MEDISON

We are **Always Ahead** | We **Grow as One** | We **Care**

יולי 2026

רופא/ה נכבד/ה
רוקח/ת נכבד/ה,

הריני להודיעכם כי העלון לרופא של התכשירים הבאים עודכן:

Voranigo 10 mg film-coated tablets	**וורניגו 10 מ"ג טבליות מצופות**
Voranigo 40 mg film-coated tablets	**וורניגו 40 מ"ג טבליות מצופות**

Film Coated Tablets

מרכיב פעיל : **vorasidenib**

התוויה מאושרת :

VORANIGO is indicated for the treatment of adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation, following surgery including biopsy, sub-total resection, or gross total resection.

<u>להלן העדכון בעלון לרופא:</u>

7 WARNINGS AND PRECAUTIONS

7.1 Hepatotoxicity

VORANIGO can cause hepatic transaminase elevations, which can lead to hepatic failure, hepatic necrosis, and autoimmune hepatitis.

In the pooled safety population *[see Adverse Reactions (8.1)]*, 58% of patients treated with VORANIGO experienced increased ALT and 44% of patients experienced increased AST. Grade 3 or 4 increased ALT or AST occurred in 9% and 4.8% of patients respectively. Among these patients, 4.1% (10/244) had concurrent Grade 3 to 4 ALT or AST elevations. A total of 34% of patients treated with VORANIGO had increased gamma-glutamyl transferase (GGT), of these 2.2% were Grade 3 or 4. Bilirubin increases occurred in 4.8% of patients treated with VORANIGO, with 0.4% Grade 3 or 4. Nine percent of patients treated with VORANIGO had increased alkaline phosphatase, with 0.9% Grade 3 or 4.

Two patients met the laboratory criteria for Hy's Law and had concurrent elevations in ALT or AST >3 times the upper limit of normal and total bilirubin >2 times the upper limit of normal; these events were associated with cases of autoimmune hepatitis and hepatic failure. The median time to first onset of increased ALT or AST was 57 days (range: 1 to 1049).

Acute hepatitis occurred in the postmarketing setting.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity studies have not been conducted with vorasidenib. Vorasidenib and its major circulating metabolite, AGI-69460, were not mutagenic in an in vitro bacterial reverse mutation (Ames) assay. Vorasidenib ~~was~~ and AGI-69460 were not clastogenic in an in vitro human lymphocyte micronucleus assay, or an in vivo rat bone marrow micronucleus assay. AGI-69460 did not induce DNA damage in rat liver in the in vivo comet assay.

לא נעשה עדכון בעלון לצרכן.

Medison Pharma Ltd.
10 Hashiloach St., P.O.B 7090, Petach-Tikva 4917002 Israel
Tel. +972. 3. 925. 0250, Fax. +972. 3. 922. 5740
medisonpharma.com

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העלון לרופא נמצא בקישור, וכן מפורסם במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס על ידי פניה לבעל הרישום.

בברכה,

מדיסון פארמה בע"מ

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