

דצמבר 2020

רופא/ה, רוקח/ת נכבד/ה,

חברת קמהדע מבקשת להודיע על עידכונים בעלון התכשיר כמפורט להלן, עבור התכשיר:

RUCONEST - POWDER FOR SOLUTION FOR INJECTION; רוקונסט- אבקה לתמיסה להזרקה

POWDER FOR SOLUTION FOR INJECTION, IV

CONESTAT ALFA 2100 U/VIAL מרכיבים פעילים בהתאם לרישיון:

התויה מאושרת:

Ruconest is indicated for treatment of acute angioedema attacks in adults and adolescents aged 12 years and above with hereditary angioedema (HAE) due to C1 esterase inhibitor deficiency.

בעלון התכשיר חלו שינויים המהווים חמרה (מודגשים בצהוב). בעלון ישנם שינויים נוספים אשר אינם מהווים חמרה:

4.4 Special warnings and precautions for use

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered products should be clearly recorded.

Conestat alfa is derived from milk of transgenic rabbits and contains traces of rabbit protein. Before initiating treatment with Ruconest, patients should be tested for the presence of IgE antibodies against rabbit allergens using a validated test for IgE antibodies against rabbit epithelium (dander) e.g. ImmunoCap system, Phadia, Sweden. Only patients who have been shown to have negative results for such a test, should be treated with Ruconest. IgE antibody testing should be repeated once a year or after 10 treatments, whichever occurs first queried about prior exposure to rabbits and signs and symptoms suggestive of an allergic reaction.

Hypersensitivity reactions cannot be excluded.

All patients must be closely monitored and carefully observed for any symptoms of hypersensitivity throughout during and after the administration period. ...

4.7 Effects on ability to drive and use machines

Based on the known pharmacology and adverse reaction profile of Ruconest, effects on the ability to drive and use machines are not expected. However, headache, vertigo and dizziness have been reported following the use of Ruconest, but may also occur as a result of an attack of HAE. Patients should be advised not to drive and use machines if they experience headache, vertigo or dizziness.

4.8 Undesirable effects

... One case of hypersensitivity was observed in clinical trials with Ruconest. The most common adverse reaction observed after administration of Ruconest is nausea headache.

Nervous system disorders	Hypoaesthesia	Uncommon
	Dizziness	Uncommon
Ear and labyrinth disorders	Auricular swelling	Uncommon
Gastrointestinal disorders	Nausea	Common

העלון לרופא המעודכן ומכתב ההחמרות נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פניה לבעל הרישום, חברת קמהדע בע"מ (טל" 08-9406472).

להלן הקישור למאגר התרופות: <https://data.health.gov.il/drugs/index.html#/byDrug>