



אפריל 2021

רופא /ה, רוקח/ת נכבד/ה,
חברת טבע מודיעה על העדכונים בעלון לצרכן של התכשירים:

Pemetrexed Teva 100 mg, 500mg, 1000mg Powder for Concentrate for Solution for Infusion

פמטרקסד טבע 100 מ"ג, 500 מ"ג, 1000 מ"ג
אבקה להכנת תמיסה מרוכזת להכנת תמיסה למתן בעירוי

Pemetrexed Teva 100 mg: each vial contains 100 mg Pemetrexed
Pemetrexed Teva 500 mg: each vial contains 500 mg Pemetrexed
Pemetrexed Teva 1000 mg: each vial contains 1000 mg Pemetrexed

עדכונים בעלון לצרכן

התוויה כפי שאושרה בתעודת הרישום:

Malignant pleural mesothelioma:

Pemetrexed Teva in combination with cisplatin is indicated for the treatment of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curatable surgery.

Non-small cell lung cancer:

Pemetrexed Teva in combination with cisplatin is indicated for the first line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.

Pemetrexed Teva is indicated as monotherapy for the maintenance treatment of locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology in patients whose disease has not progressed immediately following platinum-based chemotherapy.

Pemetrexed Teva is indicated as monotherapy for the second line treatment of patients with locally advanced or metastatic non-small cell lung cancer other than predominantly squamous cell histology.

ברצוננו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום והסרות מידע כטקסט מחוק):

THE FOLLOWING INFORMATION IS INTENDED FOR HEALTHCARE PROFESSIONALS ONLY:

1. Use aseptic technique during the reconstitution and further dilution of pemetrexed for intravenous infusion administration.
2. Calculate the dose and the number of Pemetrexed Teva vials needed.

100 mg: Reconstitute 100-mg vials with 4.2 ml of sodium chloride 9 mg/ml (0.9%) solution for injection, without preservative, resulting in a solution containing 25 mg/ml pemetrexed. Each vial contains an excess of pemetrexed to facilitate delivery of label amount.

500 mg: Reconstitute 500-mg vials with 20 ml of sodium chloride 9 mg/ml (0.9%) solution for injection, without preservative, resulting in a solution containing 25 mg/ml pemetrexed.

1000 mg: Reconstitute 1000-mg vials with 40 ml of sodium chloride 9 mg/ml (0.9%) solution for injection, without preservative, resulting in a solution containing 25 mg/ml pemetrexed.

Gently swirl each vial until the powder is completely dissolved. The resulting solution is clear and ranges in colour from colourless to yellow or green-yellow. The pH of the reconstituted solution is between 6.6 and 7.8. Further dilution is required.

3. The appropriate volume of reconstituted pemetrexed solution must be further diluted to 100 ml with sodium chloride 9 mg/ml (0.9%) solution for injection, without preservative, and administered as an intravenous infusion over 10 minutes.
4. Pemetrexed infusion solutions prepared as directed above are compatible with polyolefin-lined administration sets and infusion bags.
5. Parenteral medicinal products must be inspected visually for particulate matter and discoloration prior to administration. If particulate matter is observed, do not administer
6. Pemetrexed solutions are for single use only. Any unused medicinal product or waste material must be disposed of in accordance with local requirements.

Preparation and administration precautions:

As with other potentially toxic anticancer agents, care should be exercised in the handling and preparation of pemetrexed infusion solutions. The use of gloves is recommended. If a pemetrexed solution contacts the skin, wash the skin immediately and thoroughly with soap and water. If pemetrexed solutions contact the mucous membranes, flush thoroughly with water. Pemetrexed is not a vesicant. There is not a specific antidote for extravasation of pemetrexed. There have been a few reported cases of pemetrexed extravasation, which were not assessed as serious by the investigator. Extravasation should be managed by local standard practice as with other non-vesicants.

העלון לצרכן נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות <http://www.health.gov.il>, וניתן לקבלו מודפס ע"י פניה לחברת טבע.