PARTICULARS TO APPEAR ON THE OUTER PACKAGING

FOLDING BOX FOR BLISTER for 110 mg

1. NAME OF THE MEDICINAL PRODUCT

Pradaxa 110 mg hard capsules
Dabigatran etexilate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each hard capsule contains 110 mg dabigatran etexilate (as mesilate)

3. LIST OF EXCIPIENTS

Contains sunset yellow (E 110) (see leaflet for further information)

4. PHARMACEUTICAL FORM AND CONTENTS

10 x 1 hard capsules
[redacted]

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Do not chew
Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP MM YYYY

9. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from moisture

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim International GmbH
Binger Str. 173
D-55216 Ingelheim am Rhein
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Pradaxa 110 mg

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER FOR 75 mg

1. NAME OF THE MEDICINAL PRODUCT

Pradaxa 75 mg hard capsules
Dabigatran etexilate

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim (logo)

3. EXPIRY DATE

EXP MM YYYY

4. BATCH NUMBER

Lot

5. OTHER

Peel back

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER FOR 110 mg

1. NAME OF THE MEDICINAL PRODUCT

Pradaxa 110 mg hard capsules
Dabigatran etexilate

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim (logo)

3. EXPIRY DATE

EXP MM YYYY

4. BATCH NUMBER

Lot

5. OTHER

Peel back

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

FOLDING BOX AND LABEL FOR BOTTLE for 75 mg

1. NAME OF THE MEDICINAL PRODUCT

Pradaxa 75 mg hard capsules
Dabigatran etexilate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each hard capsule contains 75 mg dabigatran etexilate (as mesilate)

3. LIST OF EXCIPIENTS

Contains sunset yellow (E110) (see leaflet for further information)

4. PHARMACEUTICAL FORM AND CONTENTS

60 hard capsules

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Do not chew
Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP MM YYYY
Once opened, the product must be used within 30 days

9. SPECIAL STORAGE CONDITIONS

Keep the bottle tightly closed. Store in the original package in order to protect from moisture

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim International GmbH
Binger Str. 173
D-55216 Ingelheim am Rhein
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Pradaxa 75 mg [redacted]

PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING.

FOLDING BOX AND LABEL FOR BOTTLE for 110 mg

1. NAME OF THE MEDICINAL PRODUCT

Pradaxa 110 mg hard capsules
Dabigatran etexilate

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each hard capsule contains 110 mg dabigatran etexilate (as mesilate)

3. LIST OF EXCIPIENTS

Contains sunset yellow (E110) (see leaflet for further information)

4. PHARMACEUTICAL FORM AND CONTENTS

60 hard capsules

5. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Do not chew
Read the package leaflet before use

6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE REACH AND SIGHT OF CHILDREN

Keep out of the reach and sight of children

7. OTHER SPECIAL WARNING(S), IF NECESSARY

8. EXPIRY DATE

EXP MM YYYY
Once opened, the product must be used within 30 days

9. SPECIAL STORAGE CONDITIONS

Keep the bottle tightly closed. Store in the original package in order to protect from moisture

10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim International GmbH
Binger Str. 173
D-55216 Ingelheim am Rhein
Germany

12. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

13. BATCH NUMBER

Lot

14. GENERAL CLASSIFICATION FOR SUPPLY

Medicinal product subject to medical prescription

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE

Pradaxa 110 mg [redacted]

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Pradaxa 75 mg hard capsules
Pradaxa 110 mg hard capsules
dabigatran etexilate

Read all of this leaflet carefully before you start taking this medicine.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT PRADAXA IS AND WHAT IT IS USED FOR

What is Pradaxa:

Pradaxa is a medicine which is used to prevent the formation of blood clots. It works by blocking a substance in the body which is involved in blood clot formation.

What Pradaxa is used for:

Pradaxa is used to prevent the formation of blood clots in the veins after knee or hip replacement surgery.

2. BEFORE YOU TAKE PRADAXA

Do NOT take Pradaxa

- if you are allergic to dabigatran etexilate, dabigatran or any of the other ingredients of Pradaxa.
- if you have severely reduced kidney function.
- if you are currently bleeding
- if you have a disease in an organ of the body that increases the risk of serious bleeding.
- if you have an increased tendency to bleed. This may be inborn, of unknown cause or due to other medicines.
- if you have a severely reduced liver function or liver disease which could possibly cause death.
- if you are taking quinidine, a medicine to treat abnormal heart beats.

Take special care with Pradaxa

Tell your doctor 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 liver disease that is associated with changes in the blood tests, the use of Pradaxa is not recommended.

- if you have an increased bleeding risk, as could be the case in the following situations:
  - if you have had a surgical tissue removal (biopsy) in the past month.
  - if you have had a serious injury (e.g. a bone fracture, head injury or any injury requiring surgical treatment).
  - if you are receiving treatments which could increase the risk of bleeding.
  - if you are taking anti-inflammatory medicines.
  - if you are suffering from an infection of the heart (bacterial endocarditis).
  - if you have a moderately impaired kidney function.
  - Pradaxa should not be used in children.

- if you have a tube (catheters) inserted into the back:
  A tube can be inserted into your back e.g. for anesthesia or pain relief during or after surgery. If you are administered Pradaxa after removal of a catheter your doctor will examine you regularly.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. For instance:

- Blood thinners (e.g. warfarin, heparin)
- Non-steroidal anti-inflammatory medicines
- St. John´s wort, rifampicin, verapamil, clarithromycin
- Amiodarone
  If you are taking amiodarone-containing medicines you should be treated with a reduced dose of 150 mg Pradaxa

Taking Pradaxa with food and drink

Pradaxa can be taken with or without food.

Pregnancy and breast-feeding

The effects of Pradaxa on pregnancy and the unborn child are not known. You should not take Pradaxa if you are pregnant unless your doctor advises you that it is safe to do so. If you are a woman of child-bearing age, you should avoid becoming pregnant while you are taking Pradaxa.

You should not breast-feed while you are taking Pradaxa.

Driving and using machines

The effect of Pradaxa on the ability to drive and use machines is not known. Your doctor will tell you when you can start to drive.

Important information about some of the ingredients of Pradaxa

Pradaxa hard capsules contain a colorant with the name sunset yellow, which may cause allergic reactions.

3. HOW TO TAKE PRADAXA

When taking Pradaxa capsules out of the blister pack, please observe the following instructions

- take the capsules by peeling off the backing foil of the blister card.
- do not push the capsules through the blister foil.
- do not peel off the blister foil until a capsule is required.

When taking Pradaxa capsules out of the bottle, please observe the following instructions

- push and turn for opening

The generally recommended dose of Pradaxa is 220 mg once a day (taken as 2 capsules of 110 mg).

If your kidney function is decreased by more than half or if you are 75 years of age or older, the recommended dose is 150 mg once a day (taken as 2 capsules of 75 mg).

After knee replacement surgery

You should start treatment with Pradaxa within 1 – 4 hours after surgery finishes, taking a single capsule. Thereafter two capsules once a day should be taken for a total of 10 days.

After hip replacement

You should start treatment with Pradaxa within 1 – 4 hours after surgery finishes, taking a single capsule. Thereafter two capsules once a day should be taken for a total of 28 - 35 days.

For both surgery types, treatment should not be started if there is bleeding from the site of operation. If the treatment cannot be started until the day after surgery, dosing should be started with 2 capsules once daily.

Always take Pradaxa exactly as your doctor has told you. You should check with your doctor if you are not sure. The capsule should be swallowed with some water. Do not chew the capsule.

Changing from treatment with Pradaxa to anticoagulant treatment given by injection
Do not start treatment with injectable anticoagulant medicines (for example, heparin) until 24 hours after the final dose of Pradaxa.

Changing from anticoagulant treatment given by injection to treatment with Pradaxa
Stop the treatment by injection and then start taking Pradaxa at the time you would have had the next injection.

If you take more Pradaxa than you should
If you take more Pradaxa than recommended, you may have an increased risk of bleeding. Your doctor can perform a blood test to assess the risk of bleeding.
Inform your doctor as soon as possible if you take more than the prescribed dose of Pradaxa. If bleeding occurs, surgical treatment or treatment with blood transfusions may be required.

If you forget to take Pradaxa
Continue with your remaining daily doses of Pradaxa at the same time of the next day.
Do not take a double dose to make up for missed individual doses.

If you stop taking Pradaxa
Do not stop taking Pradaxa without first consulting your doctor, since the risk of developing a blood clot in a vein could be higher if you stop treatment early.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Pradaxa can cause side effects, although not in all patients.

As this medicine affects blood clotting, most side effects are related to signs such as bruising or bleeding.

The side effects are listed below, grouped by how likely they are to happen:

With Pradaxa the following common and uncommon side effects are known:

Common side effects (affects 1 to 10 users in 100):
- A fall in the number of red cells in the blood
- Haematoma formation
- Bleeding from an injury
- A fall in the amount of haemoglobin in the blood (the substance in the red blood cells)
- Wound secretion (liquid exuding from the surgical wound)
- Bruising occurring after an operation
- Bleeding occurring after an operation
- A fall in the number of red cells in the blood after an operation
- Bruising due to an injury
- Exudation of a small amount of liquid from the incision made for a surgical procedure
- Blood found in the urine on laboratory testing.

Uncommon side effects (affects 1 to 10 users in 1,000):
- Bleeding
- Bleeding into a joint
- A fall in the number of platelets in the blood
- Nose bleed
- Bleeding into the stomach or bowel
- Bleeding from piles
- Bleeding into the rectum
- Blood in the urine that stains the urine pink or red
- Bleeding under the skin
- Blood-stained discharge from the site of entry of a catheter into a vein
- Bleeding from the site of entry of a catheter into a vein
- Blood detected in the stools by a laboratory test
- A decrease in the proportion of red cells in the blood
- Bleeding from a surgical incision
- Unusual laboratory test results on liver function

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE PRADAXA

Keep out of the reach and sight of children.

Do not use Pradaxa after the expiry date which is stated on the carton, blister or bottle. The expiry date refers to the last day of that month.

Blister: Store in the original package in order to protect from moisture.
Bottle: Once opened, the product must be used within 30 days. Keep the bottle tightly closed. Store in the original package in order to protect from moisture.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Pradaxa contains

The active substance is dabigatran, which is administered in the form of 75 mg or 110 mg dabigatran etexilate given as mesilate.

The other ingredients are tartaric acid, acacia, hypromellose, dimeticone 350, talc, and hydroxypropylcellulose

The capsule shell contains carrageenan, potassium chloride, titanium dioxide, indigo carmine, sunset yellow, hypromellose and purified water

The black printing ink contains shellac, N-butyl alcohol, isopropyl alcohol, industrial methylated spirit, iron oxide black, purified water and propylene glycol

What Pradaxa looks like and contents of the pack

Pradaxa is a hard capsule.

Pradaxa 75 mg hard capsules have an opaque, light blue-coloured cap and an opaque, cream-coloured body. The Boehringer Ingelheim logo is printed on the cap and "R75" on the body of the capsule.

Pradaxa 110 mg hard capsules have an opaque, light blue-coloured cap and an opaque, cream-coloured body. The Boehringer Ingelheim logo is printed on the cap and "R110" on the body of the capsule.

Pradaxa 75 mg and 110 mg hard capsules are available in packs containing 10 x 1, 30 x 1, 60 x 1 capsules in aluminium perforated unit dose blisters.

Pradaxa 75 mg and 110 mg hard capsules are also available in polypropylene (plastic) bottles with 60 hard capsules.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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Manufacturer

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This leaflet was last approved in {MM/YYYY}.

Detailed information on this medicine is available on the European Medicines Agency (EMEA) web site: http://www.emea.europa.eu/