ינואר 2024

רופא/ה, רוקח/ת נכבד/ה,

פוסרנול 750 מ"ג אבקה למתן דרך הפה	**Fosrenol 750 mg oral powder**
פוסרנול 1000 מ"ג אבקה למתן דרך הפה	**Fosrenol 1000 mg oral powder**

חברת **טקדה** מבקשת להודיעך כי העלון לרופא של התכשיר שבנדון עודכן בינואר 2024.

<u>נוסח ההתוויה המאושר לתכשיר</u>:

Fosrenol is indicated as a phosphate binding agent for use in the control of hyperphosphataemia in chronic renal failure (CRF) patients on haemodialysis or continuous ambulatory peritoneal dialysis (CAPD). Fosrenol is also indicated in adult patients with chronic kidney disease not on dialysis with serum phosphate levels ≥1.78 mmol/L in whom a low phosphate diet alone is insufficient to control serum phosphate levels.

<u>המרכיב הפעיל</u>:

Lanthanum (as carbonate hydrate)

בעמוד הבא מפורטים עיקרי השינויים שבוצעו בעלון.
למידע נוסף, יש לעיין במאגר התרופות שבאתר משרד הבריאות.

העלונים העדכניים של התכשיר מפורסמים במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פניה לחברת טקדה ישראל בע"מ, רח' אפעל 25, פתח תקוה, 03-3733140.

בברכה,

סיון לידאני ברג
רוקחת ממונה
טקדה ישראל בע"מ

טקסט שנוסף מסומן בכחול, טקסט שהושמט מסומן בטקסט ~~אדום עם קו חוצה~~, טקסט המהווה החמרה מודגש בכחול.

העדכונים העיקריים בעלון לרופא הינם:

4.4 Special warnings and precautions for use

Tissue deposition of lanthanum has been shown with Fosrenol in animal studies. In 105 bone biopsies from patients treated with Fosrenol, some for up to 4.5 years, rising levels of lanthanum were noted over time (see section 5.1). Cases of lanthanum deposition in gastrointestinal mucosa, mainly after long term use, have been reported. Lanthanum deposition in gastroduodenal mucosa is demonstrated endoscopically as whitish lesions of different sizes and shapes. Also, various pathological features were identified in gastroduodenal mucosa with lanthanum deposition, such as chronic or active inflammation, glandular atrophy, regenerative changes, foveolar hyperplasia, intestinal metaplasia and The use of Fosrenol in clinical studies beyond 2 years is currently limited. However, neoplasia. treatment of subjects with Fosrenol for up to 6 years has not demonstrated a change in the benefit/risk profile.

There have been cases of gastrointestinal obstruction, ileus, subileus, and gastrointestinal perforation reported in association with lanthanum, some requiring surgery or hospitalisation (see section 4.8).

Lanthanum treatment~~Exercise caution~~ in ~~all~~ patients predisposed to gastrointestinal obstruction, ileus, subileus and

perforation; for example, those with altered gastrointestinal anatomy (e.g., diverticular disease,

peritonitis, history of gastrointestinal surgery, gastrointestinal cancer and gastrointestinal ulceration), hypomotility disorders (e.g., constipation, diabetic gastroparesis) and in subjects~~when used~~ with medications known to potentiate these effects

, should only be used after careful consideration.

~~.~~For all subjects,~~During treatment with lanthanum carbonate~~, physicians and patients should remain alert for signs and symptoms of gastrointestinal disorders, especially constipation and abdominal pain/distension which may indicate bowel obstruction, ileus or subileus during treatment with lanthanum carbonate.

~~.~~Withdrawal of~~Treatment with~~ lanthanum carbonate is recommended in~~should be re-evaluated in~~ patients who develop severe

constipation or other severe gastrointestinal signs and symptoms, irrespective of predisposing conditions.~~.~~

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