Store in the original package in order to protect from moisture.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 866-234-2345
 By toll-free fax: 866-678-6789
 Online: www.healthcanada.gc.ca/medeffect
 By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:
 Canada Vigilance National Office
 Marketed Health Products Safety
 and
 Effectiveness Information Bureau
 Marketed Health Products
 Directorate
 Health Products and Food Branch
 Health Canada

Tunney's Pasture, AL 0701C
 Ottawa ON K1A 0K9

NOTE: Should you require information related to the management of the side effect, please contact your health care provider before notifying Canada Vigilance. 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](http://www.boehringer-ingelheim.ca) or by contacting the sponsor, Boehringer Ingelheim (Canada) Ltd., at: 1-800-263-5103, ext. 4633 (Medical Information). Please check our website to see if more up-to-date information has been posted.

This leaflet was prepared by Boehringer Ingelheim (Canada) Ltd.

Last revised: July 31, 2009