נובמבר 2022

רופא/ה נכבד/ה
רוקח/ת נכבד/ה שלום רב,

SAPHNELO CONCENTRATE FOR SOLUTION FOR :פרסום עדכון בעלוני התכשיר
INFUSION

הרכב:

ANIFROLUMAB 300 MG

'Instructions for Preparation and חברת אסטרהזניקה ישראל מבקשת להודיע על עדכון פרק Administration' ועדכון העלונים בהתאם להוראות משרד הבריאות בתאריך **נובמבר 2022.**

התוויה:

Saphnelo is indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.

Limitations of Use:

The efficacy of SAPHNELO has not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus. Use of SAPHNELO is not recommended in these situations.

העדכונים המהותיים בעלון לרופא הינם:

5.2 Instructions for Preparation and Administration

SAPHNELO is supplied as a single-dose vial. Prepare the diluted infusion solution using aseptic technique, by the following procedure:

1. Visually inspect the vial for particulate matter and discoloration. SAPHNELO is a clear to opalescent, colorless to slightly yellow, solution. Discard the vial if the solution is cloudy, discolored or visible particles are observed. Do not shake the vial.
2. Withdraw and discard 2 mL of solution from a 50 mL or 100 mL 0.9% Sodium Chloride Injection, infusion bag.
3. Withdraw 2 mL of solution from the vial of SAPHNELO and add it to the infusion bag. Mix the solution by gentle inversion. Do not shake.
4. Each vial is intended for one time use only. Discard any unused portion remaining in the vial.
5. Administer the infusion solution immediately after preparation.

6. If the infusion solution is not administered immediately, store the diluted solution of SAPHNELO at room temperature (15°C to 25°C) for up to 4 hours, or refrigerated (2°C to 8°C) for up to 24 hours. Do not freeze. Protect from light. If refrigerated, allow the diluted SAPHNELO solution to reach room temperature prior to administration.

7. Administer the infusion solution intravenously over a 30-minute period through an infusion line containing a sterile, low-protein binding 0.2 to 15 ~~or 0.22~~ micron in-line or add-on filter.

8. To ensure the complete dose of SAPHNELO has been administered, flush the entire infusion line ~~set~~ with 25 mL of 0.9% Sodium Chloride Injection at the end of the infusion. ~~To ensure the complete dose of SAPHNELO has been administered.~~

9. Do not co-administer other medicinal products through the same infusion line.

10. Dispose of any unused medicinal product or waste material in accordance with local requirements.

עדכונים מהותיים בעלון לצרכן:

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מקרא לעדכונים המסומנים:
תוספת טקסט מהותי מסומנת בצבע כחול.
מחיקת טקסט מסומנת בקו חוצה בצבע אדום.

העלונים מפורסמים במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום.

בכבוד רב,
קארין קנבל דובסון
רוקחת ממונה
אסטרהזניקה (ישראל) בע״מ