

Package leaflet: Information for the patient

Pradaxa® 20 mg coated granules

Pradaxa® 30 mg coated granules

Pradaxa® 40 mg coated granules

Pradaxa® 50 mg coated granules

Pradaxa® 110 mg coated granules

Pradaxa® 150 mg coated granules

dabigatran etexilate

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your child's doctor or pharmacist.
- This medicine has been prescribed for your child only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your child's doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Pradaxa is and what it is used for
2. What you need to know before your child takes Pradaxa
3. How to take Pradaxa
4. Possible side effects
5. How to store Pradaxa
6. Contents of the pack and other information

1. What Pradaxa is and what it is used for

Pradaxa contains the active substance dabigatran etexilate and belongs to a group of medicines called anticoagulants. It works by blocking a substance in the body which is involved in blood clot formation.

Pradaxa is used in children to treat blood clots and to prevent blood clots from reoccurring.

2. What you need to know before your child takes Pradaxa

Do not use Pradaxa

- if your child is allergic to dabigatran etexilate or any of the other ingredients of this medicine (listed in section 6).
- if your child has severely reduced kidney function.
- if your child is currently bleeding.
- if your child has a disease in an organ of the body that increases the risk of serious bleeding (e.g. stomach ulcer, injury or bleeding in the brain, recent surgery of the brain or eyes).
- if your child has an increased tendency to bleed. This may be inborn, of unknown cause or due to other medicines.
- if your child is given medicines to prevent blood clotting (e.g. warfarin, rivaroxaban, apixaban or heparin), except when changing anticoagulant treatment or while having a venous or arterial line and your child gets heparin through this line to keep it open.
- if your child has a severely reduced liver function or liver disease which could possibly cause death.
- if your child is given oral ketoconazole or itraconazole, medicines to treat fungal infections.
- if your child is given oral cyclosporine, a medicine to prevent organ rejection after transplantation.
- if your child is given dronedarone, a medicine used to treat abnormal heart beat.
- if your child is given a combination product of glecaprevir and pibrentasvir, an antiviral medicine used to treat hepatitis C
- if your child has received an artificial heart valve which requires permanent blood thinning.

Warnings and precautions

Talk to your child's doctor before you give your child Pradaxa. You may also need to talk to your child's doctor during treatment with this medicine if your child experiences symptoms or if your child has to undergo surgery.

Tell your child's doctor if your child has or has had any medical conditions or illnesses, in particular any of those included in the following list:

- If your child has an increased bleeding risk, such as:
 - if your child has been recently bleeding.
 - if your child has had a surgical tissue removal (biopsy) in the past month.
 - if your child has had a serious injury (e.g. a bone fracture, head injury or any injury requiring surgical treatment).
 - if your child is suffering from an inflammation of the gutlet or stomach.
- if your child has problems with reflux of gastric juice into the gutlet.
- if your child is receiving medicines which could increase the risk of bleeding. See 'Other medicines and Pradaxa' below.
- if your child is given anti-inflammatory medicines such as diclofenac, ibuprofen, piroxicam.
- if your child is suffering from an infection of the heart (bacterial endocarditis).
- if you know your child has decreased kidney function, or your child is suffering from dehydration (symptoms include feeling thirsty and passing reduced amounts of dark-coloured (concentrated) / foaming urine).
- if your child has an infection around or within the brain.

- if your child has had a heart attack or if your child has been diagnosed with conditions that increase the risk to develop a heart attack.

- if your child has a liver disease that is associated with changes in the blood tests. The use of this medicine is not recommended in this case.

Take special care with Pradaxa

- if your child needs to have an operation:
 - In this case Pradaxa will need to be stopped temporarily due to an increased bleeding risk during and shortly after an operation. It is very important to give Pradaxa before and after the operation exactly at the times you have been told by your child's doctor.

- if an operation involves a catheter or injection into your child's spinal column (e.g. for epidural or spinal anaesthesia or pain reduction):
 - it is very important to give Pradaxa before and after the operation exactly at the times you have been told by your child's doctor.
 - tell your child's doctor immediately if your child gets numbness or weakness of the legs or problems with his/her bowel or bladder after the end of anaesthesia, because urgent care is necessary.

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Table 1: Dosing table for Pradaxa coated granules for patients below 12 months

Weight / age combinations	Age in MONTHS	Single dose	Total daily dose
		in mg	in mg
2.5 to less than 3 kg	4 to less than 5 months	20	40
3 to less than 4 kg	3 to less than 6 months	20	40
4 to less than 5 kg	1 to less than 3 months	20	40
5 to less than 7 kg	3 to less than 8 months	30	60
	8 to less than 10 months	40	80
	0 to less than 1 month	20	40
	1 to less than 5 months	30	60
	5 to less than 8 months	40	80
7 to less than 9 kg	8 to less than 12 months	50	100
	3 to less than 4 months	40	80
	4 to less than 9 months	50	100
	4 to less than 9 months	60	120
9 to less than 11 kg	5 to less than 6 months	50	100
	6 to less than 11 months	60	120
	11 to less than 12 months	70	140
11 to less than 13 kg	8 to less than 10 months	70	140
	10 to less than 12 months	80	160
	10 to less than 11 months	80	160
13 to less than 16 kg	10 to less than 12 months	80	160
	11 to less than 12 months	100	200

Convenient sachet combinations to achieve the single doses recommended in the dosing table are provided below. Other combinations are possible.

20 mg: One 20 mg sachet	60 mg: Two 30 mg sachets
30 mg: One 30 mg sachet	70 mg: One 30 mg plus one 40 mg sachet
40 mg: One 40 mg sachet	80 mg: Two 40 mg sachets
50 mg: One 50 mg sachet	100 mg: Two 50 mg sachets

Table 2 shows single and total daily Pradaxa doses in milligrams (mg) for patients from 1 year to less than 12 years. The doses depend on weight in kilograms (kg) and age in years of the patient.

Table 2: Dosing table for Pradaxa coated granules for patients from 1 year to less than 12 years

Weight / age combinations	Age in YEARS	Single dose	Total daily dose
		in mg	in mg
5 to less than 7 kg	1 to less than 2 years	50	100
7 to less than 9 kg	1 to less than 2 years	60	120
9 to less than 11 kg	2 to less than 4 years	70	140
	1 to less than 1.5 years	70	140
11 to less than 13 kg	1.5 to less than 7 years	80	160
	1 to less than 1.5 years	80	160
	1.5 to less than 2.5 years	100	200
13 to less than 16 kg	2.5 to less than 9 years	110	220
	1 to less than 1.5 years	100	200
	1.5 to less than 2 years	110	220
16 to less than 21 kg	2 to less than 12 years	140	280
	1 to less than 2 years	110	220
	2 to less than 12 years	140	280
21 to less than 26 kg	1.5 to less than 2 years	140	280
26 to less than 31 kg	2 to less than 12 years	180	360
	2 to less than 12 years	180	360
31 to less than 41 kg	2.5 to less than 12 years	220	440
41 to less than 51 kg	4 to less than 12 years	260	520
51 to less than 61 kg	5 to less than 12 years	300	600
61 to less than 71 kg	6 to less than 12 years	300	600
71 to less than 81 kg	7 to less than 12 years	300	600
above 81 kg	10 to less than 12 years	300	600

Convenient sachet combinations to achieve the single doses recommended in the dosing table are provided below. Other combinations are possible.

50 mg: One 50 mg sachet	140 mg: One 30 mg plus one 110 mg sachet
60 mg: Two 30 mg sachets	180 mg: One 30 mg plus one 150 mg sachet
70 mg: One 30 mg plus one 40 mg sachet	220 mg: Two 110 mg sachets
80 mg: Two 40 mg sachets	260 mg: One 110 mg plus one 150 mg sachet
100 mg: Two 50 mg sachets	300 mg: Two 150 mg sachets
110 mg: One 110 mg sachet	

Method and route of administration

This medicine is given together with apple juice or one of the soft food options mentioned in the instructions for administration. Do not mix this medicine with milk or soft food containing milk products.

Detailed instructions for the use of this medicine are provided in 'Instructions for administration' at the end of the package leaflet.

Change of anticoagulant treatment

Without specific guidance from your child's doctor do not change your child's anticoagulant treatment.

If you give more Pradaxa than you should

Taking too much of this medicine increases the risk of bleeding. Contact your child's doctor immediately if you have given too much of it. Specific treatment options are available.

If you forget to give your child Pradaxa

A forgotten dose can still be given up to 6 hours prior to the next due dose.

A missed dose should be omitted if the remaining time is below 6 hours prior to the next due dose.

Do not give a double dose to make up for a forgotten dose.

If a dose has only been taken partially, do not attempt to administer a second dose at that time-point. Give the next dose as scheduled approximately 12 hours later.

If you stop giving Pradaxa

Give Pradaxa exactly as prescribed. Do not stop giving this medicine without talking to your child's doctor first, because the risk of developing a blood clot could be higher if you stop treatment too early. Contact your child's doctor if your child experiences indigestion after giving Pradaxa.

If you have any further questions on the use of this medicine, ask your child's doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Pradaxa affects blood clotting, so most side effects are related to signs such as bruising or bleeding. Major or severe bleeding may occur, these constitute the most serious side effects and, regardless of location, may become disabling, life-threatening or even lead to death. In some cases these bleedings may not be obvious.

If your child experiences any bleeding event that does not stop by itself or if your child experiences signs of excessive bleeding (exceptional weakness, tiredness, paleness, dizziness, headache or unexplained swelling) consult your child's doctor immediately. Your child's doctor may decide to keep your child under closer observation or change the medicine.

Tell your child's doctor immediately, if your child experiences a serious allergic reaction which causes difficulty in breathing or dizziness.

Possible side effects are listed below, grouped by how likely they are to happen.

Common (may affect up to 1 in 10 people):

- A fall in the number of red cells in the blood
- A fall in the number of platelets in the blood
- Skin rash notable for dark red, raised, itchy bumps caused by an allergic reaction
- Sudden change of the skin which affects its colour and appearance
- Haematoma formation
- Nosebleed
- Reflux of gastric juice into the gutlet
- Vomiting
- Feeling sick
- Frequent loose or liquid bowel movements
- Indigestion
- Hair loss
- Liver enzymes increased

Uncommon (may affect up to 1 in 100 people):

- Decrease in the number of white blood cells (which help to fight infections)
- Bleeding may happen into the stomach or bowel, from the brain, from the rectum, from penis/vagina or urinary tract (incl. blood in the urine that stains the urine pink or red), or under the skin
- A fall in the amount of haemoglobin in the blood (the substance in the red blood cells)
- A decrease in the proportion of blood cells
- Itching
- Coughing of blood or blood stained sputum
- Belly ache or stomach ache
- Inflammation of the gutlet and stomach
- Allergic reaction
- Difficulty in swallowing
- Yellowing of the skin or whites of the eyes, caused by liver or blood problems

Not known (frequency cannot be estimated from the available data):

- Lack of white blood cells (which help to fight infections)
- Serious allergic reaction which causes difficulty in breathing or dizziness
- Serious allergic reaction which causes swelling of the face or throat
- Difficulty in breathing or wheezing
- Bleeding
- Bleeding may happen into a joint or from an injury, from a surgical incision, or from the site of entry of an injection or from the site of entry of a catheter into a vein
- Bleeding may happen from piles
- Ulcer in the stomach or bowel (incl. ulcer in the gutlet)
- Unusual laboratory test results on liver function

Reporting of side effects

If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

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 after "EXP". The expiry date refers to the last day of that month.

Before first use, do not open the aluminium bag containing the sachets with the Pradaxa coated granules in order to protect from moisture.

Once the aluminium bag containing the sachets with the coated granules and the desiccant is opened, the medicine must be used within 6 months. The opened sachet cannot be stored and must be used immediately after opening.

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 sachet of Pradaxa 20 mg coated granules contains coated granules with 20 mg dabigatran etexilate (as mesilate).
- The active substance is dabigatran. Each sachet of Pradaxa 30 mg coated granules contains coated granules with 30 mg dabigatran etexilate (as mesilate).
- The active substance is dabigatran. Each sachet of Pradaxa 40 mg coated granules contains coated granules with 40 mg dabigatran etexilate (as mesilate).
- The active substance is dabigatran. Each sachet of Pradaxa 50 mg coated granules contains coated granules with 50 mg dabigatran etexilate (as mesilate).
- The active substance is dabigatran. Each sachet of Pradaxa 110 mg coated granules contains coated granules with 110 mg dabigatran etexilate (as mesilate).
- The active substance is dabigatran. Each sachet of Pradaxa 150 mg coated granules contains coated granules with 150 mg dabigatran etexilate (as mesilate).

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

What Pradaxa looks like and contents of the pack

The sachets of Pradaxa coated granules contain yellowish coated granules.

Each pack of this medicine contains an aluminium bag which in turn contains 60 silver-coloured aluminium sachets with Pradaxa coated granules and a desiccant (labelled "DO NOT EAT" including pictogram and "SILICA GEL").

Marketing Authorisation Holder

Boehringer Ingelheim International GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

Manufacturer

Boehringer Ingelheim Pharma GmbH & Co. KG
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

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File information		Mandatory in	
TD	Printfile	TD	Printfile
Issue date of TD:	23/09/2023	Yes	Yes
PPM SKU:	805399	No	Yes
PPM SKU version:	002	No	Yes
Issue date of artwork:	19/FEB/2024	No	Yes
Print colors:	PAN Black	No	Yes
Mat. No. Pack. Size:	494884	No	Yes
Min. font size:	11 pt		
Legend case version:	V5.01 (JAN/2021) (please do not change or remove it)		

Technical colours - not for printing

Bl Check-Legendcase	Free area	Gluepoints
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Additional Requirements of Packaging Site

Dimension: 89x x 449 mm
Template name: 9954-TD-IFU LR-PP-8954469-V1
Created by: jans2edf

Instructions for administration

- Do not administer Pradaxa coated granules
- via syringes or feeding tubes
- with other than the soft foods or apple juice as indicated below

Administer Pradaxa coated granules either with soft foods or apple juice. The instructions are provided below under A) for soft foods and B) for apple juice.

The prepared medicine should be given before meals in order to ensure that the patient takes the full dose.

Administer the prepared medicine to the patient immediately or within 30 minutes after mixing. Do not give this medicine if it has been in contact with the food or apple juice for more than 30 minutes.

In case of an incomplete intake of the prepared medicine, do not apply a second dose, wait until the next dosing time-point.

A) Administration of Pradaxa coated granules with soft foods

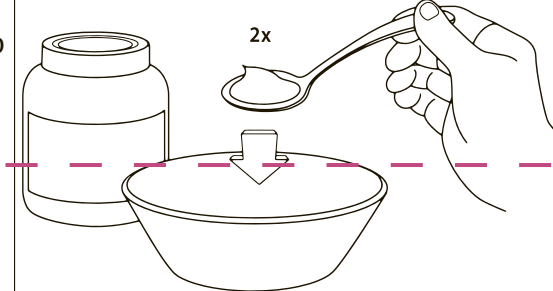
The food should be at room temperature before mixing with the coated granules. The medicine can be administered with one of the following soft foods:

- Mashed carrots
- Apple sauce (for administration with apple juice see B)
- Mashed banana

Do not use soft food containing milk products.

Step 1 – Prepare cup or bowl

- Transfer two teaspoons of the soft food into a small cup or bowl.



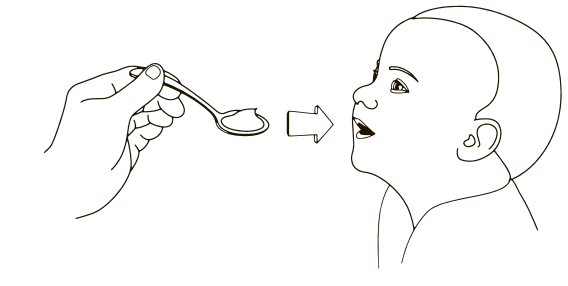
Step 5 – Stir soft food to mix coated granules

- Stir soft food with the feeding spoon to thoroughly mix the coated granules with the soft food.



Step 6 – Administer soft food

- Administer the soft food with the coated granules to the patient immediately using the feeding spoon.
- Assure that all soft food is eaten.

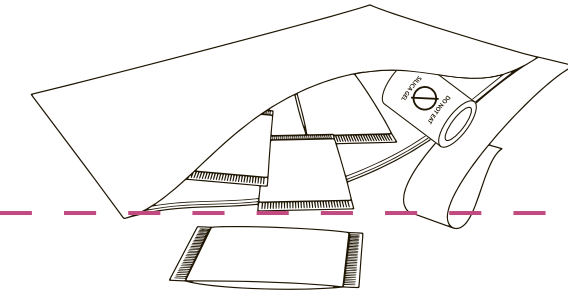


B) Administration of Pradaxa coated granules with apple juice

Step 1 – Have a cup of apple juice ready before the next step

Step 2 – Collect sachet(s)

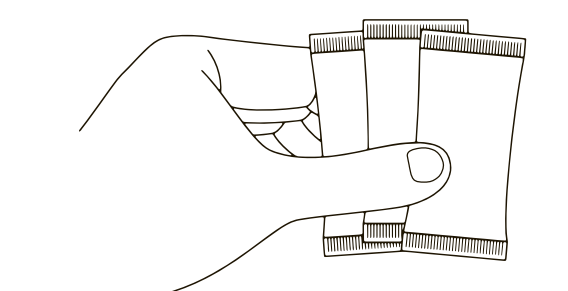
- Upon first opening, open the silver aluminium bag by cutting at the top using scissors. The aluminium bag includes 60 silver-coloured sachets (medicine) and one desiccant with the imprint "DO NOT EAT" including pictogram and "SILICA GEL".



- Do not open or consume the desiccant.

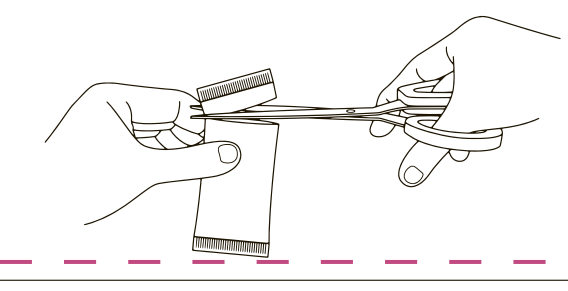


- Collect the required number of sachets with Pradaxa coated granules according to the prescribed dose.
- Put the unused sachets back into the aluminium bag.



Step 3 – Open sachet(s)

- Take the sachet containing the Pradaxa coated granules.
- Tap the sachet on the table to ensure that the contents settle to the bottom.
- Keep the sachet in an upright position.
- Open the sachet by cutting at the top using scissors.

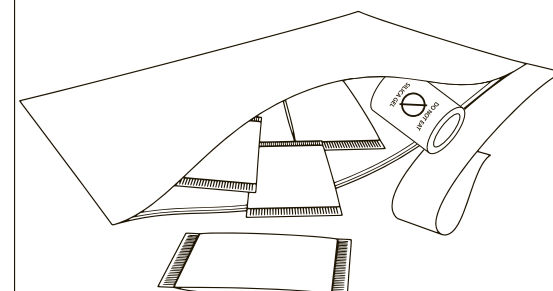


Step 4 – Administer Pradaxa coated granules with apple juice

- Administer all of the coated granules directly from the sachet or using a feeding spoon into the child's mouth and offer the child as much apple juice as needed to swallow the coated granules.
- Inspect child's mouth to ensure that all coated granules are swallowed.
- Optional: If the Pradaxa coated granules are mixed in the apple juice cup, start with a small amount of apple juice (that your child is likely to drink completely) and ensure that all coated granules are taken. If coated granules are sticking to the cup, add another small amount of apple juice and again apply to your child. Repeat until no remaining coated granules are sticking to the cup.

Step 2 – Collect sachet(s)

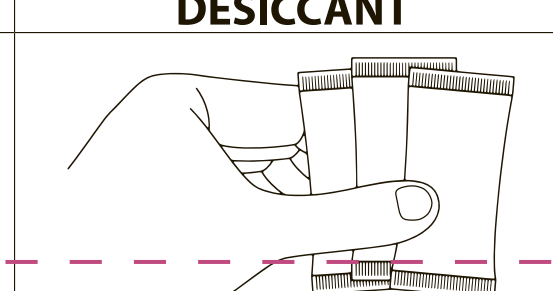
- Upon first opening, open the silver aluminium bag by cutting at the top using scissors. The aluminium bag includes 60 silver-coloured sachets (medicine) and one desiccant with the imprint "DO NOT EAT" including pictogram and "SILICA GEL".



- Do not open or consume the desiccant.

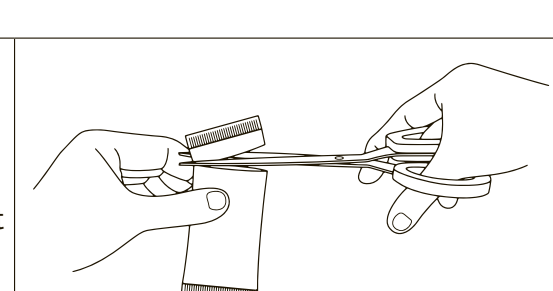


- Collect the required number of sachets with Pradaxa coated granules according to the prescribed dose.
- Put the unused sachets back into the aluminium bag.



Step 3 – Open sachet(s)

- Take the sachet containing the Pradaxa coated granules.
- Tap the sachet on the table to ensure that the contents settle to the bottom.
- Keep the sachet in an upright position.
- Open the sachet by cutting at the top using scissors.



Step 4 – Pour sachet(s) content

- Empty the entire content of the sachet into the small cup or bowl containing the soft food.
- Repeat Steps 3 and 4 if more than one sachet is needed.

