MEDISON
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12/2019

רופא/ה, רוקח/ה נכבדים,

הריני להודיעכם כי העלון לרופא של התכשיר עודכן:

פירדפסה טבליות-FIRDAPSE Tablets

הרכב:

Each tablet contains amifampridine phosphate equivalent to 10 mg of amifampridine

התוויה מאושרת:

Symptomatic treatment of Lambert-Eaton myasthenic syndrome (LEMS) in adults

להלן העדכונים בעלון לרופא:

4.2 Posology and method of administration

~~Genetic differences in N-acetyl transferase enzymes can account for the variable systemic exposure of amifampridine (see sections 4.4 and 5.2).~~

4.4 Special warnings and precautions for use

[.....]

Cardiac effects

Clinical and electrocardiogram (ECG) monitoring are indicated at the initiation of the treatment and yearly thereafter. In case of signs and symptoms indicative of cardiac arrhythmias, ECG should be performed immediately. ~~No clinically relevant ECG morphological changes following administration of amifampridine phosphate were observed in a study of healthy volunteers (see section 5.1).~~

Concomitant diseases

Patients must be told to inform any physician they consult that they are taking this medicinal product, since close monitoring of a concomitant disease, particularly asthma, may be necessary.

~~Acetylation status~~

~~The pharmacokinetics and systemic exposure to amifampridine is notably influenced by the overall metabolic acetylation activity of the polymorphic N-acetyl-transferase (NAT) enzymes (acetylator phenotype) and NAT2 genotype, which is subject to genetic variation (see section 5.2), as shown in the healthy volunteer study. In this study, slow acetylators experienced more adverse reactions than the fast acetylators. The safety profile in this study is consistent with adverse reactions observed with patients on FIRDAPSE.~~

ההסבר לשינוי בעלון לרופא:

The statements in section 4.4 and 4.2 were removed because they provided no additional instruction to the physician .In addition, the information about acetylation status that was removed from 4.4 can be found in section 5.2.

4.8 Undesirable effects

Summary of the safety profile

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~~Lambert-Eaton myasthenic syndrome is a very rare disorder. Consequently, there is little information on the adverse reactions of amifampridine treatment due to the small number of patients involved.~~

ההסבר לשינוי בעלון לרופא:

The general statement removed from 4.8 again was a statement of fact but general and did not add anything.

5.1 Pharmacodynamic properties

5.2 Pharmacokinetic properties

[.....]

In a study of healthy volunteers, systemic exposure of amifampridine was notably influenced by the overall metabolic acetylation activity of NAT enzymes and NAT2 genotype. The NAT genes are highly polymorphic and result in phenotypes with variable acetylation activity rates ranging from slow to fast. In the healthy volunteer study, fast acetylators were defined by having a caffeine metabolite ratio >0.3 and slow acetylators with a caffeine metabolite ratio <0.2. There was significantly higher exposure to amifampridine in slow acetylators compared to fast acetylators. Statistically significant differences in amifampridine PK parameters C_{max}, $AUC_{0-\infty}$, $t_{1/2}$ and apparent clearance was observed between fast and slow acetylators at all dose levels. In this study, slow acetylators experienced more adverse reactions than the fast acetylators. The safety profile in this study is consistent with adverse reactions observed with patients on amifampridine.

לא חל שינוי בעלון לצרכן.

העלון לרופא והעלון לצרכן נמצאים בקישור וכן מפורסם במאגר התרופות באתר משרד הבריאות וניתן לקבלו מודפס על ידי פניה לבעל הרישום.

בברכה,

מגר' חיה שליו
רוקחת ממונה

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