Ocrevus® (Ocrelizumab):

Indications:ocrevus is indicated for the treatment of adult patients with active relapsing forms of multiple sclerosis (MS),and primary progressive multiple sclerosis (PPMS) to delay disease progression and reduce deterioration in walking speed.

Recommended premedication: To reduce possible IRRs: The following two premedications must be given before each ocrevus infusion to reduce the frequency and severity of IRRs:100 mg IV methylprednisolone (or equivalent) approximately 30 minutes before each ocrevus infusion, an antihistamine approximately 30 to 60 minutes before each ocrevus infusion, In addition, premedication with an antipyretic (e.g. paracetamol/acetaminophen) may also be considered approximately 30 to 60 minutes before each ocrevus infusion.

Recommended dosage and administartion: The initial 600 mg dose (dose 1) is divided into two separate IV infusions, i.e. administered as two 300 mg infusions two weeks apart. Subsequent ocrevus doses are administered as a single 600 mg dose by IV infusion every 6 months. A minimum interval of 5 months should be maintained between separate ocrevus doses. If a planned infusion of ocrevus is missed, it should be administered as soon as possible; do not wait until the next scheduled dose. The treatment interval for ocrevus should be maintained between individual doses.

Contraindications: Hypersensitivity to ocrelizumab or any of the excipients, patients with severe heart failure (NYHA class IV), Patients with severe immunosuppression, including patients who are currently receiving immunosuppressive therapy (other than symptomatic treatments with corticosteroids for relapses) or whose immune system is compromised by prior therapies, presence of active infection, Existing active malignancies except for patients with cutaneous basal cell carcinoma and Initiation of treatment during pregnancy.

Warnings and precautions: Infusion-related reactions: Ocrevus can cause infusion-related reactions (IRRs) that symptoms of IRRs may occur during any infusion, but have been most frequently reported during the first infusion. IRRs can occur within 24 hours of the infusion. These reactions may present as pruritus, rash, urticaria, erythema, throat irritation, oropharyngeal pain, dyspnea, pharyngeal or laryngeal edema, flushing, hypotension, pyrexia, fatigue, headache, dizziness, nausea and tachycardia. Patients treated with ocrevus should be observed for at least one hour after the completion of the infusion for any symptom of an IRR. In patients with severe pulmonary symptoms such as bronchospasm or asthma exacerbation, the infusion must be immediately and permanently discontinued. **Infections:** In patients with an active infection, ocrevus administration must be delayed until the infection has resolved . Further information on the risk factors for serious infections associated with conditions other than MS can be found in the " Undesirable effects " section of Ocrevus Product Information. **Progressive multifocal leukoencephalopathy (PML):** No cases of PML have occurred in ocrevus clinical trials. The risk of PML with ocrevus cannot be ruled out. **Hepatitis B reactivation:** There have been no reports of hepatitis B reactivation in MS patients treated with ocrevus. HBV screening should be performed in all patients before initiation of treatment with ocrevus as per local guidelines. Patients with active hepatitis B virus (HBV) infection must not be treated with ocrevus. **Vaccinations:** No data are available on the effects of vaccination in patients receiving ocrevus. Physicians should review the immunization status of patients and follow the current vaccination recommendations before treatment with ocrevus. Vaccination should be completed at least 6 weeks prior to first administration of ocrevus. **Malignancies:** Cases of malignancy were reported in clinical trials (including 6 cases of breast cancer on ocrevus, no cases in the control arms [rebif or placebo] of the controlled trials). The incidence was within the background rate expected in MS patients. **Pregnancy:** There are no adequate and well-controlled data from studies in pregnant women; however, transient peripheral B-cell depletion and lymphopenia have been reported in infants born to mothers given other anti-CD20 antibodies during pregnancy. Treatment must not be initiated during pregnancy. Women of childbearing potential should use reliable contraception during ocrevus treatment and for 6 months after the last ocrevus infusion .Ocrevus should not be used during pregnancy unless the potential benefit to the mother outweighs the potential risk to the fetus. **Lactation:** It is not known whether ocrevus is excreted in human milk or has any effect on the breastfed child or on milk production. Because human IgG is excreted in breast milk, and the potential for B-cell depletion due to ocrevus absorption is unknown, women should be advised to discontinue breastfeeding during ocrelizumab therapy.

Undesirable effects: Summary of ADRs occurring with ocrevus in RMS or PPMS: Very common: Upper respiratory tract infection, nasopharyngitis, influenza, Infusion-related reactions, IgM serum levels decreased. Common: Bronchitis, sinusitis, gastroenteritis, viral infection, oral herpes, respiratory tract infection, cellulitis, herpes zoster, conjunctivitis, cough, catarrh, IgG serum levels decreased. Physicians should refer to the Ocrevus Product Information in relation to other adverse reactions.

Packs: Vial 300 mg/10 ml.

Prescription only medicine
Marketing authorization holder : F. Hoffmann-La Roche Ltd, Basel, Switzerland.
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For any queries on the product or report an adverse event please contact : Roche Pars (F. Hoffmann-La Roche Ltd in Iran)**:** North unit, 9th Floor, No. 3, Aftab St., Vanak St., Tehran, Iran, Postal code: 1994834592 .
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