

MEDICATION GUIDE
PRADAXA (pra dax a)
(dabigatran etexilate)
Oral Pellets

This Medication Guide is for PRADAXA Oral Pellets. If your child is over 8 years of age and your healthcare provider prescribes PRADAXA Capsules for your child, read the Medication Guide that comes with your medicine. Read this Medication Guide before you start giving PRADAXA Oral Pellets to your child and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking with your healthcare provider about your child's medical condition or their treatment.

What is the most important information I should know about PRADAXA?

Do not stop giving PRADAXA without talking to the healthcare provider who prescribes it for your child. Stopping PRADAXA increases your child's risk of a clot forming in their blood.

PRADAXA may need to be stopped, if possible, before surgery or a medical or dental procedure. Ask the healthcare provider who prescribed PRADAXA for your child when your child should stop taking it. Your healthcare provider will tell you when you may start giving PRADAXA to your child again after their surgery or procedure. If your child has to stop taking PRADAXA, your healthcare provider may prescribe another medicine to help prevent a blood clot from forming.

- PRADAXA can cause bleeding which can be serious, and sometimes lead to death. This is because PRADAXA is a blood thinner medicine that lowers the chance of blood clots forming in the body.
- **Your child may have a higher risk of bleeding if your child takes PRADAXA and:**
 - has kidney problems
 - has stomach or intestine bleeding that is recent or keeps coming back, or a stomach ulcer
 - takes other medicines that increase the risk of bleeding, including:
 - aspirin or aspirin-containing products
 - long-term (chronic) use of non-steroidal anti-inflammatory drugs (NSAIDs)
 - a medicine that contains warfarin sodium
 - a medicine that contains heparin
 - a medicine that contains clopidogrel bisulfate
 - a medicine that contains prasugrel
 - has certain kidney problems and also takes a medicine that contains dronedarone or ketoconazole tablets

Tell your healthcare provider if your child takes any of these medicines. Ask your healthcare provider or pharmacist if you are not sure if your child's medicine is one listed above.

- PRADAXA can increase your child's risk of bleeding because it lessens the ability of your child's blood to clot. During treatment with PRADAXA:
 - he or she may bruise more easily
 - it may take longer for any bleeding to stop

Call your healthcare provider or get medical help right away if your child has any of these signs or symptoms of bleeding:

- unexpected bleeding or bleeding that lasts a long time, such as:
 - unusual bleeding from the gums
 - nose bleeds that happen often
 - menstrual bleeding or vaginal bleeding that is heavier than normal
- bleeding that is severe or you cannot control
- pink or brown urine
- red or black stools (looks like tar)
- bruises that happen without a known cause or get larger
- cough up blood or blood clots
- vomit blood or your vomit looks like "coffee grounds"
- unexpected pain, swelling, or joint pain
- headaches, feeling dizzy or weak

Take PRADAXA Oral Pellets exactly as prescribed. Do not stop giving PRADAXA Oral Pellets to your child without first talking to the healthcare provider who prescribes it for your child. Stopping PRADAXA increases your child's risk of a clot forming in their blood.

- **Spinal or epidural blood clots (hematoma).** People who take a blood thinner medicine (anticoagulant) like PRADAXA, and have medicine injected into their spinal and epidural area, or have a spinal puncture have a risk of

forming a blood clot that can cause long-term or permanent loss of the ability to move (paralysis). Your child's risk of developing a spinal or epidural blood clot is higher if:

- a thin tube called an epidural catheter is placed in your child's back to give them certain medicine
- your child takes NSAIDs or a medicine to prevent blood from clotting
- your child has a history of difficult or repeated epidural or spinal punctures
- your child has a history of problems with their spine or has had surgery on their spine

If your child takes PRADAXA and receives spinal anesthesia or has a spinal puncture, your healthcare provider should watch your child closely for symptoms of spinal or epidural blood clots. Tell your healthcare provider right away if your child has back pain, tingling, numbness, muscle weakness (especially in the legs and feet), loss of control of the bowels or bladder (incontinence).

See "What are the possible side effects of PRADAXA?" for more information about side effects.

What is PRADAXA Oral Pellets?

PRADAXA Oral Pellets is a prescription medicine that is used to:

- treat blood clots in children who are age 3 months to less than 12 years of age who have received an injectable medicine to treat their blood clots for at least 5 days.
- reduce the risk of blood clots happening again in children who are age 3 months to less than 12 years of age who have already been treated for blood clots.

Do not give PRADAXA if your child:

- currently has certain types of abnormal bleeding. Talk to your healthcare provider before giving PRADAXA if your child currently has unusual bleeding.
- has had a serious allergic reaction to any of the ingredients in PRADAXA. See the end of this Medication Guide for a complete list of ingredients in PRADAXA. Ask your healthcare provider if you are not sure.
- has ever had or if there are plans for your child to have a valve in their heart replaced with a mechanical (artificial) prosthetic heart valve.

Before giving PRADAXA to your child, tell your healthcare provider about all of your child's medical conditions, including if they:

- have kidney problems
- have ever had bleeding problems
- have ever had stomach ulcers
- have antiphospholipid syndrome (APS)
- are pregnant or plan to become pregnant. It is not known if PRADAXA will harm your child's unborn baby.
 - If your child is able to become pregnant, talk with your healthcare provider about your child's risk for severe uterine bleeding during treatment with blood thinner medicines, including PRADAXA.
 - Tell your healthcare provider right away if your child becomes pregnant during treatment with PRADAXA Oral Pellets.
- are breastfeeding or plan to breastfeed. It is not known if PRADAXA passes into your child's breastmilk. Your child should not breastfeed during treatment with PRADAXA.

Tell all of your healthcare providers and dentists that your child is taking PRADAXA. They should talk to the healthcare provider who prescribed PRADAXA for your child before your child has **any** surgery or a medical or dental procedure.

Tell your healthcare provider about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Some of your child's other medicines may affect the way PRADAXA works. Certain medicines may increase your child's risk of bleeding. See "**What is the most important information I should know about PRADAXA?**"

Especially tell your healthcare provider if your child takes a medicine that contains rifampin.

Know the medicines your child takes. Keep a list of them and show it to your healthcare provider and pharmacist when your child gets a new medicine.

How should I give PRADAXA?

- See the detailed "**Instructions for Use**" that comes with PRADAXA Oral Pellets for information about the right way to prepare and give your child a dose of PRADAXA Oral Pellets.
- Your healthcare provider will decide how long your child should take PRADAXA Oral Pellets. **Do not stop giving your child PRADAXA Oral Pellets without first talking with your healthcare provider. Stopping PRADAXA Oral Pellets may increase your child's risk of forming blood clots.**
- **Give PRADAXA Oral Pellets exactly as prescribed by your healthcare provider.** Check with your healthcare provider if you are not sure.
- Your healthcare provider will prescribe the correct dose of PRADAXA Oral Pellets for your child. Your healthcare provider will change your child's dose as they grow, and as needed during treatment.

- Give PRADAXA Oral Pellets 2 times a day, 1 dose in the morning and 1 dose in the evening. The doses should be given as close as possible to every 12 hours, and at about the same time every day.
- Give PRADAXA Oral Pellets before meals to help ensure that your child takes the full dose.
- You can mix PRADAXA Oral Pellets with apple juice or the following soft foods at room temperature:
 - Mashed carrots
 - Apple sauce
 - Mashed bananas
- **Do not** mix PRADAXA Oral Pellets with any food or liquid other than the ones listed above.
- **Do not mix PRADAXA Oral Pellets with milk or with foods that contain milk.**
- Give PRADAXA Oral Pellets right away or within 30 minutes after mixing. **Do not** give PRADAXA Oral Pellets if they have been in contact with the soft food or apple juice for more than 30 minutes.
- **Do not** give PRADAXA Oral Pellets using a syringe or through a feeding tube.
- **Do not** run out of PRADAXA Oral Pellets. Refill your child’s prescription before you run out.
- If you plan for your child to have surgery, or a medical or a dental procedure, tell your healthcare provider and dentist that your child is taking PRADAXA Oral Pellets. Your child may have to stop taking PRADAXA Oral Pellets for a short time. See **“What is the most important information I should know about PRADAXA?”**
- If your child only takes part of their dose, **do not** give another dose at that time. Give your child their next dose at the regular scheduled time, about 12 hours later.
- If your child misses a dose of PRADAXA Oral Pellets, give it as soon as you remember. If your child’s next dose is less than 6 hours away, skip the missed dose. **Do not** give your child a double dose of PRADAXA Oral Pellets to make up for a missed dose.
- If your child takes too much PRADAXA Oral Pellets, go to the nearest hospital emergency room or call your healthcare provider right away.
- Call your healthcare provider right away if your child falls or injures himself, especially if your child hits his head. Your healthcare provider may need to check your child.

PRADAXA Oral Pellets come in an aluminum bag that contains packets of the Oral Pellets used to prepare your child’s dose of medicine. After opening the aluminum bag, the packets of PRADAXA Oral Pellets must be used within 6 months. See **“How should I store PRADAXA Oral Pellets?”**

What are the possible side effects of PRADAXA?

PRADAXA can cause serious side effects. See “What is the most important information I should know about PRADAXA?”

- **Allergic Reactions.** Some adults taking PRADAXA capsules have developed symptoms of an allergic reaction.
 - Call your healthcare provider if your child gets symptoms of an allergic reaction, such as:
 - hives
 - rash
 - itching
 - **Get medical help right away if your child gets any of the following symptoms of a serious allergic reaction with PRADAXA Oral Pellets:**
 - chest pain or chest tightness
 - swelling of the face or tongue
 - trouble breathing or wheezing
 - feeling dizzy or faint

Common side effects of PRADAXA in children include:

- indigestion, upset stomach, burning
- nausea, vomiting, or diarrhea
- stomach-area (abdominal) pain or discomfort

Call your healthcare provider if your child develops any of the signs and symptoms of stomach and intestine problems listed above.

Tell your healthcare provider if your child has any side effect that bothers them or that does not go away.

These are not all of the possible side effects of PRADAXA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store PRADAXA Oral Pellets?

- Store PRADAXA Oral Pellets at room temperature 68°F to 77°F (20°C to 25°C).
- After opening the silver aluminum bag that contains the packets of Oral Pellets:
 - The silver aluminum bag contains a desiccant container. Throw away (dispose of) the desiccant container in your household trash.
 - PRADAXA Oral Pellets must be used within 6 months. Safely throw away any unused PRADAXA Oral Pellets after 6 months.
- Keep PRADAXA Oral Pellets packets in the original silver aluminum bag to keep them dry (protect the packets from moisture). **Do not** open packets of PRADAXA Oral Pellets until you are ready to use them.
- Throw away any PRADAXA Oral Pellets that have not been given within 30 minutes after the Oral Pellets come into contact with apple juice or soft food.

Keep PRADAXA and all medicines out of the reach of children.

General information about the safe and effective use of PRADAXA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use PRADAXA for a condition for which it was not prescribed. Do not give PRADAXA to other people, even if they have the same symptoms that your child has. It may harm them.

This Medication Guide summarizes the most important information about PRADAXA. If you would like more information, talk with your child's healthcare provider. You can ask your child's pharmacist or healthcare provider for information about PRADAXA that is written for health professionals.

What are the ingredients in PRADAXA Oral Pellets?

Active ingredient: dabigatran etexilate mesylate

Inactive ingredients: acacia, dimethicone, hypromellose, hydroxypropyl cellulose, talc, and tartaric acid.

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For more information about PRADAXA Oral Pellets, call Boehringer Ingelheim Pharmaceuticals, Inc. at 1-800-542-6257.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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