

אפריל 2025

Abecma / אבקמה
(Idcabtagene Vicleucel)
תרחיף לעירוני תוך ורידי / Dispersion for IV infusion

רופא/ה, רוקח/ת יקר/ה,

חברת בריסטול-מאיירס סקוויב (ישראל) מבקשת להודיע על עדכונים בעלון לרופא ובעלון לצרכן של התכשיר שבנדון.

להלן התוויית התכשיר כפי שמאושרת ע"י משרד-הבריאות:

Abecma is indicated for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior therapies, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 antibody and have demonstrated disease progression on the last therapy.

המרכיב הפעיל: Idecabtagene Vicleucel 260-500 x 10⁶ anti-BCMA CAR-positive viable T cells

השינויים בעלון לרופא ובעלון לצרכן משוקפים בעמודים הבאים (תוספת טקסט מסומנת ב**קו תחתון**), מחיקת טקסט ב**קו חוצה**).

למידע מלא על התרופה יש לעיין בעלון לרופא ובעלון לצרכן כפי שאושרו על ידי משרד-הבריאות.

העלון לרופא והעלון לצרכן נשלחו לפרסום במאגר התרופות שבאתר משרד-הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום בריסטול-מאיירס סקוויב (ישראל) בע"מ.

בברכה,

לנה גיטלין
מנהלת רגולציה ורוקחת ממונה
בריסטול-מאיירס סקוויב (ישראל)

6.6 Special precautions for disposal and other handling

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Thawing

- Remove the Abecma infusion bag from the cassette and inspect the infusion bag for any breaches of container integrity such as breaks or cracks before thawing. If the infusion bag appears to have been damaged or to be leaking, it should not be infused and should be disposed of according to local guidelines on handling of waste of human-derived material.
- Place the infusion bag inside a second sterile bag.
- Thaw Abecma at approximately 37°C using an approved thaw device or water bath until there is no visible ice in the infusion bag. Gently mix the contents of the bag to disperse **visible** clumps of cellular material. ~~If visible cell clumps remain, continue to gently mix the contents of the bag.~~ Small clumps of cellular material ~~should disperse with gentle manual mixing~~ **are expected in Abecma**. Do not wash, spin down and/or resuspend Abecma in new media prior to infusion.

Administration

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- Prime the tubing of the infusion set with sodium chloride 9 mg/mL (0.9%) solution for injection prior to infusion. **Infusion set with in-line filter (a non-leukodepleting filter with a pore size range of 170 to 260 µm) should be used for thawed products.**
- Infuse Abecma within 1 hour from start of thaw as quickly as tolerated by gravity flow.
- After the entire content of the infusion bag is infused, rinse the tubing, **inclusive of the in-line filter**, with sodium chloride 9 mg/mL (0.9%) solution for injection at the same infusion rate to ensure ~~all product is delivered~~ **as many cells as possible are infused into the patient.**
- Follow the same procedure for all subsequent infusion bags for the identified patient.

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השינויים העיקריים בעלון לצרכן:

המידע הבא מיועד לצוות רפואי בלבד:

The following information is intended for healthcare professionals only:

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