

Dabigatran Sandoz®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Dabigatran Sandoz?

Dabigatran Sandoz contains the active ingredient dabigatran etexilate. Dabigatran Sandoz is used for one of the following:

- to prevent the formation of blood clots in the veins after knee or hip replacement surgery in adults
- to reduce the risk of brain (stroke) and/or other body vessel obstruction by blood clot formation in adults with an abnormal heart beat rhythm called non-valvular atrial fibrillation
- to treat blood clots in the veins of your legs and lungs and to prevent blood clots from re- occurring in the veins of your legs and/or lungs.

For more information, see Section [1. Why am I using Dabigatran Sandoz?](#) in the full CMI.

2. What should I know before I use Dabigatran Sandoz?

Do not use if you have ever had an allergic reaction to dabigatran etexilate or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Dabigatran Sandoz?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Dabigatran Sandoz and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use Dabigatran Sandoz?

- Follow the instructions provided to you by your doctor or pharmacist carefully.

More instructions can be found in Section [4. How do I use Dabigatran Sandoz?](#) in the full CMI.

5. What should I know while using Dabigatran Sandoz?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using Dabigatran Sandoz.• Tell your doctor if you fall or injure yourself during treatment, especially if you hit your head, please seek urgent medical attention.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking your medicine or lower the dosage without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• No studies on the effects of Dabigatran Sandoz on the ability to drive and operate machinery have been performed.• Driving or operating machinery should be avoided for a period of time after orthopaedic surgery.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Store below 25°C.• Keep your capsules in the blister pack until it is time to take them.

For more information, see Section [5. What should I know while using Dabigatran Sandoz?](#) in the full CMI.

6. Are there any side effects?

Common side effects: bruising, nose bleeds. **Serious side effects:** long or excessive bleeding, exceptional weakness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

Dabigatran Sandoz®

Active ingredient: *dabigatran etexilate (as mesilate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Dabigatran Sandoz. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Dabigatran Sandoz.**

Where to find information in this leaflet:

1. [Why am I using Dabigatran Sandoz?](#)
2. [What should I know before I use Dabigatran Sandoz?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use Dabigatran Sandoz?](#)
5. [What should I know while using Dabigatran Sandoz?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using Dabigatran Sandoz?

Dabigatran Sandoz contains the active ingredient dabigatran etexilate (as dabigatran etexilate mesilate). Dabigatran Sandoz belongs to a group of medicines called anticoagulant. Some people refer to anticoagulant medicines as "blood thinners". Dabigatran works by inhibiting a specific protein in the blood, called thrombin. Thrombin contributes to the formation of blood clots. Dabigatran prevents the formation of blood clots.

Dabigatran Sandoz is used for one of the following:

- to prevent the formation of blood clots in the veins after knee or hip replacement surgery in adults
- to reduce the risk of brain (stroke) and/or other body vessel obstruction by blood clot formation in adults with an abnormal heart beat rhythm called non-valvular atrial fibrillation
- to treat blood clots in the veins of your legs and lungs and to prevent blood clots from re- occurring in the veins of your legs and/or lungs.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

2. What should I know before I use Dabigatran Sandoz?

Warnings

Do not use Dabigatran Sandoz if:

- you are allergic to dabigatran etexilate, or any of the ingredients listed at the end of this leaflet. Always

check the ingredients to make sure you can use this medicine.

- if you are currently bleeding
- if you have severely reduced kidney function (your doctor will know how to determine your kidney function)
- if you have an increased tendency of bleeding complications (this may be inherited, of unknown cause or due to other medicines)
- if you have a medical condition which increases your risk of serious bleeding, such as recent brain or spinal injury, and cancer
- if you have active stomach ulcers or have experienced stomach bleeding in the past year, unless the cause has been permanently eliminated, e.g. by surgery
- if you have a history of bleeding in the head, eyes, spine, abdomen and joints
- if you have an indwelling spinal or epidural catheter, and during the first two hours after their removal (your doctor will know about the kind of catheters and precautionary measures)
- if you have liver problems or liver disease
- if you are currently taking oral ketoconazole or itraconazole, medicines used to treat fungal infections
- if you are taking dronedarone, a medicine used to treat abnormal heart beat
- if you are taking ciclosporin or tacrolimus, medicines used to prevent organ rejection after transplantation
- if you are taking glecaprevir/ pibrentasvir, a combination medicine used to treat hepatitis C infection
- if you are taking medicines to prevent blood clotting (e.g. warfarin, rivaroxaban, apixaban or heparin), except when changing anticoagulant treatment, while having a venous or arterial line and you get heparin through this line to keep it open or while your heart beat is being restored to normal by a procedure called catheter ablation for atrial fibrillation
- if you have a prosthetic heart valve.

Do not start Dabigatran Sandoz and verapamil treatment at the same time.

Do not start verapamil if you are currently taking Dabigatran Sandoz and have just undergone major orthopaedic surgery.

Do not give this medicine to a child or adolescent under 18 years old.

Do not take this medicine after the expiry date printed on the box or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal. If you use this medicine after the expiry date has passed, it may not work as well.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Check with your doctor if you:

- have any allergies to any other medicines or any other substances, such as foods, preservatives or dyes.
- are pregnant or intend to become pregnant.
- are breastfeeding or intend to breastfeed.
- have had a heart attack or if you have been diagnosed with conditions that increase the risk to develop a heart attack.
- have reduced liver function, life-threatening liver disease or increased liver enzymes.
- you know that you have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk of blood clots).

Tell your doctor if you have an increased bleeding risk, as could be the case in the following situations:

- if you are older than 75 years, your doctor may prescribe a lower dose of Dabigatran Sandoz
- if you know you have reduced kidney function, or you are suffering from dehydration (symptoms include feeling thirsty and passing reduced amounts of dark-coloured urine)
- if you have been recently bleeding
- if you have any problems with your blood
- if you have had a recent tissue sampling (biopsy)
- if you have cancer
- if you have had a serious injury (e.g. a bone fracture, head injury or any injury requiring treatment)
- if you are suffering from an inflammation of the food pipe (oesophagus) or stomach
- if you have problems with reflux of gastric juice into the food pipe (oesophagus)
- if you are receiving medicines which could increase the risk of bleeding, such as clopidogrel and warfarin
- if you are taking anti-inflammatory medicines such as diclofenac
- if you are suffering from an infection of the heart (bacterial endocarditis).

If you have not told your doctor about any of the above, tell them before you use Dabigatran Sandoz.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

The active ingredient in Dabigatran Sandoz passes into breast milk.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Dabigatran Sandoz and affect how it works.

Medicines that may increase the effect of Dabigatran Sandoz include:

- aspirin, salicylates or other NSAID (anti-inflammatory) medicines
- medicines used to thin your blood (such as warfarin, unfractionated heparins, heparin derivatives (fondaparinux and desirudin), low molecular weight heparins (enoxaparin), clopidogrel, tirofiban, bivalirudin, prasugrel, ticagrelor, eptifibatide, ticlopidine, dextran, sulfinpyrazone, rivaroxaban and apixaban)
- amiodarone, dronedarone, medicines used to treat irregular heartbeats
- verapamil, a calcium channel blocker used to treat high blood pressure and angina
- quinidine, a medicine used to treat malaria and irregular heartbeats
- clarithromycin, medicines used to treat infections
- lopinavir, nelfinavir, ritonavir, tipranavir or saquinavir, medicines used to treat HIV infections
- ciclosporin or tacrolimus, medicines used to help the body's immune system
- glecaprevir/pibrentasvir, a combination medicine used to treat hepatitis C infection
- selective serotonin re-uptake inhibitors (SSRI) (e.g. citalopram, escitalopram, fluoxetine), selective serotonin norepinephrine re-uptake inhibitors (SNRI) (e.g. duloxetine, venlafaxine, desvenlafaxine), medicines used to treat mood disorders

Medicines that may reduce the effect of Dabigatran Sandoz include:

- herbal medicines derived from St John's wort (*Hypericum perforatum*)
- carbamazepine, a medicine used to treat fits or convulsions
- rifampicin, medicine used to treat infections
- medicines used to treat reflux and stomach ulcers (such as pantoprazole and ranitidine).

These medicines may be affected by Dabigatran Sandoz or may affect how well it works. You may need different amounts of your medicines, change the timing of your medicine-taking routine or take different medicines. Your doctor or pharmacist will advise you.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking Dabigatran Sandoz.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Dabigatran Sandoz.

4. How do I use Dabigatran Sandoz?

How much to take

- **Follow the instructions provided to you by your doctor or pharmacist carefully.**
They may differ from the information contained in this leaflet.
- **If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

AFTER KNEE AND HIP REPLACEMENT SURGERY

- The recommended dose of Dabigatran Sandoz is 220 mg (2 capsules of 110 mg) taken as a single dose once daily.
- Patients with moderately reduced kidney function (e.g. over 75 years) or patients taking certain medicines may have an increased risk of bleeding. The doctor may prescribe the lower dose of 150 mg once daily, taken as 2 capsules of Dabigatran Sandoz 75 mg.
- Treatment with Dabigatran Sandoz should be started within 1 - 4 hours of completed surgery, using a single capsule of 110 mg and continuing with 2 capsules of 110 mg once daily for a total of 10 days (after knee replacement surgery) or for a total of 28 - 35 days (after hip replacement surgery).
- If, within 4 hours after surgery, post-operative bleedings can still be observed, initiation of treatment should be delayed. If treatment is not started on the day of surgery then treatment should be initiated with 2 capsules of 110 mg once daily.

Follow the initiation instructions given to you by your doctor carefully.

FOR STROKE PREVENTION IN PATIENTS WITH ATRIAL FIBRILLATION

- The recommended dose of Dabigatran Sandoz is 300 mg taken as 1 capsule of 150 mg in the morning and 1 capsule of 150 mg in the evening.
- Patients over 75 years should take a lower dose of 220 mg, taken as 1 capsule of 110 mg in the morning and 1 capsule of 110 mg in the evening.
- Patients with an increased risk of major bleeding (as determined by your doctor) should take a lower dose of 220 mg, taken as 1 capsule of 110 mg in the morning and 1 capsule of 110 mg in the evening.

FOR THE TREATMENT OF BLOOD CLOTS AND PREVENTION OF BLOOD CLOTS RE-OCCURRING IN THE VEINS OF YOUR LEGS AND/OR LUNGS

- The recommended dose of Dabigatran Sandoz is 300 mg taken as 1 capsule of 150 mg twice a day following

treatment with an injectable blood thinner for at least 5 days. To prevent blood clots re-occurring, continue on 1 capsule of 150 mg twice a day.

- Patients over 75 years should take a lower dose of 220 mg, taken as 1 capsule of 110 mg in the morning and 1 capsule of 110 mg in the evening. To prevent blood clots re-occurring, continue on 1 capsule of 110 mg twice a day.
- Patients with an increased risk of major bleeding (as determined by your doctor) should take a lower dose of 220 mg, taken as 1 capsule of 110 mg in the morning and 1 capsule of 110 mg in the evening. To prevent blood clots re-occurring, continue on 1 capsule of 110 mg twice a day.

Your doctor will decide how long you need to be on this treatment for.

When to take Dabigatran Sandoz

Take Dabigatran Sandoz at about the same time each day.

Taking your capsules at the same time each day will have the best effect. It will also help you remember when to take it. It does not matter if you take this medicine with or without food.

How to take Dabigatran Sandoz

- **Swallow the capsules whole with a full glass of water.**
- **Do not chew or open the capsule. Do not sprinkle the pellets on food or mix with liquids.**
This may cause an overdose of Dabigatran Sandoz and increase the risk of bleeding.

How long to take Dabigatran Sandoz

Continue taking your medicine for as long as your doctor tells you.

Dabigatran Sandoz will continue to be prescribed while there is a risk of excessive clotting.

AFTER KNEE REPLACEMENT SURGERY:

- This will usually be for a period of 10 days.

AFTER HIP REPLACEMENT SURGERY:

- This will usually be for a period of 28 - 35 days.

It is important to keep taking your medicine even if you feel well.

If you stop using Dabigatran Sandoz before your doctor tells you to stop, you are at risk of developing a blood clot in a vein of your leg which can move to the lungs and be life-threatening.

Tell your doctor immediately or go to Emergency at your nearest hospital if you notice swelling of the leg or cough and shortness of breath.

These could be signs of a blood clot.

Tell your doctor if you intend stopping treatment earlier.

FOR STROKE PREVENTION IN PATIENTS WITH ATRIAL FIBRILLATION:

- It is important to keep taking your medicine even if you feel well.
- If you stop using Dabigatran Sandoz before your doctor tells you to stop, you are at risk of developing a blood clot. This can lead to serious health problems such as strokes.

FOR TREATMENT AND PREVENTION OF BLOOD CLOTS RE-OCCURRING IN THE VEINS OF YOUR LEGS AND LUNGS:

- It is important to keep taking your medicine even if you feel well.
- If you stop using Dabigatran Sandoz before your doctor tells you to stop, you are at risk of developing a blood clot. This can lead to serious health problems if those clots stop blood flowing normally.

If you forget to take Dabigatran Sandoz

After knee and hip replacement surgery continue with your remaining daily doses of Dabigatran Sandoz at the same time of the next day.

Do not take a double dose to make up for the dose you missed.

For stroke prevention in patients with atrial fibrillation a forgotten dose of Dabigatran Sandoz can still be taken up to 6 hours prior to the next dose.

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

Do not take a double dose to make up for missed individual doses.

For the treatment and prevention of blood clots re-occurring in the veins of your legs and lungs a forgotten dose of Dabigatran Sandoz can still be taken up to 6 hours prior to the next dose.

A missed dose should be omitted if the remaining time is less than 6 hours prior to the next dose. **Do not take a double dose to make up for missed individual doses.**

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you use too much Dabigatran Sandoz

If you think that you have used too much Dabigatran Sandoz, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

If you take too much Dabigatran Sandoz you may have bleeding. Blood may be seen in stools or urine. Abnormal bruising may also be experienced.

5. What should I know while using Dabigatran Sandoz?

Things you should do

- **Tell your doctor if, for any reason, you have not used Dabigatran Sandoz exactly as prescribed.**
Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.
- **If you become pregnant while using Dabigatran Sandoz, tell your doctor immediately.**
- **If you are going to have surgery, including dental surgery, tell your doctor or dentist that you are taking Dabigatran Sandoz.**
Your doctor may decide to temporarily stop your treatment with Dabigatran Sandoz.
- **Tell your doctor if you fall or injure yourself during treatment, especially if you hit your head, please seek urgent medical attention.**
You may need to be checked by a doctor, as you may be at increased risk of bleeding.

Remind any doctor, dentist or pharmacist you visit that you are using Dabigatran Sandoz.

Things you should not do

- Do not give Dabigatran Sandoz to anyone else, even if they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Dabigatran Sandoz affects you.

No studies on the effects of Dabigatran Sandoz on the ability to drive and operate machinery have been performed.

Driving or operating machinery should be avoided for a period of time after orthopaedic surgery.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Keep your capsules in the blister pack until it is time to take them.

If you take them out of the blister pack they may not keep well.

Keep Dabigatran Sandoz in a cool dry place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Bleeding related <ul style="list-style-type: none"> • bruising • nose bleeds 	Speak to your doctor if you have any of these less serious side effects and they worry you. They are generally mild and do not cause patients to stop taking Dabigatran Sandoz.
Gastrointestinal/ Gut related <ul style="list-style-type: none"> • stomach ache • diarrhoea • indigestion • feeling sick • discomfort when swallowing 	
Infection related <ul style="list-style-type: none"> • sore nasal passages and throat • frequent infections such as fever, severe chills, sore throat or mouth ulcers (signs of lack of white blood cells). 	
Lungs related <ul style="list-style-type: none"> • cough 	
Skin related <ul style="list-style-type: none"> • hair loss • itchy skin, rash 	
Musculoskeletal related <ul style="list-style-type: none"> • painful, swollen joints 	

Serious side effects

Serious side effects	What to do
Bleeding related <ul style="list-style-type: none"> • long or excessive bleeding • red or dark brown urine • red or black bowel motions. 	Call your doctor straight away, or go straight to the Emergency

<ul style="list-style-type: none"> • tiredness, headaches, dizziness and looking pale (signs of anaemia) • symptoms related to a condition called anticoagulant-related nephropathy: blood in urine, reduced urine output, swelling of the legs, ankles and feet, increased time for blood to clot (high INR test values), heavy bleeding. 	Department at your nearest hospital if you notice any of these serious side effects.
General disorders <ul style="list-style-type: none"> • exceptional weakness • chest pain or being short of breath 	
Musculoskeletal related <ul style="list-style-type: none"> • swelling of hands, ankles and feet 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Dabigatran Sandoz contains

Active ingredient (main ingredient)	dabigatran etexilate mesilate
Other ingredients (inactive ingredients)	Capsule fill <ul style="list-style-type: none"> • tartaric acid • hypromellose • purified talc • hypromellose • croscarmellose sodium • magnesium stearate Capsule shell <ul style="list-style-type: none"> • titanium dioxide • hypromellose

Do not take this medicine if you are allergic to any of these ingredients.

What Dabigatran Sandoz looks like

- AUST R 380831 Dabigatran Sandoz 75 mg - white-coloured, opaque cap and body size 2 filled with yellowish pellets, cap imprinted “MD” and body with “75”
- AUST R 380833 Dabigatran Sandoz 110 mg - white-coloured, opaque body size 1 and cap, body filled with yellowish pellets, cap imprinted “MD” and body with “110”
- AUST R 373066 Dabigatran Sandoz 150 mg – white-coloured, opaque cap and body size 0 filled with yellowish pellets, cap imprinted “MD” and body with “150”

Available in blister packs of 10 and 60 capsules.*

*Not all pack size may be marketed

Who distributes Dabigatran Sandoz

Sandoz Pty Ltd

ABN 60 075 449 553

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Macquarie Park, NSW 2113

Tel: 1800 726 369

This leaflet was revised in September 2023.