PRADAXA Oral Pellets Are Approved for Pediatric Patients

PRADAXA Oral Pellets are indicated for the treatment of venous thromboembolic events (VTE) in patients aged 3 months to less than 12 years who have been treated with a parenteral anticoagulant for at least 5 days and to reduce the risk of recurrence of VTE in patients aged 3 months to less than 12 years who have already been treated. See Important Safety Information below.

Access Support for PRADAXA Oral Pellets

FOR PRODUCT ASSISTANCE

- Eligible patients may pay as little as $10 for PRADAXA Oral Pellets. Please call 1-833-400-3472 to speak with a case manager at IQVIA*
- To speak with Boehringer Ingelheim Product Support, please call 1-800-542-6257

FOR ASSISTANCE WITH PRIOR AUTHORIZATION

- Boehringer Ingelheim offers a toolkit which contains resources to help navigate the prior authorization process for patients who have been prescribed PRADAXA Oral Pellets. Download here

For help with specialty pharmacy availability, please call 1-800-593-0310 or fax 1-877-709-9184

Click here to access the Manual Claim Form for PRADAXA Oral Pellets

For help with dosing, please use the PRADAXA Oral Pellets Prescribing Information

VTE includes deep vein thrombosis, when a blood clot occurs in a deep vein, and pulmonary embolism, when a blood clot breaks free and travels to the lungs[1]

*Terms and conditions apply.

Indications and Usage

Pradaxa® (dabigatran etexilate) Oral Pellets are indicated:

- for the treatment of venous thromboembolic events (VTE) in pediatric patients aged 3 months to less than 12 years of age who have been treated with a parenteral anticoagulant for at least 5 days
- to reduce the risk of recurrence of VTE in pediatric patients aged 3 months to less than 12 years of age who have been previously treated

IMPORTANT SAFETY INFORMATION ABOUT *PRADAXA*

WARNING: (A) PREMATURE DISCONTINUATION OF PRADAXA INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HEMATOMA

(A) PREMATURE DISCONTINUATION OF PRADAXA INCREASES THE RISK OF THROMBOTIC EVENTS

Premature discontinuation of any oral anticoagulant, including PRADAXA, increases the risk of thrombotic events. If anticoagulation with PRADAXA is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant

(B) SPINAL/EPIDURAL HEMATOMA

Epidural or spinal hematomas may occur in patients treated with PRADAXA who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:

- use of indwelling epidural catheters
- concomitant use of other drugs that affect hemostasis, such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants
- a history of traumatic or repeated epidural or spinal punctures
- a history of spinal deformity or spinal surgery
- optimal timing between the administration of PRADAXA and neuraxial procedures is not known

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary. Consider the benefits and risks before neuraxial intervention in patients who are or will be anticoagulated.

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Please see additional Important Safety Information on the following page and Prescribing Information, including Boxed WARNING and Medication Guide.

Pradaxa® dabigatran etexilate ORAL PELLETS

IMPORTANT SAFETY INFORMATION ABOUT *PRADAXA* (cont'd)

CONTRAINDICATIONS

PRADAXA is contraindicated in patients with:

- active pathological bleeding;
- history of a serious hypersensitivity reaction to dabigatran, dabigatran etexilate, or to one of the excipients of PRADAXA (e.g., anaphylactic reaction or anaphylactic shock);
- mechanical prosthetic heart valve

WARNINGS & PRECAUTIONS

Increased Risk of Thrombotic Events after Premature Discontinuation

Premature discontinuation of any oral anticoagulant, including PRADAXA, in the absence of adequate alternative anticoagulation, increases the risk of thrombotic events. If PRADAXA Oral Pellets are discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant and restart PRADAXA Oral Pellets as soon as medically appropriate.

Risk of Bleeding

- PRADAXA increases the risk of bleeding and can cause significant and, sometimes, fatal bleeding. Promptly evaluate any signs or symptoms of blood loss (e.g., a drop in hemoglobin and/or hematocrit or hypotension). Discontinue PRADAXA Oral Pellets in patients with active pathological bleeding.
- Risk factors for bleeding include concomitant use of medications that increase the risk of bleeding (e.g., anti-platelet agents, heparin, fibrinolytic therapy, and chronic use of NSAIDs). PRADAXA's anticoagulant activity and half-life are increased in patients with renal impairment.
- *Reversal of Anticoagulant Effect*: Hemodialysis can remove dabigatran; however the clinical experience supporting the use of hemodialysis as a treatment for bleeding is limited [see Overdosage (10)]. Prothrombin complex concentrates or recombinant Factor VIIa may be considered but their use has not been evaluated in clinical trials. Protamine sulfate and vitamin K are not expected to affect the anticoagulant activity of dabigatran. Consider administration of platelet concentrates in cases where thrombocytopenia is present or long-acting antiplatelet drugs have been used.
- In adults, a specific reversal agent (idarucizumab) for PRADAXA is available when reversal of the anticoagulant effect of dabigatran is needed. In pediatric patients, the efficacy and safety of idarucizumab have not been established.

Thromboembolic and Bleeding Events in Patients with Prosthetic Heart Valves

The use of PRADAXA is contraindicated in all patients with mechanical prosthetic valves due to a higher risk for thromboembolic events, especially in the post-operative period, and an excess of major bleeding for PRADAXA vs. warfarin. Use of PRADAXA for the prophylaxis of thromboembolic events in patients with AFib in the setting of other forms of valvular heart disease, including bioprosthetic heart valve, has not been studied and is not recommended.

Effect of P-gp Inducers & Inhibitors on Dabigatran Exposure

Concomitant use of PRADAXA with P-gp inducers (e.g., rifampin) reduces exposure to dabigatran and should generally be avoided. P-gp inhibition and impaired renal function are major independent factors in increased exposure to dabigatran. Concomitant use of P-gp inhibitors in patients with renal impairment is expected to increase exposure of dabigatran compared to either factor alone. The concomitant use of PRADAXA Oral Pellets with P-gp-inhibitors has not been studied in pediatric patients but may increase exposure to dabigatran.

Increased Risk of Thrombosis in Patients with Triple-Positive Antiphospholipid Syndrome

There is an increased risk of thrombosis in patients with triple-positive antiphospholipid syndrome. PRADAXA use is not recommended.

ADVERSE REACTIONS

The most common adverse reactions (>5%) reported with PRADAXA are gastrointestinal adverse reactions and bleeding.

USE IN SPECIFIC POPULATIONS

Pregnancy: The limited available data on PRADAXA use in pregnant women are insufficient to determine drug-associated risks for adverse developmental outcomes.
Lactation: Breastfeeding is not recommended.
Females and Males of Reproductive Potential: Discuss pregnancy planning with females of reproductive potential requiring anticoagulation. Assess the risk of clinically significant uterine bleeding, potentially requiring gynecological surgical interventions, in females of reproductive potential and those with abnormal uterine bleeding.
Pediatric Use: The safety and effectiveness of PRADAXA Oral Pellets for the treatment and the reduction in risk of recurrence of venous thromboembolism have been established in pediatric patients less than 12 years of age. Other age-appropriate pediatric dosage forms of dabigatran etexilate are available for pediatric patients 12 years and older for these indications. Safety and effectiveness of PRADAXA Oral Pellets have not been established in pediatric patients with non-valvular atrial fibrillation or those who have undergone hip replacement surgery.
Geriatric: Clinical studies of PRADAXA Oral Pellets did not include patients 65 years of age or older. See the Prescribing Information for PRADAXA Capsules for information on the use in patients 65 years of age or older.

CL-PX-100074 03.29.2022

Reference: 1. What is venous thromboembolism? National Institutes of Health. Updated September 19, 2022. Accessed October 19, 2022. https://www.nhlbi.nih.gov/health/venous-thromboembolism

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