ינואר 2021

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רופא/ה, רוקח/ת נכבד/ה,

הנדון: **עדכון עלון לרופא של ולטסה 8.4 גר', ולטסה 16.8 גר'**

VELTASSA 8.4 G, VELTASSA 16.8 G

אנו מבקשים להודיעכם כי העלון לרופא של התכשיר שבנדון עודכן.

ההתוויה המאושרת:

Veltassa is indicated for the treatment of hyperkalaemia in adults.

הרכב וחוזק חומר פעיל:

PATIROMER (AS SORBITEX CALCIUM) 8.4 G, 16.8 G

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

The ability of patiromer to enable concomitant spironolactone treatment in patients with resistant hypertension and CKD was further investigated in a randomised, double-blind, placebo-controlled study over 12 weeks. Normokalaemic patients initiated spironolactone at 25 mg QD together with their randomised treatment (patiromer 8.4 g QD or placebo). Patiromer/placebo was titrated weekly (up to 25.2 g QD) to maintain serum potassium ≥4.0 mEq/L and ≤5.1 mEq/L. At week 3 or after, spironolactone dose was increased to 50 mg QD for subjects with systolic blood pressure ≥120 mmHg and serum potassium ≤5.1 mEq/L.

Of the 295 randomized patients receiving study treatment (patiromer 147; placebo 148), mean age was 68.1 years, 51.9% were men, 98.3% were Caucasian, and mean eGFR was 35.73 mL/min/1.73m2. At randomization, mean baseline serum potassium values were 4.74 mEq/L for patiromer and 4.69 mEq/L for placebo. The primary efficacy endpoint, the proportion of subjects remaining on spironolactone at Week 12, was significantly higher (p<0.0001) in the patiromer group (85.7%) compared to the placebo group (66.2%). Significantly more patients received spironolactone 50 mg/day (69.4% versus 51.4%).

Overall, patients in the patiromer group remained on spironolactone 7.1 days longer (95% CI 2.2–12.0; p=0.0045) compared to the placebo group and received significantly higher cumulative doses of spironolactone (2942.3 (SE 80.1) mg vs 2580.7 (SE 95.8) mg, p=0.0021).

There were also significantly fewer patients in the patiromer group with serum potassium values ≥5.5 mEq/L (35.4% vs. 64.2%, p<0.001).

At Week 12, the mean systolic blood pressure had decreased by 11.0 mmHg (SD 15.34) in the spironolactone + placebo group and by 11.3 mmHg (SD 14.11) in the spironolactone + patiromer group. These decreases from baseline were statistically significant within each treatment group (p<0.0001), but not statistically significant between the groups.

Overall, in the phase 2 and 3 clinical studies, 99.~~4~~5% of patients were receiving RAAS inhibitor therapy at baseline, ~~81.2~~87% had CKD with eGFR <60 mL/min/1.73 m^2, ~~72.8~~65.6% had diabetes mellitus and ~~48.7~~47.5% had heart failure.

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

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