



יולי 2024

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

חברת פרופארם בע"מ מזדעעה על העדכונים הבאים בעלון לרופא של התכשיר בעקבות הארכת חיי המדף לאחר שיחזור/מיהול:

DACARBAZINE-DACIN 200 MG

דקרביזין-דצין 200 מ"ג

DACARBAZINE 200MG/VIAL : חומר פעיל:
POWDER FOR SOLUTION FOR INJECTION/INFUSION : צורת מינון:

עדכונים בעלון לרופא

התויה כפי שאושרה בתעודת הרישום:

For the treatment of metastatic malignant melanoma, Hodgkin's disease as a second line therapy when used in combination with other agents.

ברצונינו להודיע שהעלון לרופא עודכן בעקבות הארכת חיי המדף לתכשיר לאחר שיחזור/מיהול, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות /שינויים מסומנים באדום והחמרות/מידע חדש על רקע צהוב):

6.4 Reconstitution & Dilution of the product

Shelf life and storage conditions after reconstitution:

The reconstituted solution for injection does not contain any preservative. Chemical and physical in-use stability has been demonstrated for 8 hours at room temperature and under light protection and for 5 days at 2 to 8°C and under light protection. From a microbiological point of view, the reconstituted solution should be used immediately. If the reconstituted solution is not used immediately in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours in a refrigerator (2 to 8°C) and protected from light, unless the reconstitution has taken place under controlled and validated aseptic conditions.

Shelf life and storage conditions after dilution:

The diluted solution for infusion does not contain any preservatives. Chemical and physical in-use stability has been demonstrated for 8 hours at room temperature and under light protection and for 5 days at 2 to 8°C and under light protection. From a microbiological point of view, the diluted solution for infusion should be used immediately. If the diluted solution is not used immediately, in -use storage times and conditions prior to **USE** are the responsibility of the user and would normally not be longer than 24 hours in a refrigerator (2 to 8°C) and protected from light, unless the reconstitution and dilution have taken place under controlled and validated aseptic conditions.

Preparation and administration of the solution for injection/infusion:—

~~DACARBAZINE-DACIN is supplied in vials containing 200 mg powder for solution for injection/infusion for reconstitution with 10.7 ml of sterile water. The resulting solution contains 10 mg/ml of dacarbazine and has a pH of 3.0 to 4.0.~~

~~The required amount of solution is drawn up into a syringe and injected intravenously within approximately one minute.~~

~~The reconstituted solution for injection is physically and chemically stable for 1 hour at 25 °C and for 24 hours at 4 °C.~~

Propharm Ltd., P.O.B. 4046, Zichron Yaacov 30900, Israel, Tel. +972-4-6294242, Fax. +972-4-6392049

Email: info@propharm.co.il , Web: www.propharm.co.il



The solution contains no preservatives and should therefore, from a microbiological point of view, be used immediately after preparation; given aseptic handling, it can be kept at 4 °C for a maximum of 24 hours.

The diluted solution for infusion is physically and chemically stable for 30 minutes at 25 °C and for 8 hours at 4 °C.

From a microbiological point of view, it should be used immediately after preparation. Given aseptic handling and protection from light, it can be kept at 4 °C for a maximum of 8 hours.

[...]

העלון לרופא מצורף להודעה זו וכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות.

ניתן לקבל את העלון מודפס ע"י פניה לבעל הרישום, חברת פרופארם בע"מ, טל 04-6294242.

בברכה,

מירי חזן

רוקחת ממונה