



2024 ספטמבר

רופא/ה נכבד/ה,

רוקח/ת נכבד/ה,

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

VITAMINE B12 STEROP 1 MG/ML

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 גשר העץ 31, פארק

תעשיות עמק חפר.

בברכה,

לירון שמש

רוקחת ממונה

מרכיב פעיל וחוזק:

CYANOCOBALAMIN 1 MG / 1 ML

התוויה מאושרת:

Pernicious anemia and its neurological complications, subacute combined degeneration of the spinal cord.

Treatment of vitamin B12 deficiency states and macrocytic anemias associated with nutritional deficiencies, gastrectomy and abnormalities of, or malabsorption from, the gastrointestinal tract such as celiac disease, sprue and accompanying folic acid deficiency.

Also suitable for use as the flushing dose in the schilling test for pernicious anemia.

להלן העדכונים המהותיים שבוצעו בעלון לרופא:

...

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance : Cyanocobalamin (vitamin B12) 1 mg/ml

Excipients with known effect:

Each 1 ml of solution contains 3.5 mg of sodium.

For the full list of excipients, see section 6.1.



3. PHARMACEUTICAL FORM

Solution for injection.

Aqueous, clear, red solution free of visible particles.

4. CLINICAL PARTICULARS

...

4.4 Special warnings and precautions for use

...

Important information about some of the ingredients:

This medicine contains less than 1 mmol sodium (23 mg) per 1 ml, that is to say essentially 'sodium-free'.

...

5. PHARMACOLOGICAL PROPERTIES

...

5.2 Pharmacokinetic properties

Vitamin B12 undergoes first-pass metabolism; Excreted mainly in the bile, two-thirds or three quarters is reabsorbed in the intestine in patients with intrinsic factor. After injection of high doses of vitamin B12, a large proportion, 50 to 70% of the dose administered within the first 18 hours depending on the state of the reserves, is excreted in the urine via glomerular filtration.

After intramuscular or subcutaneous injection, resorption is slow resulting in long-lasting concentrations in the blood and high serum and tissue binding, particularly in the liver parenchyma.

~~After intravenous injection, resorption is more rapid and about 90% of the dose administered is excreted in the urine.~~

...

6. PHARMACEUTICAL PARTICULARS

...

6.6 Special precautions for disposal and other handling

- ~~At the end of the infusion procedure, any remaining solution and parts of the infusion kit containing this solution must be disposed of in compliance with current legislation.~~
- When administered by injection, VITAMINE B12 STEROP 1mg/1ml must be withdrawn from the ampoule as recommended in current good practices, using optimally aseptic technique, into a sterile syringe immediately after the ampoule is opened. The medicinal solution must be then administered immediately. Any unused or remaining medicinal solution must be disposed of as stipulated in current good practices.
- ~~If the solution is administered by infusion, both the medicinal solution and the infusion kit will be maintained under sterile conditions throughout the procedure as described in current good practices. It is standard good clinical practice to use any prepared medicinal solution within 24 hours.~~
- VITAMINE B12 STEROP 1mg/1ml does not contain any antimicrobial preservatives and will not prevent growth of microorganisms. The medicinal solution and any syringe containing this medicinal solution are for single and individual use only.

...