ספטמבר 2022

Ocrevus® 300 mg/10 ml
ocrelizumab
Concentrate for solution for infusion

רופא/ה יקר/ה, רוקח/ת יקר/ה,

חברת רוש פרמצבטיקה (ישראל) בע"מ מבקשת להודיעכם על עדכונים שבוצעו בעלון לרופא של התכשיר אוקרווא‌ס.

בהודעה זו מצוינים רק עדכונים מהותיים.

ההתוויות הרשומות לתכשיר בישראל:

Ocrevus is indicated for the treatment of adult patients with relapsing or primary progressive forms of multiple sclerosis.

הסבר:
טקסט עם קו תחתי מציין טקסט שהוסף לעלון.
~~טקסט עם קו חוצה~~ מציין טקסט שהוסר מן העלון.

למידע נוסף יש לעיין בעלון לרופא כפי שנשלח למשרד הבריאות.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפס ע"י פנייה לבעל הרישום: רוש פרמצבטיקה (ישראל) בע"מ, ת.ד 6391 , הוד השרון 4524079
טלפון 09-9737777. כתובתנו באינטרנט: www.roche.co.il.

ב ב ר כ ה,

בתאור צפרי-חג'ג'
מחלקת רישום

לביא עמי-עד
רוקח ממונה

עדכונים מהותיים בעלון לרופא

בסעיף 5 Warnings and Precautions עודכן המידע הבא:

5.2 Infections

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Hepatitis B Virus (HBV) Reactivation

~~There were no reports of hepatitis B reactivation in MS patients treated with Ocrevus.~~ Hepatitis B reactivation has been reported in MS patients treated with Ocrevus in the postmarketing setting. Fulminant hepatitis, hepatic failure, and death caused by HBV reactivation have occurred in patients treated with ~~other~~ anti-CD20 antibodies. Perform HBV screening in all patients before initiation of treatment with Ocrevus. Do not administer Ocrevus to patients with active HBV confirmed by positive results for HBsAg and anti-HB tests. For patients who are negative for surface antigen [HBsAg] and positive for HB core antibody [HBcAb+] or are carriers of HBV [HBsAg+], consult liver disease experts before starting and during treatment.

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5.3 Progressive Multifocal Leukoencephalopathy (PML)

Cases of progressive multifocal leukoencephalopathy (PML) have been reported in patients with MS treated with Ocrevus in the postmarketing setting. PML is an opportunistic viral infection of the brain caused by the JC virus (JCV) that typically only occurs in patients who are immunocompromised, and that usually leads to death or severe disability. PML has occurred in Ocrevus-treated patients who had not been treated previously with natalizumab (which has a known association with PML), were not taking any immunosuppressive or immunomodulatory medications associated with the risk of PML prior to or concomitantly with Ocrevus, and did not have any known ongoing systemic medical conditions resulting in compromised immune system function.

JCV infection resulting in PML has also been observed in patients treated with other anti-CD20 antibodies and other MS therapies.

At the first sign or symptom suggestive of PML, withhold Ocrevus and perform an appropriate diagnostic evaluation. Typical symptoms associated with PML are diverse, progress over days to weeks, and include progressive weakness on one side of the body or clumsiness of limbs, disturbance of vision, and changes in thinking, memory, and orientation leading to confusion and personality changes.

MRI findings may be apparent before clinical signs or symptoms. Cases of PML, diagnosed based on MRI findings and the detection of JCV DNA in the cerebrospinal fluid in the absence of clinical signs or symptoms specific to PML, have been reported in patients treated with other MS medications associated with PML. Many of these patients subsequently became symptomatic with PML. Therefore, monitoring with MRI for signs that may be consistent with PML may be useful, and any suspicious findings should lead to further investigation to allow for an early diagnosis of PML, if present. Following discontinuation of another MS medication associated with PML, lower PML-related mortality and morbidity have been reported in patients who were initially asymptomatic at diagnosis compared to patients who had characteristic clinical signs and symptoms at diagnosis.

It is not known whether these differences are due to early detection and discontinuation of MS treatment or due to differences in disease in these patients.

If PML is confirmed, treatment with Ocrevus should be discontinued.

5.5 Immune-Mediated Colitis

Immune-mediated colitis, which can present as a severe and acute-onset form of colitis, has been reported in patients receiving Ocrevus in the postmarketing setting. Some cases of colitis were serious, requiring hospitalization, with a few patients requiring surgical intervention. Systemic corticosteroids were required in many of these patients. The time from treatment initiation to onset of symptoms in these cases ranged from a few weeks to years. Monitor patients for immune-mediated colitis during Ocrevus treatment, and evaluate promptly if signs and symptoms that may indicate immune-mediated colitis, such as new or persistent diarrhea or other gastrointestinal signs and symptoms, occur.

בסעיף 6 Adverse Reactions עודכן המידע הבא:

The following serious adverse reactions are discussed in greater detail in other sections of the labeling:

- Infusion Reactions *[see Warnings and Precautions (5.1)]*
- Infections *[see Warnings and Precautions (5.2)]*
- Progressive Multifocal Leukoencephalopathy *[see Warnings and Precautions (5.3)]*
- Malignancies *[see Warnings and Precautions (5.4)]*
- Immune-Mediated Colitis *[see Warnings and Precautions (5.5)]*

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6.3 Postmarketing Experience

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Gastrointestinal Disorders: Immune-mediated colitis [see Warnings and Precautions (5.5)]

Infections and Infestations: Serious herpes infections ~~have been identified during postapproval use of Ocrevus~~ [see Warnings and Precautions (5.2)] and progressive multifocal leukoencephalopathy [see Warnings and Precautions (5.3)].

בסעיף 8 Use in Specific Populations עודכן המידע הבא:

8.3 Females and Males of Reproductive Potential

Contraception

Women of childbearing potential should use effective contraception while receiving Ocrevus and for 6 months after the last infusion of Ocrevus *[see Clinical Pharmacology (12.3)]*.