מרשל איזוטופ בע"מ
ח.פ. 512705484
אזור התעשיה באר-טוביה ישראל 83815
לדואר: ת.ד. 21154 תל-אביב 61211
טלפונים: 08-8506504
פקס : 08-8506503

רופא/ה נכבד/ה,
רוקח/ת נכבד/ה,

מרץ 2021

LUTATHERA 370 MBq/ML SOLUTION FOR INFUSION

חברת מרשל איזוטופ בע"מ מבקשת להודיע על עדכון בעלון לרופא של התכשיר שבנדון.

ההתוויה הרשומה של התכשיר בישראל:
Lutathera is indicated for the treatment of unresectable or metastatic, progressive, well
differentiated (G1 and G2), somatostatin receptor positive gastroenteropancreatic neuroendocrine tumours (GEP NETs) in adults.

צורת המתן של התכשיר:
Solution for infusion, I.V

מרכיב פעיל:
LUTETIUM (^{177}Lu) OXODOTREOTIDE 370 MBQ/ML

עדכונים בעלון לרופא המהווים החמרה נעשו בסעיפים הבאים:

4.4 Special warnings and precautions for use

Renal toxicity
For patients with creatinine clearance < 50 mL/min, an increased risk for transient hyperkalemia due to the amino acid solution should also be taken into consideration (see Warning and precaution regarding the co-administered renal protective amino acid solution).

Hyperkalemia
A transient increase in serum potassium levels may occur in patients receiving arginine and lysine, usually returning to normal levels within 24 hours from the start of the amino acid infusion.
Serum potassium levels must be tested before each treatment with amino acid solutions. In case of hyperkalemia, patient's history of hyperkalemia and concomitant medication should be checked. Hyperkalemia must be corrected accordingly before starting the infusion.
In case of pre-existing clinically significant hyperkalemia, a second monitoring prior to amino acid infusion must confirm that hyperkalemia has been successfully corrected. The patient should be monitored closely for signs and symptoms of hyperkalemia, e.g. dyspnea, weakness, numbness, chest pain and cardiac manifestations (conduction abnormalities and cardiac arrhythmias). An electrocardiogram (ECG) should be performed prior to discharging the patient.
Vital signs should be monitored during the infusion regardless of baseline serum potassium levels. Patients should be instructed to drink substantial quantities of water

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(at least 1 glass every hour) on the day of infusion to remain hydrated and facilitate excretion of excess serum potassium.
In case hyperkalemia symptoms develop during amino acid infusion, appropriate corrective measures must be taken. In case of severe symptomatic hyperkalemia, discontinuation of amino acid solution infusion should be considered, taking into consideration the risk-benefit of renal protection versus acute hyperkalemia.

Metabolic acidosis
Metabolic acidosis has been observed with complex amino-acid solutions administered as part of total parenteral nutrition (TPN) protocols. Shifts in acid-base balance alter the balance of extracellular-intracellular potassium and the development of acidosis may be associated with rapid increases in plasma potassium.

העלון לצרכן במתכונת עלון לרופא מפורסם במאגר התרופות שבאתר משרד הבריאות:
https://data.health.gov.il/drugs/index.html#!/byDrug

ניתן לקבלו מודפס באמצעות פניה לבעל הרישום, חברת מרשל איזוטופ בע"מ, ת.ד 21154, תל-אביב, טל. 08-8506504

בברכה,

אבנר דור
רוקח ממונה