



## Medicine: andexanet alfa (brand name: Ondexxya®)

Portola Pharmaceuticals UK Ltd

The Scottish Medicines Consortium (SMC) has assessed andexanet alfa for reversing the effects of the anticoagulant medicines apixaban or rivaroxaban in adults who have uncontrolled or life threatening bleeding. This document summarises the SMC decision and what it means for patients.

### What has SMC said?

After careful consideration, SMC has accepted andexanet alfa on an interim basis (interim acceptance) for reversing the effects of anticoagulant medicines as described above. Interim acceptance is an option available to SMC for medicines which have received a conditional marketing authorisation or licence. This means that andexanet alfa is accepted for use subject to ongoing evaluation and reassessment once further evidence is available.

This advice takes into account a confidential discount offered by the pharmaceutical company that improves the cost-effectiveness of andexanet alfa.

### What does SMC's decision mean for patients?

The decision to accept andexanet alfa on an interim basis means that if your healthcare professional thinks that it is the right medicine for you, you should be able to have the treatment on the NHS in Scotland. Once further evidence is available, SMC will reassess the medicine and provide an updated decision on its routine availability in NHSScotland. For further information about the interim acceptance option please see:

<https://www.scottishmedicines.org.uk/how-we-decide/interim-acceptance-decision-option/>



### What is andexanet alfa used for?

Andexanet alfa is used in adults being treated with the anticoagulant medicines rivaroxaban or apixaban (medicines that help to prevent the blood clotting). It is used to reverse the anticoagulant effects when the adult is suffering from uncontrolled or life threatening bleeding

### How does andexanet alfa work?

Rivaroxaban and apixaban are anticoagulant medicines that block a protein (called Factor Xa) in blood that helps blood to clot. Andexanet alfa binds to these anticoagulant medicines and stops

them blocking Factor Xa. This helps to stop any excessive bleeding caused by the anticoagulant medicines.

## How does SMC make its decision?

SMC carefully considers every new medicine to make sure it benefits patients and is considered to be an acceptable use of the limited resources in NHSScotland.

To do this SMC consider the following:

- Evidence from the company about how well the medicine works compared with current treatments available in Scotland, in relation to how much they will cost to buy and administer.
- The potential impact of the medicine on patients and carers.
- Advice from healthcare professionals about any benefits of the new medicine compared to current treatment, along with how the new medicine is likely to be used.

When SMC assesses a medicine it takes account of the needs of all patients in NHSScotland, not just those who may be treated with the medicine under consideration.

You can find more detailed information about the SMC assessment of andexanet alfa by looking at the SMC Detailed Advice Document (SMC2273).

## More information

The organisations below can provide more information and support for people who take anticoagulant medicines and their families. SMC is not responsible for the content of any information provided by external organisations.

### Anticoagulation UK

 <https://www.anticoagulationuk.org>

### Chest Heart and Stroke Scotland

 <https://www.chss.org.uk>

 0808 801 0899

### Pumping Marvellous Foundation

 <https://www.pumpingmarvellous.org>

 01772 796542

### Thrombosis UK

 <http://www.thrombosisuk.org>

 0300 772 9603

You can find out more about andexanet alfa (Ondexxya®) in the European public assessment report (EPAR) summary for the public by searching for the medicine name on the European Medicines Agency (EMA) website.

 <http://www.ema.europa.eu>