Package Leaflet: Information for the patient and user

Ondexxya® 200 mg powder for solution for infusion
andexanet alfa

▼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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully, because it contains important information for you. Please note this medicine is mainly used in emergency situations, and the doctor will have decided that you needed it.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Ondexxya is and what it is used for
2. What you need to know before you receive Ondexxya
3. How Ondexxya is used
4. Possible side effects
5. How Ondexxya is stored
6. Contents of the pack and other information

1. What Ondexxya is and what it is used for

Ondexxya contains the active ingredient andexanet alfa. It reverses the effects of certain anticoagulants called factor Xa inhibitors (apixaban or rivaroxaban). Factor Xa inhibitors are given to prevent clots in your blood vessels. Your doctor may decide to give you Ondexxya to rapidly reverse the effects of the anticoagulant in case of a life-threatening or uncontrolled bleeding situation.

2. What you need to know before you receive Ondexxya

Do not use Ondexxya:
- if you are allergic to andexanet alfa or any of the other ingredients of this medicine (listed in section 6).
- if you are allergic to hamster proteins
- if you are receiving heparin

Warnings and precautions
Reversing the effect of a factor Xa inhibitor with Ondexxya may increase the risk of blood clots. After treatment with Ondexxya, your doctor will decide when to restart anticoagulant therapy.

An independent pro-coagulant effect of andexanet alfa may pose an additional risk of developing thrombosis.

If you suffer side effects when you are being given Ondexxya by infusion (drip), your doctor may decide to slow down or pause your treatment. Your doctor may give you an antihistamine medicine to help with any side effects (see section 4).

If a surgery is planned for you which requires anticoagulation with heparin, Ondexxya should be

avoided.

Children and adolescents
There is no information on the use of Ondexxya in children and adolescents.

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

This medicine has been designed to reverse the effects of factor Xa inhibitor medicines only. It is unlikely that Ondexxya will influence the effect of other medicines or that other medicines will influence Ondexxya.

Ondexxya-treatment should be avoided if anticoagulation with heparin might become necessary. Ondexxya causes unresponsiveness to heparin.

Pregnancy and breast-feeding
Tell your doctor if you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby.

Ondexxya is not recommended during pregnancy or if you have the potential to become pregnant and are not using birth control.

Do not breast-feed your child while you are taking this medicine. It is unknown if andexanet alfa is excreted in human milk.

Driving and using machines
This medicine is unlikely to affect your ability to drive and use machines.

3. How Ondexxya is used

This medicine is for hospital use only.

Your doctor or nurse will give you this medicine by injection or infusion into a vein.

Your doctor or nurse will work out the dose of this medicine that you need. This is based on the specific anticoagulant medicine you take as well as on the dose and the time since your last dose of anticoagulant medicine.

After you have received Ondexxya, your doctor will decide when to restart your anticoagulant treatment.

Detailed instructions for your doctor or nurse on how to give Ondexxya are given at the end of this package leaflet (see ‘Handling instructions’).

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

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

List of side effects seen in bleeding people

Common (may affect up to 1 in 10 people)
- Stroke

- Heart-attack
- Blood clot in the leg, arm, lung or brain
- Fever

Uncommon (may affect up to 1 in 100 people)
- Mini stroke
- Cardiac arrest
- Signs/symptoms of infusion related reactions such as chills, high blood pressure, shortness of breath, confusion or agitation.

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system below: Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How Ondexxya is stored

This medicine will be stored in the hospital, and these instructions are intended for hospital staff only.

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 vial and the carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C).

Do not freeze.

Once reconstituted, Ondexxya is for immediate use.

6. Contents of the pack and other information

What Ondexxya contains
- The active substance is andexanet alfa.
- The other ingredients are Tris base, Tris hydrochloride, L-arginine hydrochloride, sucrose, mannitol, and polysorbate 80.

What Ondexxya looks like and contents of the pack
Ondexxya is supplied in glass vials as a white to off-white powder for solution for infusion, which is reconstituted (dissolved) before use. The reconstituted solution is a clear, colourless, or slightly yellow solution.

Each pack contains four or five vials.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

AstraZeneca UK Limited,
1 Francis Crick Avenue
Cambridge
CB2 0AA

UK

Manufacturer

Alexion Pharma International Operations Limited
Alexion Dublin Manufacturing Facility
College Business and Technology Park
Blanchardstown Rd North
Dublin D15 R925
Ireland

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Other sources of information

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:

0800 198 5000

Please be ready to give the following information:

Product name Ondexxya 200 mg powder for solution for infusion

Reference number 17901/0367

This is a service provided by the Royal National Institute of the Blind.

This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine.
The Medicines and Healthcare products Regulatory Agency (MHRA) will review new information on this medicine at least every year and this leaflet will be updated as necessary.