



ינואר 2024

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

חברת רז רוקחות מבקשת להודיעכם על עדכון העלון לרופא של התכשיר:

EPHEDRINE HCl STEROP 50MG/1ML

בהודעה זו מצוינים רק הסעיפים בהם נעשו שינויים מהותיים בעלון לרופא.

התוספות סומנו בצבע כחול, ההחמרות סומנו בצהוב והמחיקות סומנו בצבע אדום עם קו מחיקה.

העלון המעודכן נשלח למשרד הבריאות לצורך פרסומו במאגר התרופות שבאתר משרד הבריאות:

www.health.gov.il וניתן לקבלו מודפס על ידי פנייה לבעל הרישום: רז רוקחות בע"מ, רחוב המתכת 6, א.ת. קדימה.

בברכה,

לירון שמש

רוקחת ממונה

מרכיב פעיל וחוזק:

EPHEDRINE HYDROCHLORIDE 50 MG / 1 ML

התוויה מאושרת:

Ephedrine Hydrochloride is used in the prevention and treatment of hypotension from spinal or epidural anesthesia and during general anesthesia, with or without a reduction in the heart rate, administered for a surgical or obstetric procedure.

להלן העדכונים המהותיים שבוצעו בעלון לרופא:

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6. PHARMACEUTICAL PARTICULARS

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6.2 Incompatibilities

~~In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.~~

EPHEDRINE HCl STEROP 50mg/1ml must not be mixed with other medicinal products except those mentioned in section 6.6.



6.3 Shelf life

Unopened: The expiry date of the product is indicated on the packaging material.

After first opening: the product must be used immediately.

After dilution: For storage conditions and shelf life after dilution see section 6.6.

6.4 Special precautions for storage

Do not store above 25°C. Store in the original package in order to protect from light.

6.5 Nature and contents of container

Type I uncolored glass flat bottom ampoule.

Boxes of 5, 10 or 100 ampoules containing 1ml of solution.

6.6 Special precautions for disposal and other handling

Instructions for use:

The ampoule is for single use only. The solution should be used immediately after the opening of the container.

The drug product EPHEDRINE HCl STEROP 50 mg/1 ml solution for injection is stable for 24 hours when diluted with sodium chloride 0.9 % solution for injection at room temperature (15 -25°C), without protection from light, when diluted as follows:

1. One ampoule is diluted to a final volume of 5 ml (4 ml of saline + 1 ml of ephedrine).
2. One ampoule is diluted to a final volume of 10 ml (9 ml of saline + 1 ml of ephedrine).

Chemical and physical in-use stability has been demonstrated for 24 hours at room temperature (15 - 25°C). From a microbiological point of view, unless the method of opening/dilution precludes the risk of microbial contamination, the diluted product should be used immediately after preparation. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user.

Any unused product or waste material should be disposed of in accordance with local requirements.

Discard the ampoule after use. DO NOT REUSE.

The content of un-opened and un-damaged ampoule is sterile and must not be opened until use. The product should be inspected visually for particles and discoloration prior to administration. Only clear colorless solution free from particles or precipitates should be used.