

ינואר 2024

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

SKYRIZI 600mg (Risankizumab 60 mg/1ml)

Concentrate for solution for infusion

חברת AbbVie Biopharmaceuticals Ltd. שמחה לבשר כי מעתה תכשיר סקיריזי 600 מ"ג המיועד למתן דרך אינפוזיה, ניתן למהילה גם בתמיסת 0.9% saline. העלון לרופא וכן הוראות ההכנה לצוות הרפואי הנמצאות בעלון לצרכן התעדכנו בהתאם.

בהודעה זו מצוינים סעיפים בהם נעשה שינוי מהותי או שינוי המהווה חמרה. מידע שהתווסף מסומן באדום.

התכשיר מותווה לטיפול במחלה הבאה:

Risankizumab is indicated for the treatment of patients 16 years and older with moderately to severely active Crohn's disease who have had an inadequate response to, lost response to, or were intolerant to conventional therapy or a biologic therapy, or if such therapies are not advisable.

העלון לרופא עודכן בסעיפים הבאים:

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products. Skyrizi 600mg should only be diluted in a 5% dextrose in water (D5W) or **0.9% saline** IV infusion bag or glass bottle. Skyrizi 600mg should not be administered concomitantly in the same intravenous line with other medicinal products.

6.3 Shelf life

[...]

Diluted solution for intravenous infusion:

The prepared infusion should be used immediately. If not used immediately, the diluted Skyrizi solution can be stored (protected from light) for up to 20 hours between 2°C to 8°C. **Immediately after preparation or removal from refrigerator**, **Subsequently**, the diluted Skyrizi solution can be stored **at room temperature** (protected from **direct and indirect** sunlight) for **4 8 hours at room temperature after dilution** (cumulative time from start of dilution to start of infusion **eumulative time after preparation including the storage and infusion period**). **Exposure to indoor light is acceptable during room temperature storage and administration.** Do not freeze.

[...]

6.6 Special precautions for disposal

Skyrizi 600mg

~~The solution in the vial and dilutions should not be shaken.~~ The solutions should be visually inspected for particulate matter or discoloration prior to administration. The solution should be colourless to slightly yellow and clear to slightly opalescent. The medicinal product and its dilutions should not be used if the solution is discoloured or cloudy, or if foreign particulate matter is present.

Instructions for dilution

Skyrizi should be prepared by a healthcare professional using aseptic technique.

Skyrizi medicinal product must be diluted before administration.

Solutions of Skyrizi for intravenous administration are prepared by dilution of the drug product into an intravenous infusion bag or glass bottle containing 5% dextrose in water (D5W) **or 0.9% saline** (600 mg/10 mL in 100 mL, 250 mL or 500 mL) to a final drug concentration of approximately 1.2 mg/mL to 6 mg/mL.

Prior to the start of the intravenous infusion, the content of the IV infusion bag or glass bottle should be at room temperature.

Infuse the diluted solution over a period of at least one hour. ~~Once diluted, the infusion should be completely administered within 8 hours of the dilution in the infusion bag.~~

The solution in the vial and the dilutions should not be shaken.

Each vial is for single use only and any unused medicinal product or waste material should be disposed of in accordance with local requirements.

[...]

העלוו לזרכו עוּדכוּ בסעיף הבא :

המידע הבא מיועד לאנשי צוות רפואי בלבד

Instructions for intravenous induction dosing regimen

1. Skyrizi should be prepared by a healthcare professional using aseptic technique.
2. Skyrizi medicinal product must be diluted before administration.
3. Skyrizi for intravenous administration must be diluted into an **intravenous** infusion bag **or glass bottle** containing 5% dextrose in water (D5W) ~~IV infusion bag or glass bottle~~ **or 0.9% saline** (600 mg/10 mL in 100 mL, 250 mL or 500 mL) to a final drug concentration of approximately 1.2 mg/mL to 6 mg/mL.

~~The solution in the vial and dilutions should not be shaken.~~

- ~~3-4~~ Prior to the start of the intravenous infusion, the content of the infusion bag or glass bottle should be at room temperature.
- ~~4-5~~ Infuse the diluted solution over a period of at least one hour. ~~The infusion should be completely administered within 8 hours of the dilution in the infusion bag.~~
- ~~5-6~~ Skyrizi vial solution should not be administered concomitantly in the same intravenous line with other medicinal products.

Each vial is for single use only and any unused medicinal product or waste material should be disposed of in accordance with local requirements.

Handling and Storage of **the vial and** diluted solution:

- **The solution in the vial and dilutions should not be shaken.**
- The prepared infusion should be used immediately. If not used immediately, the diluted Skyrizi solution can be stored (protected from light) for up to 20 hours between 2°C to 8°C.

- ~~Subsequently,~~ Immediately after preparation or removal from refrigerator, the diluted Skyrizi solution can be stored at room temperature (protected from ~~direct and indirect~~ sunlight) for ~~8~~ 4 hours ~~at room temperature after dilution~~ (cumulative time from start of dilution to start of infusion) (~~cumulative time after preparation including the storage and infusion period~~).
- Exposure to indoor light is acceptable during room temperature storage and administration.
- Do not freeze.

העלון לרופא ולצרכן נשלחו למאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום, AbbVie, Biopharmaceuticals Ltd, רחוב החרש 4, הוד השרון או בטלפון 7909600 – 09.

בברכה,

אייאת עיסה

רוקחת ממונה