

ינואר 2021

משרד ראשי

רח' החרש 4
הוד השרון 45240
ת.ד. 10 ת"א 61000

Head Office

4 Haharash St.
Hod-Hasharon 45240
P.O.Box 10 Tel-Aviv 61000
Israel

רופא/ה, רוקח/ת נכבד/ה,

Tel. +972-9-7626333
Fax. +972-9-7626300

הנדון: עדכון עלון לרופא של וולפור VELPHORO

אנו מבקשים להודיעכם כי העלון לרופא של התכשיר שבנדון עודכן.

ההתוויה המאושרת:

Velphoro is indicated for the control of serum phosphorus levels in adult chronic kidney disease (CKD) patients on haemodialysis (HD) or peritoneal dialysis (PD).

Velphoro should be used within the context of a multiple therapeutic approach, which could include calcium supplement, 1,25-dihydroxy vitamin D3 or one of its analogues, or calcimimetics to control the development of renal bone disease.

הרכב וחוזק חומר פעיל:

SUCROFERRIC OXYHYDROXIDE 500 MG

בפירוט שלהלן מובא המידע בו בוצעו שינויים מהותיים בלבד.
תוספת טקסט או טקסט בעל שינוי משמעותי מסומן בצבע. מחיקת טקסט מסומנת בקו חוצה.

העדכונים בעלון לרופא נעשו בסעיפים הבאים:

5.1 Pharmacodynamic properties

Post-authorisation data

A prospective, non-interventional, post-authorisation safety study (VERIFIE) has been conducted, evaluating the short- and long-term (up to 36 months) safety and effectiveness of Velphoro in adult patients on haemodialysis (N=1,198) or peritoneal dialysis (N=160), who were followed in routine clinical practice for 12 to 36 months (safety analysis set, N=1,365). During the study, 45% (N=618) of these patients were concomitantly treated with phosphate binder(s) other than Velphoro.

In the safety analysis set, the most common ADRs were diarrhoea and discoloured faeces, reported by 14% (N=194) and 9% (N=128) of patients, respectively. The incidence of diarrhoea was highest in the first week and decreased with duration of use. Diarrhoea was of mild to moderate intensity in most patients and resolved in the majority of patients within 2 weeks. Discoloured (black) faeces is expected for an oral iron-based compound, and may visually mask gastrointestinal bleeding. For 4 of the 40 documented concomitant gastrointestinal bleeding events, Velphoro-related stool discolouration was reported as causing an insignificant delay in diagnosis of



gastrointestinal bleeding, without affecting patient health. In the remaining cases, no delay in diagnosis of gastrointestinal bleeding has been reported.

The results from this study showed that the effectiveness of Velphoro in a real-life setting (including concomitant use of other phosphate binders in 45% of patients), was in line with that observed in the phase 3 clinical study.

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות
http://www.health.gov.il
ניתן לקבלם מודפסים על ידי פניה לחברת כצט בע"מ, רח' החרש 4 הוד השרון, 09-7626323

בברכה,
אלון אופיר
רוקח ממונה
כצט בע"מ