אושר – 5.16

הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך **25.05.2016**

שם תכשיר באנגלית ומספר הרישום **EZETROL 10 MG TABLETS (128-41-30721)**

שם בעל הרישום **Merck Sharp & Dohme (Israel-1996) Company Ltd.**

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
Adolescents ≥ 10 : The safety and efficacy of ezetimibe in adolescents aged 10 to 17 years has not been established. Current available data are described in sections 4.4, 4.8, 5.1 and 5.2 but no recommendation on a posology can be made.	Adolescents ≥ 10 years (pubertal status: boys Tanner Stage II and above and girls who are at least one year post–menarche): No dosage adjustment is required (see section 5.2). The clinical experience in paediatric and adolescent patients (aged 10-17 years old) is, however, limited.	**4. CLINICAL PARTICULARS** **4.2 Posology and method of administration**
Liver Enzymes In the IMProved Reduction of Outcomes: Vytorin Efficacy International Trial (IMPROVE-IT), 18,144 patients with coronary heart disease and ACS event history were randomized to receive ezetimibe/simvastatin 10/40 mg daily (n=9067) or simvastatin 40 mg daily (n=9077). During a median follow-up of 6.0 years, the incidence of consecutive elevations of transaminases (≥3 X ULN) was 2.5% for ezetimibe/simvastatin and 2.3% for simvastatin. (See section 4.8)		**4.4 Special warnings and precautions for use**
Skeletal Muscle In IMPROVE-IT, 18,144 patients with coronary heart disease and ACS event history were randomized to receive ezetimibe/simvastatin 10/40 mg daily (n=9067) or simvastatin 40 mg daily (n=9077). During a median follow-up of 6.0 years, the incidence of myopathy was 0.2% for ezetimibe/simvastatin and 0.1% for simvastatin, where myopathy was defined as unexplained muscle weakness or pain with a serum CK ≥10 times ULN or two consecutive observations of CK		

≥5 and <10 times ULN. The incidence of rhabdomyolysis was 0.1% for ezetimibe/simvastatin and 0.2% for simvastatin, where rhabdomyolysis was defined as unexplained muscle weakness or pain with a serum CK ≥10 times ULN with evidence of renal injury, ≥5 times ULN and <10 times ULN on two consecutive occasions with evidence of renal injury or CK ≥10,000 IU/L without evidence of renal injury. (See section 4.8.)		
Paediatric (6 to 17 years of age) Patients ~~In a study involving paediatric (6 to10 years of age) patients with heterozygous familial or non-familial hypercholesterolaemia (n = 138), elevations of ALT and/or AST (≥ 3X ULN, consecutive) were observed in 1.1% (1 patient) of the ezetimibe patients compared to 0% in the placebo group.~~ There were no elevations of CPK (≥ 10X ULN). No cases of myopathy were reported.		**4.8 Undesirable effects**
Patients with Coronary Heart Disease and ACS Event History In the IMPROVE-IT study (see section 5.1), involving 18,144 patients treated with either ezetimibe/simvastatin 10/40 mg (n=9067; of whom 6% were uptitrated to ezetimibe/simvastatin 10/80 mg) or simvastatin 40 mg (n=9077; of whom 27% were uptitrated to simvastatin 80 mg), the safety profiles were similar during a median follow-up period of 6.0 years. Discontinuation rates due to adverse experiences were 10.6% for patients treated with ezetimibe/simvastatin and 10.1% for patients treated with simvastatin. The incidence of myopathy was 0.2% for ezetimibe/simvastatin and 0.1% for simvastatin, where myopathy was defined as unexplained muscle weakness or pain with a serum CK ≥10 times ULN or two consecutive observations of CK ≥5 and <10 times ULN. The incidence of rhabdomyolysis was 0.1% for ezetimibe/simvastatin and 0.2% for simvastatin, where rhabdomyolysis was defined as unexplained muscle weakness or pain with a serum CK ≥10 times ULN with evidence of renal injury, ≥5 times ULN and <10 times ULN on two consecutive occasions with evidence of renal injury or CK ≥10,000 IU/L without evidence of renal injury. The incidence of consecutive elevations of transaminases (≥3 X ULN) was 2.5% for ezetimibe/simvastatin and 2.3% for simvastatin. (See section 4.4.)		

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פרק בעלון	**טקסט נוכחי**	**טקסט חדש**
	בראש העלון ובסעיף **3. איך תשתמש באזטרול?** **אזטרול** אינו מומלץ לילדים מתחת לגיל 10.	**2.8 ילדים ומתבגרים** אין לתת תרופה זו לילדים ומתבגרים בגילאים (10 עד 17 שנים), אלא אם המרשם ניתן על ידי מומחה, מכיוון שקיים מידע מוגבל בנוגע לבטיחות ויעילות. תרופה זו אינה מומלצת לילדים מתחת לגיל 10.