מאי 2018

Empliciti (elotuzumab) 300 mg & 400mg
Powder for concentrate for solution for infusion

רופא/ה ,רוקח/ת יקר/ה,

ברצוננו להודיעך על עדכון בעלון לרופא של התכשיר אמפליסיטי (elotuzumab) בישראל.

התווית התכשיר כפי שאושרה ע"י משה"ב:

Empliciti is indicated in combination with lenalidomide and dexamethasone for the treatment of multiple myeloma in adult patients who have received at least one prior therapy.

בפירוט שלהלן כלולים העדכונים המהותיים בלבד (טקסט שנוסף מסומן בצבע אדום ובקו תחתון,טקסט שהוסר מסומן בצבע אדום ~~ובקו אמצעי~~).

למידע מלא על התרופה יש לעיין בעלון לרופא כפי שאושר על ידי משרד הבריאות.

העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס על ידי פנייה לבעל הרישום בריסטול-מאיירס סקוויב (ישראל) בע"מ, ת.ד 3661, קרית אריה, פתח תקווה 4951448 או בטלפון 03-5231021.

בכבוד רב,
מיכל ניר ורדימון
מנהלת רגולציה

689IL1803007-01

BMS ISRAEL

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עדכונים מהותיים בעלון לרופא:

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Empliciti 300 mg powder for concentrate for solution for infusion
Each vial contains 300 mg elotuzumab*.

Empliciti 400 mg powder for concentrate for solution for infusion
Each vial contains 400 mg elotuzumab.

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4. CLINICAL PARTICULARS

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4.2 Posology and method of administration

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Special populations

Paediatric population
There is no relevant use of Empliciti in the paediatric population for the indication of multiple myeloma.
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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antineoplastic agents, monoclonal antibodies. ATC code: L01XC23

5.2 Pharmacokinetic properties

The pharmacokinetics (PK) of elotuzumab was studied in patients with multiple myeloma. Elotuzumab exhibits nonlinear PK with decrease in clearance with increase in dose from 0.5-20 mg/kg.

Absorption
Elotuzumab is dosed via intravenous route and therefore is immediately and completely bioavailable.

Distribution
~~Mean~~ The geometric mean volume of distribution of elotuzumab ~~ranged from 36 mL/kg to 70 mL/kg (2.3 4.6 L for a typical patient) and was independent from the dose in a dose range of 0.5~~

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at 10 mg/kg ~~to 20 mg/kg~~ (in combination with lenalidomide and dexamethasone) at steady state is 6.02 L (CV: 22.1%).

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Biotransformation

The metabolic pathway of elotuzumab has not been characterized. As an IgG monoclonal antibody, elotuzumab is expected to be degraded into small peptides and amino acids via catabolic pathways.

Elimination

~~Following a single dose of 10 mg/kg, the elotuzumab clearance was 13.2 mL/day/kg. Elotuzumab exhibits nonlinear pharmacokinetics with clearance of elotuzumab decreasing from 17.5 to 5.8 mL/day/kg with an increase in dose from 0.5 to 20 mg/kg, suggesting target mediated clearance, resulting in greater than proportional increases in Area under the Concentration time curve (AUC).~~ The geometric mean total clearance of elotuzumab at 10 mg/kg (in combination with lenalidomide and dexamethasone) at steady state is 0.194 L/day (CV: 62.9%). Upon discontinuation of elotuzumab in combination with lenalidomide and dexamethasone, concentrations of elotuzumab will decrease to approximately 3% (approximately 97% washout as estimated by 5 half lives) of the population predicted steady state maximal serum concentration by 3 months.

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