MEDISON

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ספטמבר 2026

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

הריני להודיעכם כי העלונים לרופא ולצרכן של התכשיר עודכנו:

SKYCLARYS **סקייקלריס**

PER OS

מרכיב פעיל : omaveloxolone

התוויה מאושרת :

Skyclarys is indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older.

להלן העדכונים בעלון לרופא שהינם מהווים החמרות (מסומנים בירוק):

4.6 Fertility, pregnancy and lactation

~~There are no data on the presence of omaveloxolone in human milk.~~

In a clinical lactation study, omaveloxolone was shown to be excreted into human breast milk, and a minimal (<2%) mean relative infant dose of 0.37% was determined after a single 150 mg oral dose of omaveloxolone (see section 5.2). Plasma concentration of omaveloxolone in breastfed infants is unknown.

There is no clinical experience in breastfed infants, and aA risk of omaveloxolone to the newbornbreastfed infant cannot be excluded.

The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for omaveloxolone and any potential adverse effects on the breastfed child from omaveloxolone or from the underlying maternal condition.

Omaveloxolone is present in the milk of lactating rats and resulted in treatment-related effects in offspring (see section 5.3). ~~A risk to the newborn infant cannot be excluded. Skyclarys should not be used during breast-feeding.~~

5.2 Pharmacokinetic properties

Distribution into breast milk

The distribution of omaveloxolone into human breast milk was studied in a group of 12 healthy lactating women following oral administration of a single dose of 150 mg. The results indicate that breast milk-fed infants may be exposed to a small fraction of the adult dose, with a geometric mean

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daily infant dose of 0.0076 mg/kg/day, resulting in a geometric mean relative infant dose of 0.37%. Lactation did not alter the pharmacokinetic profile of omaveloxolone in lactating women. The plasma protein binding of omaveloxolone in this population was 98.4%.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology~~, and~~ genotoxicity~~, and carcinogenic~~ potential.

~~Based on a panel of in vitro and in vivo mutagenicity tests, omaveloxolone is considered of low genotoxic potential. Omaveloxolone was not carcinogenic in a 6-month carcinogenicity study in rasH2 mice up to doses corresponding to approximately 14.6 and 54.5 times in males and females, respectively, the maximum human recommended dose (MHRD) and systemic exposure (AUC) in patients with Friedreich's ataxia.~~

Repeat dose toxicity

~~Preclinical data revealed toxicities related to omaveloxolone.~~ In rats, ~~findings of~~omaveloxolone administration was associated with irreversible kidney injury (multifocal renal tubular degeneration/regeneration accompanied by proteinuria) ~~were observed~~ at clinically relevant dose levels in rats after 28 days of daily oral exposure up to 6 months.
Furthermore, reversible ~~observations of~~ hyperplasia of the GI tract (forestomach, oesophagus, larynx) was observed in rats and monkeys already after 28 days of dosing, up to 6 or 9 months in rats and monkeys, respectively. In one male rat from the high dose group at 6 months dosing, the squamous epithelial hyperplasia was associated with a squamous cell carcinoma involving the non-glandular and glandular stomach.

Genotoxicity

Based on a panel of in vitro and in vivo mutagenicity tests, omaveloxolone is considered of low genotoxic potential.

Carcinogenicity

Omaveloxolone was not carcinogenic in a 6-month study in male and female rasH2 transgenic mice at each 14.6- and 54.5-fold the AUC-based systemic exposure in humans receiving the maximum recommended human dose (MRHD). A long-term carcinogenicity study of omaveloxolone over 85 and 87 weeks in female and male rats revealed neoplastic findings in the liver (bile ducts: cholangioma and cholangiocarcinoma), mammary gland (adenocarcinoma and sarcoma), testis (Leydig cell adenoma), and rectum (squamous cell papillomas) at dose levels of ≥1 mg/kg corresponding to an exposure level of less than 1-fold the clinical plasma exposure at the MRHD. The human relevance is currently unknown.
[…]

להלן העדכונים בעלון לצרכן שהינם מהווים החמרות (מסומנים בירוק):

הנקה

~~לא ידוע אם~~התרופה עוברת לחלב האם. ~~אל תניקי את תינוקך בזמן שאת מטופלת~~עליך לדון עם הרופא שלך על סיכון ותועלת של נטילת ב~~סקייקלריס~~ במהלך הנקה.

העלון לרופא והעלון לצרכן נמצאים בקישור, וכן מפורסמים במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על ידי פניה לבעל הרישום.

בברכה,

מדיסון פארמה בע"מ

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