If you are taking Pradaxa:

- If you have a possible higher risk for bleeding, your doctor may decide to prescribe a dose of 150 mg taken as one 75 mg capsule twice a day.
- If you have liver disease, your heart rate needs to be monitored to ensure normal rhythm.
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Pradaxa®
150 mg hard capsules

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

1. What Pradaxa is and what it is used for
Pradaxa contains the active substance dabigatran etexilate and belongs to the group of anticoagulants. Taking a dabigatran etexilate will reduce the risk of death from a heart attack or stroke in people with atrial fibrillation who are at high risk of these events. However, dabigatran etexilate will increase the risk of bleeding. Also, Pradaxa is used in children to:

- 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 severely reduced liver function or liver disease which could increase the risk to develop a heart attack.
  - if you have an 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 have a disease called antiphospholipid syndrome.
  - if you are receiving medicines which could increase the risk of bleeding.
  - if you have been recently bleeding.
  - if you know you have decreased kidney function, or you are suffering from an infection of the heart (bacterial endocarditis).

2. How to take Pradaxa
Pradaxa can be used in adults and children aged 7 to 13 years or under who are able to swallow the capsules when they have an atrial fibrillation which is caused by a procedure called cardioversion or by a procedure called catheter ablation for atrial fibrillation. Take Pradaxa as your physician has told you.

3. How much Pradaxa should be taken daily
The recommended dose is 220 mg taken as one 110 mg capsule twice a day.

- if you are able to swallow the capsules whole. There are other age appropriate dose combinations if you are not able to swallow the capsules whole. Consult your doctor if you experience any difficulties in swallowing.

4. Possible side effects
Pradaxa affects blood clotting, so most side effects are related to signs such as bruising or bleeding. These constitute the most serious side effects and, regardless of whether, may become disabling. The bleeding or bruising that can occur in some cases may be serious, may require medical intervention or treatment, and may lead to a reduction of dose or to stopping your treatment.

5. How to store Pradaxa
Pradaxa should be taken twice daily, one dose in the morning and one dose in the evening, approximately at the same time every day. This dosing interval should be at least 12 to 24 hours.

The recommended dose for weight is at least 80 kg, 110 mg plus two 75 mg capsules. Your doctor will adjust the treatment if required. Pradaxa can be taken with or without food. Take one 75 mg capsule twice daily.

Table 1 shows single and total daily Pradaxa doses in kilograms. The dose should be taken over a period of time according to age and sex of patients.
5. How to store Pradaxa

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton.

Store in the original package to protect from moisture.

Bottle: Once opened, the medicine must be used within 1 month. Keep the bottle tightly closed. once the original package has been opened, the medicine must be used within 1 month. Do not throw away any medicines via wastewater. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Pradaxa contains

The active substance is dabigatran. Each hard capsule contains: 6 mg of dabigatran mesilate.

The other ingredients are tannin acid, acacia, hypromellose, dextrose, IBD, tesl and hypromelloseophosphate.

The capsule shell contains component, potassium chloride, titantium dioxide, indigo carmine and hypromellose.

What Pradaxa looks like and contents of the pack

Pradaxa is available in hard capsules (22.5 mg each) with an opaque, light orange, rectangular, biconvex, film-coated capsule shape. Each capsule contains exactly 100 mg of dabigatran etexilate (as mesilate).

This medicine is available in packs containing 10 x 1 hard capsules, 30 x 1 hard capsules (300 mg) and 45 x 1 hard capsules (450 mg) at least 2 hard capsules (450 mg). Furthermore, Pradaxa is available in packs containing 1 x 1 hard capsules in aluminium enveloped and dose within minibags. This medicine is also available in propylene (plastic) bottles with 40 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Boehringer Ingelheim International GmbH
Binger Strasse 173
65216 Ingelheim am Rhein
Germany

Manufacture

Boehringer Ingelheim Pharma GmbH & Co. KG
Binger Strasse 173
65216 Ingelheim am Rhein
Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder

United Kingdom

Boehringer Ingelheim Ltd.

55216 Ingelheim am Rhein

This leaflet was last revised in 01/2022.