ANDEXXA®

Active ingredient(s): andexanet alfa

Consumer Medicine Information

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.

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?