

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.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I receiving ANDEXXA?

ANDEXXA contains the active ingredient andexanet alfa. ANDEXXA is used to reverse the effects of certain blood thinning medications called factor Xa inhibitors (apixaban or rivaroxaban) in case of a life-threatening or uncontrolled bleeding situation.

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

2. What should I know before I am given ANDEXXA?

Do not use if you have ever had an allergic reaction to ANDEXXA 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 am given ANDEXXA?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor or nurse if you are taking, have recently taken, or might take any other medicines.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How will I be given ANDEXXA?

- ANDEXXA will be given to you in a hospital or clinic by a doctor or nurse.

More instructions can be found in Section [4. How will I be given ANDEXXA?](#) in the full CMI.

5. What should I know while receiving ANDEXXA?

Things you should do	<ul style="list-style-type: none">• Tell your doctor if surgery is planned for you which requires treatment with heparin.• Tell your doctor if any urgent surgery is planned for you.
Looking after your medicine	<ul style="list-style-type: none">• ANDEXXA will be stored by your healthcare providers at the hospital or clinic where you receive treatment.

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

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. The most common side effects are sweating or chills (fever) and feeling hot (flushing). The more serious side effects are sudden numbness or weakness in the face, arm, or leg, especially on one side of the body (stroke), pressure, tightness, pain, or a squeezing or aching sensation in your chest or arms that may spread to your neck, jaw or back (heart-attack), rapid or irregular heartbeat, loss of consciousness or unresponsiveness (cardiac arrest), swelling, change in skin colour, trouble breathing (blood clot in the leg, arm, or lung)

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.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ANDEXXA®

Active ingredient(s): andexanet alfa

This medicine has **provisional approval** in Australia for adult patients treated with a direct factor Xa (FXa) inhibitors apixaban or rivaroxaban when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding. The decision to approve this medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. Why am I receiving ANDEXXA?](#)
- [2. What should I know before I am given ANDEXXA?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given ANDEXXA?](#)
- [5. What should I know while receiving ANDEXXA?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I receiving ANDEXXA?

ANDEXXA contains the active ingredient andexanet alfa. ANDEXXA is factor Xa (FXa) decoy molecule that binds to certain blood thinning medications called FXa inhibitors (apixaban or rivaroxaban).

ANDEXXA is used to reverse the effects of certain FXa inhibitors (apixaban or rivaroxaban).

FXa inhibitors are given to prevent clots in your blood vessels. Your doctor may decide to give you ANDEXXA to rapidly reverse the effects of these blood thinning medications in case of a life-threatening or uncontrolled bleeding situation.

2. What should I know before I am given ANDEXXA?

Warnings

Do not use ANDEXXA if:

- you are allergic to andexanet alfa or any of the ingredients listed at the end of this leaflet

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other condition
- have surgery planned for you which requires treatment with heparin
- have any urgent surgery planned for you

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

ANDEXXA is not recommended during pregnancy or if you have the potential to become pregnant and are not using contraception. It is not known if ANDEXXA can harm your unborn baby.

Do not breast-feed your child while you are taking ANDEXXA. It is not known whether ANDEXXA is passed into breast milk.

Children and adolescents

There is no information on the use of ANDEXXA in children and adolescents under 18 years of age.

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.

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

4. How will I be given ANDEXXA?

ANDEXXA will be given to you in a hospital or clinic

- Your doctor or nurse will give you ANDEXXA by injection or infusion into a vein
- Your doctor will decide how much ANDEXXA you need to take. This is based on the type and dose of blood thinning medication you take, as well as the time since your last dose of blood thinning medication
- After you have received ANDEXXA, your doctor will decide when to restart your blood thinning medication

If you stop taking ANDEXXA

- Do not stop treatment with ANDEXXA unless you have discussed this with your doctor
- If you have any further questions about your treatment, ask your doctor

5. What should I know while receiving ANDEXXA?

Things you should do

- Tell your doctor if surgery is planned for you which requires treatment with heparin
- Tell your doctor if any urgent surgery is planned for you

Tell your doctor if any urgent surgery is planned for you
Call your doctor straight away if you:

- have a serious allergic reaction to ANDEXXA. Symptoms may include swelling of your face, tongue or mouth, breathing difficulties, feeling faint, dizzy or lightheaded

Things you should not do

- Do not stop taking this medicine suddenly, unless you have discussed this with your doctor

Driving or using machines

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

ANDEXXA is not expected to affect your ability to drive or use any machines or tools. Be careful if you feel tired, dizzy, or have a headache.

Looking after your medicine

ANDEXXA will be stored by your healthcare providers at the hospital or clinic where you receive treatment.

Unopened vials should be stored refrigerated at 2°C to 8°C. Do not freeze. Protect from light.

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
<ul style="list-style-type: none">• Sweating or chills (fever)• feeling hot (flushing)	Speak to your doctor if you have any of these less serious side effects and they worry you.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• sudden numbness or weakness in the face, arm, or leg, especially on one side of the body (stroke)• pressure, tightness, pain, or a squeezing or aching sensation in your chest or arms that may spread to your neck, jaw or back (heart-attack)• rapid or irregular heartbeat, loss of consciousness or unresponsiveness (cardiac arrest)• swelling, change in skin colour, trouble breathing (blood clot in the leg, arm, or lung)	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.

The above list includes serious side effects that require medical attention or hospitalisation.

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 ANDEXXA contains

Active ingredient (main ingredient)	andexanet alfa
Other ingredients (inactive ingredients)	Trometamol, trometamol hydrochloride, arginine hydrochloride, sucrose, mannitol, and polysorbate 80

You should not receive this medicine if you are allergic to any of these ingredients.

What ANDEXXA looks like

ANDEXXA (AUST R 388713) is a white to off-white powder supplied in a clear glass vial closed by a rubber stopper. There are 4 or 5 vials in each pack.

Who distributes ANDEXXA

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
Macquarie Park NSW 2113
Telephone: 1800 805 342

This leaflet was prepared in January 2024.

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