Apexa®

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 APEXA?

APEXA contains the active ingredient apixaban. APEXA is used to treat various conditions.

For more information, see Section 1. Why am I using APEXA? in the full CMI.

2. What should I know before I use APEXA?

Do not use if you have ever had an allergic reaction to apixaban 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 APEXA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APEXA 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 APEXA?

- Your doctor will tell you how many tablets you need to take each day.
- Swallow the tablet(s) whole with a full glass of water.

More instructions can be found in Section 4. How do I use APEXA? in the full CMI.

5. What should I know while using APEXA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using apixaban. • APEXA should be temporarily stopped before surgery. Tell your surgeon, doctor or dentist that you are using apixaban if you are going to have any surgery or procedure. Your doctor will tell you when to stop and restart taking APEXA after your surgery or procedure. • Tell your doctor immediately if you become pregnant while taking this medicine.
Things you should not do	• Do not stop using this medicine suddenly or lower the dosage without first checking with your doctor.
Driving or using machines	• APEXA is not expected to affect your ability to drive a car or operate machinery; however, use caution when performing these activities and notify your doctor if you notice any changes to your ability.
Looking after your medicine	• Store it in a cool dry place away from moisture, heat or sunlight. • Keep your tablets in the pack until it is time to take them.

For more information, see Section 5. What should I know while using APEXA? in the full CMI.

6. Are there any side effects?

Like all medicines, APEXA can cause side effects. Your doctor will discuss potential side effects with you and will explain the risks and benefits of your treatment. Some side effects can be serious and you may require medical attention. Contact your doctor immediately or go to the Emergency Department at your nearest hospital if you have any signs or symptoms (changes to your normal self), particularly if they are getting worse or do not go away.

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.

APEXA®

Active ingredient(s): *apixaban* (a pix' a ban)

Consumer Medicine Information (CMI)

This leaflet provides important information about using APEXA. **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 APEXA.**

Where to find information in this leaflet:

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

1. Why am I using APEXA?

APEXA contains the active ingredient apixaban.
APEXA belongs to a group of medicines called antithrombotic agents. It works by inhibiting a blood clot forming substance called Factor Xa.

APEXA is used to:

- prevent blood clots in your veins after a hip or knee replacement surgery.

  After an operation you are at an increased risk of getting blood clots.
- treat blood clots occurring in deep veins (Deep Vein Thrombosis [DVT]) and clots in your lungs (Pulmonary Embolism [PE]) and also to prevent these from recurring.
- prevent stroke and blood clots in a condition called atrial fibrillation, which is a type of abnormal heart rhythm.

  With atrial fibrillation, part of the heart does not beat the way it should. This can lead to blood clots forming and increase your risk of having a stroke.

2. What should I know before I use APEXA?

Warnings

Do not use APEXA if:

- you are allergic to apixaban, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

Do not use APEXA if you have, or have had, any of the following medical conditions:

- any disease or injury to a body organ that is actively bleeding or at high risk of bleeding e.g. bleeding ulcer in the stomach or bowel, recent bleeding in the brain,cancer at high risk of bleeding
- liver disease which leads to an increased risk of bleeding
- severely reduced kidney function. Your doctor will determine your kidney function
- a recent operation on the brain, spinal column or eye(s)
- recent brain or spine injury
- abnormalities of any blood vessels that may lead to an increase in bleeding
- any blood vessel abnormalities of your oesophagus or "gullet"
- any disease or injury to a body organ that could lead to significant bleeding e.g. stomach ulcers, bowel ulcers.

Do not use APEXA if you are taking the following medicines:

- medicines for fungal infections e.g. ketoconazole, itraconazole, voriconazole or posaconazole, unless they are only applied to the skin
- anti-viral medicines for HIV/AIDS e.g. ritonavir
- other medicines to stop your blood from clotting e.g. heparin, enoxaparin, warfarin, rivaroxaban or dabigatran.

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

Check with your doctor if you:

- have allergies to any other medicines, foods, preservatives or dyes.
- have ever been hospitalised for a heart condition (heart attack or unstable angina).
- have ever received a stent placed in the coronary arteries of your heart.
- are 75 years or older or if you have or have had any of the following medical conditions which may lead to an increased risk of bleeding:
  - a heart condition known as bacterial endocarditis
  - type of stroke called "haemorrhagic stroke"
  - blood disorders that affect your ability to form clots and stop bleeding
  - recent or past ulcer of your stomach or bowel
  - moderate or mild kidney disease
  - liver disease
  - have a lung condition called bronchiectasis
  - have had a history of bleeding in your lungs
  - high blood pressure that is not controlled with medications.

  Your doctor may decide to keep you under closer observation.

Tell your doctor if you:

- have a prosthetic heart valve or severe rheumatic heart disease, especially mitral stenosis (problem with the mitral valve in your heart).
- know that you have a disease called antiphospholipid syndrome (a disorder of the immune system that causes an increased risk of blood clots).

  Your doctor who will decide if the treatment may need to be changed.

- are having hip or knee replacement surgery and your operation involves a catheter or injection into your spinal column e.g. for epidural or spinal anaesthesia or pain reduction:

  Tell your doctor immediately if you get numbness or weakness of your legs or problems with your bowel or bladder after the end of anaesthesia, because urgent care is necessary.

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

Check with your doctor if you are pregnant or intend to become pregnant.

APEXA is not recommended for use in pregnant women. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

APEXA is not recommended during breastfeeding. You should not breastfeed and take APEXA at the same time. The active ingredient in APEXA may be present in breast milk and poses a bleeding risk to the baby. You and your doctor should decide if you will take APEXA or breastfeed.

If you have not told your doctor about any of the above, tell him/her before you start taking APEXA.

Use in Children

There is not enough information to recommend the use of this medicine in children and adolescents under the age of 18 years.

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 be affected by Apexa or may affect how it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor will advise you.

Tell your doctor or pharmacist if you are taking any of the following:

- medicines used to treat fungal infections such as ketoconazole, itraconazole, voriconazole and posaconazole
- anti-viral medicines for HIV/AIDS e.g. ritonavir
- rifampin or rifampicin
- medicines to treat epilepsy such as phenytoin, carbamazepine, phenobarbitone
- St John's wort
- medicines to treat depression such as sertraline, citalopram and venlafaxine
- medicines used to treat pain and inflammation including non-steroidal anti-inflammatory drugs (NSAIDs) such as naproxen or aspirin
- other medicines used to prevent blood clots such as enoxaparin, clopidogrel, ticagrelor, prasugrel, heparin, fondaparinux, bivalirudin, rivaroxaban, dabigatran, dipyridamole
- quinidine
- verapamil
- diltiazem
- amiodarone
- the antibiotic, clarithromycin.

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

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

4. How do I use APEXA?

How much to use

Your doctor will tell you how many tablets you need to take each day.

If you are having hip or knee replacement surgery

The recommended dose is one 2.5 mg tablet taken twice a day.

If you have blood clots

The recommended dose to treat blood clots is two 5 mg tablets taken twice a day for 7 days, then one 5 mg tablet taken twice a day.

The recommended dose to prevent blood clots that recur is one 2.5 mg tablet taken twice daily.

If you have atrial fibrillation

The recommended dose is normally one 5 mg tablet taken twice a day.

The recommended dose is one 2.5 mg tablet taken twice a day if you meet any two of the following:

- are 80 years or older
- weigh 60 kilograms or under
- have reduced kidney function.

When to take / use APEXA

APEXA should be used as directed by your doctor.

If you are having hip or knee replacement surgery, it is usual to start taking your tablets 12 to 24 hours after your operation.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

How long to take APEXA

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

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, you may be at an increased risk of developing a blood clot, which can lead to serious problems such as a stroke if you have atrial fibrillation.

If you are having hip or knee replacement surgery

If you have had a hip replacement, you will usually take the tablets for about 5 weeks.

If you have had a knee replacement, you will usually take the tablets for about 2 weeks.

If you have blood clots

To treat blood clots, you will usually take the tablets for up to 6 months. If necessary, you may need to continue taking the tablets, usually at a lower dose, to prevent further blood clots.

If you have atrial fibrillation

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

If you require cardioversion

If your abnormal heartbeat needs to be restored by a procedure called cardioversion, take your medicine at the times your doctor tells you, to help prevent blood clots that may result in strokes or other problems.

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

How to take APEXA

Swallow the tablet(s) whole with a full glass of water.

If you are unable to swallow the tablet(s) whole, follow the steps below to crush the tablet(s). This will help make sure that all of the crushed tablet(s) will be taken.

- use a mortar and pestle or a similar device to crush the tablet(s)
- transfer the powder to a drinking glass or a small bowl
- when using water, 5% glucose in water or apple juice:
    - add a small amount of water/5% glucose in water/ apple juice (30 mL) to the mortar and pestle/device and stir
    - transfer the water/5% glucose in water/apple juice to the drinking glass
    - mix the powder with the water/5% glucose in water/ apple juice and drink right away
    - rinse the glass with a small amount of water/5% glucose in water/apple juice and drink right away.

If necessary, your doctor may also give you the crushed tablet(s) mixed in 60 mL of water or 5% glucose in water, through a nasogastric tube.

It does not matter if you take this medicine before or after food.

If you forget to use APEXA

APEXA should be used regularly at the same time each day. If you miss your dose at the usual time, take your next tablet as soon as you remember, then continue taking the tablets as normal (twice a day).

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

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

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

If you use too much APEXA

If you think that you or anyone else may have used too much APEXA, 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.

Symptoms of an overdose may include bleeding that does not stop.

If bleeding occurs, surgery, blood transfusions, or other treatments that may reverse apixaban may be required.

5. What should I know while using APEXA?

Things you should do

If you are about to be started on any new medicine, remind your doctor, dentist or pharmacist that you are taking APEXA.

If you are going to have any surgery or procedure, including dental surgery, tell your surgeon, doctor or dentist that you are taking this medicine.

APEXA should be temporarily stopped before surgery.

Your doctor will tell you when to stop using APEXA before your surgery or procedure.

Your doctor will also tell you when you can start taking APEXA after your surgery.

Tell your doctor that you are taking APEXA if your doctor is planning for you to have an anaesthetic injection in your back (spinal or epidural injection).

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Things you should not do

Do not stop using this medicine suddenly or lower the dosage without first checking with your doctor.

If you stop taking it suddenly, your condition may worsen, or you may have serious side effects.

Do not take APEXA to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Things to be careful of

APEXA contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking it.

Driving or using machines

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

This medicine is not expected to affect your ability to drive a car or operate machinery.

Looking after your medicine

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

If you take the tablets out of the pack, they may not keep well.

Follow the instructions on 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 windowsills.

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. Heat and dampness can destroy some medicines.

Getting rid of any unwanted medicine

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

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

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.

It can be difficult to tell whether side effects are the result of taking APEXA, effects of your condition or side effects of other medicines you may be taking. For this reason it is important to tell your doctor of any change in your condition.

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

Serious side effects

Serious side effects	What to do
Bleeding: • bleeding from your nose • if you have dark brown urine or blood in your urine • if you cough up blood • if you vomit and it is black • if you have black stools or blood in your stools • excessive bleeding or prolonged bleeding. It is important to contact your doctor immediately if you experience excessive or prolonged bleeding.	**Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**
Allergic reaction (if you have an allergic reaction to Pharmacor Apixaben): • shortness of breath • wheezing or difficulty breathing • swelling of the face, lips, tongue or other parts of the body • rash, itching or hives on the skin. **The following symptoms may be 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 **Others** • stomach swelling, yellowing of the skin or whites of the eyes (due to liver problems) • oozing from your surgical wound • swelling of the hands, ankles or feet due to water retention.	

Other side effects

Common side effects	What to do
• tiredness, weakness, paleness, dizziness, light-headedness, headache - which can be due to low iron in the blood • bleeding from any part of your body, no matter how minor, as these may be difficult to control • bruising • nausea (feeling sick), vomiting • diarrhoea or constipation • fever • sore nasal passages and throat • frequent need to urinate or pain while urinating • coughing.	**Speak to your doctor if you have any of these side effects and they worry you.**

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.

Some of the other possible side effects (for example, changes in liver or kidney function) can only be found when your doctor does tests from time to time to check your progress.

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 doctors prescription

What Apexa contains

Active ingredient (main ingredient)	apixaban
Other ingredients (inactive ingredients)	lactose monohydrate microcrystalline cellulose croscarmellose sodium sodium lauryl sulfate magnesium stearate titanium dioxide glycerol triacetate yellow iron oxide (2.5mg tablets) red iron oxide (5mg tablets)

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

This medicine does not contain sucrose, gluten, tartrazine or any other azo dyes.

What APEXA looks like

APEXA 2.5 mg tablets are yellow and round with "2 1/2" on one side and plain on the other.

Packed in 2 pack configurations:

• Cartons containing PVC/PVDC/Al blisters of 10, 14, 20, 30, 60, 100 film-coated tablets. (AUSTR 451769)

• HDPE bottle containing 30, 60, 100 film-coated tablets. (AUSTR 451772)

APEXA 5 mg tablets are pink and oval-shaped with "5" on one side and plain on the other.

Packed in 2 pack configurations:

• Cartons containing PVC/PVDC/Al blisters of 10, 14, 20, 28, 56, 60, 112, 120 or 168 film-coated tablets (AUSTR 439710).

• HDPE bottle containing 30, 56, 60, 100, 112, 120 or 168 film-coated tablets. (AUSTR 451766)

Who distributes APEXA

Sponsored and Supplied by:

Pharmacor Pty. Ltd.
821 Pacific Highway, Chatswood NSW 2067
Australia

www.pharmacor.com.au

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