

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

 **ONDEXXYA®**

andexanet alfa for injection

Read this carefully before you start taking **ONDEXXYA**. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ONDEXXYA**.

Serious Warnings and Precautions

- Treatment with ONDEXXYA has been associated with serious and life-threatening adverse events, including:
 - Formation of blood clots in your veins or arteries which could lead to a heart attack or stroke
 - Cardiac arrest (heart suddenly stops pumping blood)
- Blood thinners such as FXa inhibitors apixaban and rivaroxaban help prevent clots in your blood vessels. In case of a life-threatening or uncontrolled bleeding, ONDEXXYA is used to reverse the blood thinning effects of apixaban and rivaroxaban which may lead to an increased risk of blood clot formation. To reduce this risk, your physician will restart your blood thinner as soon as medically appropriate.

What is ONDEXXYA used for?

ONDEXXYA reverses the effects of certain drugs (apixaban and rivaroxaban) called Factor Xa inhibitors. Factor Xa inhibitors are blood thinners that are used to prevent clots in your blood vessels. ONDEXXYA is for use in adult patients. Your doctor may decide to give you ONDEXXYA to rapidly reverse the effects of the blood thinners in case of a life-threatening or uncontrolled bleed.

For the following indication ONDEXXYA has been approved with conditions (NOC/c). This means it has passed Health Canada's review and can be bought and sold in Canada, but the manufacturer has agreed to complete more studies to make sure the drug works the way it should. For more information, talk to your healthcare professional.

- ONDEXXYA reverses the effects of certain drugs (apixaban and rivaroxaban) called Factor Xa inhibitors. Factor Xa inhibitors are anticoagulants, or blood thinners, given to prevent clots in your blood vessels. ONDEXXYA is to be used in adult patients who have bleeding that is life-threatening while they are taking rivaroxaban or apixaban.

What is a Notice of Compliance with Conditions (NOC/c)?

A Notice of Compliance with Conditions (NOC/c) is a type of approval to sell a drug in Canada.

Health Canada only gives an NOC/c to a drug that treats, prevents, or helps identify a serious or life-threatening illness. The drug must show promising proof that it works well, is of high quality, and is reasonably safe. Also, the drug must either respond to a serious medical need in Canada, or be much safer than existing treatments.

Drug makers must agree in writing to clearly state on the label that the drug was given an NOC/c, to complete more testing to make sure the drug works the way it should, to actively monitor the drug's performance after it has been sold, and to report their findings to Health Canada.

How does ONDEXXYA work?

ONDEXXYA contains the active ingredient andexanet alfa which is a specific type of protein that is an antidote for blood thinners called Factor Xa inhibitors (apixaban or rivaroxaban). ONDEXXYA rapidly binds to and reverses the effects of apixaban or rivaroxaban.

What are the ingredients in ONDEXXYA?

Medicinal ingredients: andexanet alfa

Non-medicinal ingredients: L-arginine hydrochloride, Mannitol, Polysorbate 80, Sucrose, Tris base (tromethamine), Tris hydrochloride.

ONDEXXYA comes in the following dosage form:

Vial containing 200 mg of andexanet alfa.

Do not use ONDEXXYA if:

- You are allergic to andexanet alfa or to any ingredients in ONDEXXYA. If you are not sure, talk to your healthcare professional before you are given ONDEXXYA.
- You are receiving heparin.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ONDEXXYA. Talk about any health conditions or problems you may have, including if you:

- Are planning to have surgery which requires blood thinning with heparin.
- Are pregnant, think you may be pregnant or are planning to have a baby.
- Are breast-feeding. It is not known if ONDEXXYA is excreted in human milk.

Other warnings you should know about:

- ONDEXXYA has not been shown to be effective for, and is not indicated for, the treatment of bleeding related to any FXa inhibitors other than apixaban and rivaroxaban.
- 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 you should start taking blood thinners again.
- If you experience side effects during the infusion of ONDEXXYA, your doctor may decide to slow down or pause the treatment. Your doctor may give other medicines to help with the side effects.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**The following may interact with ONDEXXYA:**

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

How to take ONDEXXYA:

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

Usual dose:

The dose of ONDEXXYA is based on the specific FXa inhibitor that you are taking (apixaban or rivaroxaban), the dose of FXa inhibitor, and the time since your last dose of FXa inhibitor.

- You will receive 2 doses: a dose of either 400 mg or 800 mg given at a rate of 30 mg/min followed by a continuous dose of 480 mg or 960 mg over 2 hours at a rate of 4 mg/min.

Overdose:

If you think you, or a person you are caring for, have taken too much ONDEXXYA, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

What are possible side effects from using ONDEXXYA?

These are not all the possible side effects you may have when taking ONDEXXYA. If you experience any side effects not listed here, tell your healthcare professional.

Common

- Flushing (redness, feeling hot)
- Cough
- Bad taste in mouth (dysgeusia)
- Shortness of breath (dyspnea)
- Fever (pyrexia)
- Headache

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
COMMON			
Stroke: - Sudden numbness or weakness in the face, arm, or leg, especially on one side of the body. - Sudden confusion, trouble speaking, or difficulty understanding speech. - Sudden trouble seeing in one or both eyes. - Sudden trouble walking, dizziness, loss of balance, or lack of coordination.		√	
Heart Attack: - Chest pain or discomfort. - Feeling weak, light-headed, or faint. - Pain or discomfort in the jaw, neck, back, in one or both arms or shoulders. - Shortness of breath.		√	
Blood clot in leg, arm, lung or brain: - Throbbing or cramping pain, swelling, redness and warmth in a leg or arm. - Sudden breathlessness, sharp chest pain (may be worse when you breathe in) and a cough or coughing up blood.		√	
RARE			
Mini stroke: Sudden numbness or weakness in the face, arm, or leg, especially on one side of the body.		√	

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
- Sudden confusion, trouble speaking, or difficulty understanding speech. - Sudden trouble seeing in one or both eyes. - Sudden trouble walking, dizziness, loss of balance, or lack of coordination.			
Cardiac arrest: - Chest pain or discomfort. - Heart palpitations. - Shortness of breath. - Sudden collapse. No pulse. No breathing.		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage of ONDEXXYA for Health Care professionals:

ONDEXXYA will be stored by the healthcare professionals at the hospital or clinic where you receive treatment.

Keep out of reach and sight of children.

If you want more information about ONDEXXYA:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: <https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>; the manufacturer's website: www.astrazeneca.ca, or by calling 1-800-668-6000.
- This Patient Medication Information is current at the time of printing. The most up-to-date version can be found at www.astrazeneca.ca.

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