

September 2022

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא של התכשיר הבא:

CYMEVENE 500 MG (110-89-26101-00)

המאושר להתוויה הבאה:

Cymevene IV is indicated for the treatment of CMV retinitis in immunocompromised patients, including patients with acquired immunodeficiency syndrome (AIDS). Cymevene IV is also indicated for the prevention of CMV disease in transplant recipients at risk for CMV disease.

השינויים המהותיים בעלון לרופא מופיעים בסעיפים הבאים:

QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains ganciclovir sodium equivalent to 500 mg ganciclovir, 543 mg ganciclovir sodium equivalent to 500 mg ganciclovir

5.6 Excipients

This medicinal product contains 2 mmol (43mg) sodium per 500 mg dose. To be taken into consideration by patients on a controlled sodium diet.

15 HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

CYMEVENE 500 MG (ganciclovir sodium) for injection is supplied in 10 mL sterile vials, each containing ganciclovir sodium equivalent to 500 mg of ganciclovir as a white to off-white powder. The concentration of ganciclovir in the reconstituted solution is 50 mg/mL. Because ganciclovir shares some of the properties of antitumor agents (i.e., carcinogenicity and mutagenicity), consideration should be given to handling and disposal according to guidelines issued for antineoplastic drugs. CYMEVENE 500 MG is supplied in cartons of 5 single dose vials.

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Storage

Do not store above 30°C.

Store reconstituted solution in the vial at 25°C for no longer than 12 hours. Do not refrigerate or freeze. Discard any unused portion of the reconstituted solution.

Store diluted infusion solution under refrigeration at 2° to 8°C for no longer than 24 hours. Do not freeze.

בברכה,

מירי חזן

רוקחת ממונה