J-C Health Care Ltd.

Kibbutz Shefayim 6099000, ISRAEL
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ספטמבר 2021

רופא/ה נכבד/ה
רוקח/ת נכבד/ה

ברצוננו להביא לידיעתכם את העדכונים בעלון לרופא ולצרכן של התכשירים:

Eprex 2000, solution for injection. Epoetin alfa 2000 IU/0.5 mL 116-78-29671-00
Eprex 3000, solution for injection. Epoetin alfa 3000 IU/0.3 mL 116-79-29672-00
Eprex 4000, solution for injection. Epoetin alfa 4000 IU/ mL 116-80-29673-00
Eprex 5000, solution for injection. Epoetin alfa 5000 IU/0.5 mL 123-41-30339-00
Eprex 6000, solution for injection. Epoetin alfa 6000 IU/0.6 mL 123-42-30340-00
Eprex 8000, solution for injection. Epoetin alfa 8000 IU/ 0.8 mL 123-44-30340-00
Eprex 10,000, solution for injection. Epoetin alfa 10,000 IU/0.5 mL 116-81-29674-00
Eprex 20,000, solution for injection. Epoetin alfa 20,000 IU/0.5 mL 138-30-31794-00
Eprex 30,000, solution for injection. Epoetin alfa 30,000 IU/0.75 mL 138-31-31795-00
Eprex 40,000, solution for injection. Epoetin alfa 40,000 IU/0 mL 126-52-30480-00

הרשומים להתוויות:

Treatment of severe anemia associated with chronic renal failure, anemia in Zidovudine treated HIV infected
patients, anemia in cancer patients on chemotherapy.
To increase the yield of autologous blood from patients in a predonation programme initiated to avoid the use of homologous blood.
Treatment is indicated in patients with moderate anemia (packed cell volume (PCV) approximately 33 to 39% , no iron deficiency) if blood conserving procedures are not available or insufficient either: a: when the scheduled major elective surgery requires a large volume of blood (4 or more units of blood for females or 5 or more units for males) or b: when the period necessary to obtain the required volume of autologous blood is too short.
Perisurgery:
Reduction of allogeneic blood transfusion in surgery patients:
Eprex is indicated for the treatment of anemic patients (hemoglobin 9-11 g/dl) scheduled to undergo elective, noncardiac, nonvascular surgery to reduce the need for allogeneic blood transfusions.
Eprex is indicated for patients at high risk for periopertive transfusions with significant, anticipated blood loss.
Eprex is not indicated for anemic patients who are willing to donate autologous blood.
The safety of the perioperative use of Eprex has been studied only in patients who are receiving anticoagulant prophylaxis. Eprex is indicated before surgerios known be associated with excessive blood loss (at least 2 units).

השינויים המהותיים בעלון לרופא מופיעים בסעיפים הבאים:

4.3 Special warnings and precautions for use

Traceability

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In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

[…]

If the patient has developed a severe cutaneous skin reaction such as SJS or TEN due to the use of EPREX treatment with EPREX must not be restarted in this patient at any time.

The needle cover on the pre-filled syringe contains dry natural rubber (a derivative of latex), which may cause severe allergic reactions in individuals sensitive to latex

~~In order to improve the traceability of erythropoiesis-stimulating agents (ESAs), the trade name of the administered ESA should be clearly recorded (or stated) in the patient file. patients~~

Patients should only be switched from one ESA to another under appropriate supervision.

5.1 Pharmacodynamic properties

[…]

Treatment of patients with chemotherapy-induced anaemia

[…]

A randomised, open-label, multicentre study was conducted in 2,098 anaemic women with metastatic breast cancer, who received first line or second line chemotherapy. This was a non-inferiority study designed to rule out a 15% risk increase in tumour progression or death of epoetin alfa plus standard of care (SOC) as compared with SOC alone. ~~The~~At the time of clinical data cutoff, the median progression free survival (PFS) per investigator assessment of disease progression was 7.4 months in each arm (HR 1.09, 95% CI: 0.99, 1.20), indicating the study objective was not met. ~~At clinical cutoff, 1337 deaths were reported. Median overall survival in the epoetin alfa plus SOC group was 17.2 months compared with 17.4 months in the SOC alone group (HR 1.06, 95% CI: 0.95, 1.18).~~ Significantly fewer patients received RBC transfusions in the epoetin alfa plus SOC arm (5.8% versus 11.4%); however, significantly more patients had thrombotic vascular events in the epoetin alfa plus SOC arm (2.8% versus 1.4%). At the final analysis, 1653 deaths were reported. Median overall survival in the epoetin alfa plus SOC group was 17.8 months compared with 18.0 months in the SOC alone group (HR 1.07, 95% CI: 0.97, 1.18). The median time to progression (TTP) based on investigator-determined progressive disease (PD) was 7.5 months in the epoetin alfa plus SOC group and 7.5 months in the SOC group (HR 1.099, 95% CI: 0.998, 1.210). The median TTP based on IRC-determined PD was 8.0 months in the epoetin alfa plus SOC group and 8.3 months in the SOC group (HR 1.033, 95% CI: 0.924, 1.156).

השינויים המהותיים בעלון לצרכן מופיעים בסעיפים הבאים:

[...]

לפני הטיפול באפרקס, ספר לרופא:

- אם הינך סובל או סבלת בעבר מ:
  - לחץ דם גבוה

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- מהתקפים אפילפטיים או שבץ.
- מחלת כבד
- מאנמיה שונה מאלה המוזכרות בסעיף 1 "למה מיועדת התרופה?".
- מפורפיריה (הפרעה נדירה במערכת הדם).
- אלרגיה ללטקס. המכסה של המחט בתכשיר מכיל גומי לטקס העלול לגרום לתגובות אלרגיות חמורות בחולים הרגישים ללטקס. ראה סימנים לתגובה אלרגית בסעיף 4 "תופעות לוואי".

העלון לרופא והעלון לצרכן נשלחו לפרסום במלואם למאגר התרופות שבאתר משרד הבריאות. כמו כן, ניתן לקבלם מודפסים בפניה אלינו לטלפון 09-9591111 .

בברכה,

צפריר כהן

רוקח ממונה