אוקטובר 2021

שם התכשיר:

Fabrazyme 35 mg

חומר פעיל:

Agalsidase beta 35 MG/VIAL

ההתוויה המאושרת הינה:

Fabrazyme is indicated for use as long-term enzyme replacement therapy in patients with a confirmed diagnosis of Fabry disease (alfa - galactosidase A deficiency).

חברת סאנופי אוונטיס מבקשת להודיע על עדכון העלון לרופא בספטמבר 2021.

העדכון העיקרי הוא:

4.2 Posology and method of administration

Fabrazyme treatment should be supervised by a physician experienced in the management of patients with Fabry Disease or other inherited metabolic diseases.

Posology

The recommended dose of Fabrazyme is 1 mg/kg body weight administered once every 2 weeks as an intravenous infusion.

~~Lower dosing regimens have been used in clinical studies. In one of these studies, after an initial dose of 1.0 mg/kg every 2 weeks for 6 months, 0.3 mg/kg every 2 weeks may maintain clearance of GL-3 in certain cell types in some patients; however, the long-term clinical relevance of these findings has not been established (see section 5.1).~~

~~The initial infusion rate should be no more than 0.25 mg/min (15 mg/hour) to minimise the potential occurrence of infusion-associated reactions. After patient tolerance is well established, the infusion rate may be increased gradually with subsequent infusions.~~

Infusion of Fabrazyme at home may be considered for patients who are tolerating their infusions well. The decision to have a patient move to home infusion should be made after evaluation and recommendation by the treating physician. Patients experiencing adverse events during the home infusion need to immediately **stop the infusion process** and seek the attention of a healthcare professional. Subsequent infusions may need to occur in a clinical setting. Dose and infusion rate should remain constant while at home, and not be changed without supervision of a healthcare professional.

...

סאנופי אוונטיס ישראל, רח' בני גאון 10, פארק פולג, ת.ד. 8090, נתניה דרום 42504
טל': 09-8633700 פקס: 09-8851444

Method of administration

Fabrazyme should be administered as an intravenous infusion.

The initial infusion rate should be no more than 0.25 mg/min (15 mg/hour) to minimise the potential occurrence of infusion-associated reactions. After patient tolerance is established, the infusion rate may be increased gradually with subsequent infusions.

For instructions on reconstitution and dilution of the medicinal product before administration, see
section 6.6.

העלון בו מסומנים כלל העדכונים מצורף להודעה זו.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום- סאנופי-אוונטיס ישראל בע"מ, רח' בני גאון 10 נתניה או בטלפון: 09-8633700.

להלן הקישור לאתר משרד הבריאות: https://data.health.gov.il/drugs/index.html#/byDrug

בברכה,

ד"ר תמר גבע
רוקחת ממונה