03/2023

Ondexxya
אונדקסיה

ANDEXANET ALFA 200 MG/VIAL
Powder for Solution for Infusion

רופא/ה, רוקח/ת נכבד/ה,

חברת אלקסיון פארמה ישראל בע"מ מבקשת להודיע על עדכון העלון לרופא של התכשיר שבנדון.
העלון עודכן בתאריך 03/2023.

ההתוויה הרשומה לתכשיר בישראל:
For adult patients treated with a direct factor Xa (FXa) inhibitor (apixaban or rivaroxaban) whenreversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding

בהודעה זו מצוינים השינויים המהותיים בלבד.

מקראה לעדכונים המסומנים:
מידע שהוסר -מסומן בקו אדום חוצה ~~XXX~~
תוספת -כתב **כחול**

עדכונים מהותיים שנעשו בעלון לרופא:

4.8 Undesirable effects

Summary of the safety profile
The safety of andexanet alfa has been evaluated in clinical trials including ~~247~~ 417 healthy subjects administered an FXa inhibitor, as well as in 419 patients in a Phase IIIb/IV trial (study 14-505), who had acute major bleeding and were under treatment with an FXa inhibitor (apixaban and rivaroxaban).

In clinical studies in healthy subjects who were administered a FXa inhibitor and then received andexanet alfa, the frequency of adverse reactions was similar in the andexanet alfa-treated group (16.8%) and in the placebo treated group (12.2%). ~~In the clinical trials in healthy subjects administered an FXa inhibitor and then receiving andexanet alfa, no serious or severe adverse reactions were reported.~~ The most frequently observed adverse reactions were mild or moderate infusion-related reactions (see table 4) comprising symptoms such as flushing, feeling hot, cough, dysgeusia, and dyspnoea occurring within a few minutes to a few hours of the infusion. Among the healthy subjects studied, women experienced more adverse reactions (mainly infusion-related reactions) than men.

(…)

Tabulated list of adverse reactions

Table 4 provides the list of adverse reactions ~~from clinical studies in healthy subjects and~~ in patients with major bleeds from study 14-505 including 419 patients on apixaban and rivaroxaban with acute major bleeding treated with andexanet alfa. The adverse reactions are classified by system organ class (SOC) and frequency, using the following convention: very common (≥ 1/10); common (≥ 1/100 to < 1/10); uncommon (≥ 1/1,000 to < 1/100); rare (≥ 1/10,000 to < 1/1,000); very rare (< 1/10,000); or not known (cannot be estimated from available data).

Table 4: List of adverse reactions in ~~healthy volunteers and~~ patients with major bleeds

~~System organ class/ Preferred term~~	~~Frequency in healthy volunteers~~	~~Frequency in patients with major bleeds~~
~~Immune system disorders~~		
~~Urticaria~~	~~common~~	
~~Nervous system disorders~~		
~~Cerebral infarction~~		~~uncommon~~
~~Cerebrovascular accident~~		~~common~~
~~Dizziness postural~~	~~common~~	
~~Headache~~	~~common~~	
~~Ischaemic stroke~~		~~common~~
~~Transient ischaemic attack~~		~~uncommon~~
~~Cardiac disorders~~		
~~Acute myocardial infarction~~		~~common~~
~~Cardiac arrest~~		~~uncommon~~
~~Myocardial infarction~~		~~common~~
~~Palpitations~~	~~common~~	
~~Vascular disorders~~		
~~Deep vein thrombosis~~		~~common~~
~~Iliac artery occlusion~~		~~uncommon~~
~~Respiratory, thoracic and mediastinal disorders~~		
~~Cough~~	~~common~~	
~~Dyspnoea~~	~~common~~	
~~Pulmonary embolism~~		~~common~~
~~Gastrointestinal disorders~~		
~~Abdominal discomfort~~	~~common~~	
~~Abdominal pain~~	~~common~~	
~~Dry mouth~~	~~common~~	
~~Dysgeusia~~	~~common~~	
~~Nausea~~	~~common~~	
~~Skin and subcutaneous tissue disorders~~		
~~Pruritus~~	~~common~~	
~~Pruritus generalised~~	~~common~~	
~~Musculoskeletal and connective tissue disorders~~		
~~Back pain~~	~~common~~	
~~Muscle spasms~~	~~common~~	
~~General disorders and administrative site conditions~~		

~~Flushing~~	~~very common~~	
~~Feeling hot~~	~~very common~~	
~~Chest discomfort~~	~~common~~	
~~Hyperhidrosis~~	~~common~~	
~~Peripheral coldness~~	~~common~~	
~~Pyrexia~~		~~common~~
~~Investigations~~		
~~Transient elevations of D-dimer and F1+2 fragments~~	~~very common~~	

System organ class	Very common ≥ 1/10	Common ≥ 1/100 to < 1/10	Uncommon ≥ 1/1,000 to < 1/100
Nervous system disorders		Cerebrovasculr accident Ischaemic stroke	Cerebral infarction Transient ischaemic attack
Cardiac disorders		Acute myocardial infarction Myocardial infarction	Cardiac arrest
Vascular disorders		Deep vein thrombosis	Iliac artery occlusion
Respiratory, thoracic and mediastinal disorders		Pulmonary embolism	
General disorders and administrative site conditions		Pyrexia	
Injury, poisoning and procedural complications			Infusion related reaction[a]

[a]reported signs/symptoms (rigors, chills, hypertension, oxygen desaturation, agitation and confusion) were transient and mild to moderate in severity.

(…)

7. MANUFACTURER

Alexion Pharma International Operations Limited,~~Alexion Pharma GmBH~~
College Business and Technology Park, Blanchardstown, Dublin 15, Ireland ~~Giesshubelstrasse 30, 8045, Zurich Switzerland~~

בעלון קיימים עדכונים נוספים.

למידע נוסף יש לעיין בעלון לרופא המעודכן אשר נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות. כמו כן, ניתן לקבלו מודפס על ידי פניה לבעל הרישום: אלקסיון פארמה ישראל בע"מ, ת.ד. 7063, פתח תקווה 4917001.
טלפון: 03-9373753, פקס: 03-9373774

בברכה, עוז וולך, רוקח/ת ממונה של בעל הרישום