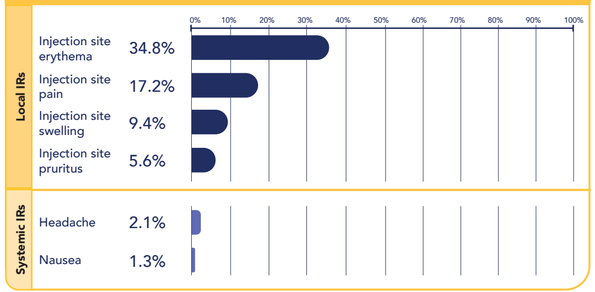
The benefits of OCREVUS®, delivered in just 10 minutes[1]

- OCREVUS® SC offers the **speed** and **convenience** of subcutaneous administration and delivers **comparable efficacy and safety** to that of OCREVUS® IV[1]
- Administration of OCREVUS® SC showed non-inferior serum exposure to OCREVUS® IV during the first 12 weeks of clinical trial[1,2]
- The safety profile of OCREVUS® SC was consistent with the known safety profile of intravenous ocrelizumab, except for the very common adverse reaction of injection reactions (IRs):[2]

Most common IRs with OCREVUS® Subcutaneous injection:[2]



Dosing of OCREVUS® Subcutaneous injection[1]

DAY 1

Initial dose: One single subcutaneous injection of 920 mg (23 mL)

Injection time: Administration of the injection itself takes around 10 minutes, and should be done under clinical observation with appropriate instruments

NOTE: See timing for all OCREVUS® administration stages at the end of this page

EVERY 6 MONTHS

Subsequent doses are given as a single injection of 920 mg (23 mL) every 6 months

NOTE: A minimum interval of 5 months should be maintained between each dose of OCREVUS®

PRE-INJECTION MEDICATION

Pre-medication is given orally shortly before each administration. This will include:

- 20 mg oral dexamethasone (or equivalent)
- Oral antihistamine (desloratadine or equivalent)
- Pre-medication with antipyretic (e.g. paracetamol) may also be considered shortly before each administration

Total administration time[1]

Administration time for OCREVUS® Subcutaneous injection takes approximately 10 minutes. **Please factor in enough time for check-In and pre-medication administration.**

OCREVUS® SC: Administration stages & times[1]

Injection time:	approx 10 minutes
Post-injection observation time*: **NOTE:** Mandatory post-injection time for first dose.	1 hr

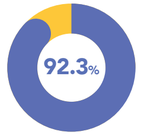
*For subsequent doses, post-observation time is at the treating physician's discretion.

OCREVUS® subcutaneous injection (SC) demonstrates comparable clinical benefits and safety vs OCREVUS® for IV use[1]

- The overall safety profile of OCREVUS® SC observed in OCARINA I and II is comparable with the well-established safety profile of OCREVUS® IV:[1]
  - Difference in AEs between IV and SC routes was driven by nonserious, mild and moderate IRs, which were non-treatment limiting and resolved[1]
  - There were no AEs leading to withdrawal from treatment in either group and few patients required symptomatic treatment with analgesics and antihistamines[1]
  - No anti-drug antibodies to OCREVUS® were found. The incidence of treatment-emergent anti rHuPH20 antibodies was low for OCARINA I (2.3% or 3/132) and none for OCARINA II[1]

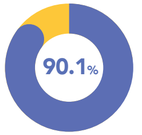
Select a new mode of administration with high patient satisfaction

- Patient satisfaction is highly correlated with adherence to treatment[3]



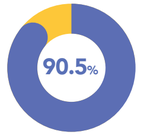
Satisfaction

The majority of patients were either satisfied or very satisfied with the SC procedure (205/222 patients)[2]



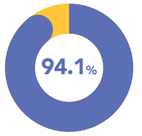
Convenience

The majority of patients felt that the SC procedure was convenient or very convenient (200/222 patients)[2]



Time Taken

The majority of patients felt that the time taken to get the injection was just right (200/221 patients)[2]



Recommended

Most of the patients would recommend the SC route of administration to other patients (209/222 patients)[2]

How could OCREVUS® SC redefine what MS care means for your patients?

OCREVUS® SC: Ten years of experience in MS, delivered in ten minutes

The heritage you trust – Comparable efficacy and safety to OCREVUS® IV[1]

At the speed you need – The speed and convenience of 10-minute SC administration with the established benefits of OCREVUS® IV[1]

With the impact you want – Reduced time-to-treatment compared to IV with streamlined dosing to help reduce treatment burden for patients and HCP workload[1]

Comparable clinical benefits vs OCREVUS® IV[2]

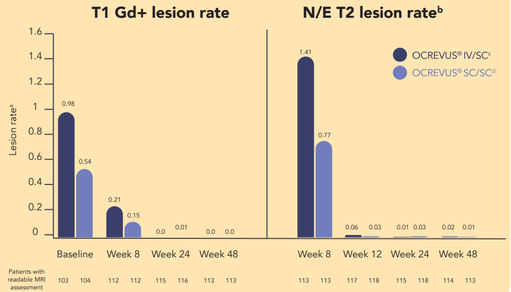
Similar to OCREVUS® IV, OCREVUS® SC 920 administration resulted in near complete supression at week 48 of:

Relapses

97.2% (n=104/107) of patients at Week 48 were free of relapses following OCREVUS® SC administration during the treatment phase or safety follow-up[6]

Radiological MRI disease activity

Radiologic and clinical effects at Week 48[6]



[a]The lesion rate is the total number of lesions divided by the number of patients with a readable MRI assessment at the visit; [b]New or enlarging T2 lesion count measurement is performed with respect to the previous scheduled available visit; [c]At baseline for T1 Gd+ lesions, 78/103 (75.7%) patients had no lesions and 11/103 (10.7%) had ≥4 lesions; [d]At baseline for T1 Gd+ lesions, 82/104 (78.8%) patients had no lesions and 5/104 (4.8%) had ≥4 lesions. *Two patients (1.9%) in each arm had one relapse and one patient (0.9%) in the OCR SC/SC arm had two relapses at Week 48; unadjusted relapse rate per year was 0.04 and 0.02 in the SC/SC and IV/SC arms, respectively. The unadjusted annualized relapse rate is the total number of relapses for all patients in the considered group divided by the total follow-up time.

SC, subcutaneous; MS, multiple sclerosis; IV, intravenous; AUC, area under the serum concentration–time curve; CI, confidence interval; Cmax, maximum serum concentration; GMR, geometric mean ratio; PK, pharmacokinetic; IR, injection reaction; AE, adverse event; rHuPH20, recombinant human hyaluronidase; HCP, healthcare professional

References:

1. OCREVUS Subcutaneous®(ocrelizumab subcutaneous) prescribing information. Roche[April] 2024.
2. OCARINA II Oral – Newsome et al; April 13–18, 2024; Denver, CO, USA.
3. Barbosa CD et al. Patient Prefer Adherence. 2012;6:39–48. doi: 10.2147/PPA.S24752.

ABRIDGED PRESCRIBING INFORMATION (API)

Ocrevus (ocrelizumab)

Ocrevus Solution for subcutaneous injection: 920 mg/23 mL (40 mg/mL) in a single-dose vial. **For full prescribing information, please refer to locally approved Product Information (PI) prior to use of Ocrevus.** Indications Ocrevus is indicated for the treatment of adult patients with relapsing forms of multiple sclerosis (RMS) with active disease defined by clinical or imaging features and treatment of adult patients with early primary progressive multiple sclerosis (PPMS) in terms of disease duration and level of disability, and with imaging features characteristic of inflammatory activity. **Dosage and Administration:** 920 mg administered as a subcutaneous injection in the abdomen in approximately 10 minutes every 6 months. No division of the initial dose or subsequent doses into separate administrations is required. Injection instructions should be followed as per the PI. **Contra-indications** Hypersensitivity to Ocrevus or any of the excipients. Patients in a severely immunocompromised state. Known active malignancies. **Precautions:** Treatment with subcutaneous Ocrevus is associated with IRs, which may be related to cytokine release and/or other chemical mediators. Hypersensitivity reactions may occur (acute IgE-mediated allergic reaction to the medicinal product). If a hypersensitivity reaction is suspected, the injection must be stopped immediately and permanently. Administration of Ocrevus must be delayed in patients with an active infection until the infection is resolved. Ocrevus must not be administered to severely immunocompromised patients. Progressive multifocal leukoencephalopathy (PML): Infections with the John-Cunningham (JC) virus, which caused PML, have been observed very rarely in patients treated with anti-CD20 antibodies, including Ocrevus, and mostly associated with risk factors. Physicians should be vigilant for the early signs and symptoms of PML, which can include any new onset, or worsening of neurological signs or symptoms, as these can be similar to MS disease. Hepatitis B virus (HBV) reactivation has been reported in patients treated with anti-CD20 antibodies Patients with active HBV (i.e. an active infection confirmed by positive results for HBsAg and anti HB testing) should not be treated with Ocrevus. Cases of late onset of neutropenia have been reported. Although some cases were Grade 3 or 4, the majority of the cases were Grade 1 or 2. Cases of late onset of neutropenia have been reported at least 4 weeks after the latest Ocrevus infusion. In patients with signs and symptoms of infection, measurement of blood neutrophils is recommended. Although some cases were Grade 3 or 4, the majority of the cases were Grade 1 or 2. In other autoimmune conditions, coadministration of Ocrevus and immunosuppressive medications (e.g. chronic corticosteroids, non-biologic and biologic disease-modifying antirheumatic drugs [DMARDS], mycophenolate mofetil, cyclophosphamide, azathioprine) resulted in an increase of serious infections, including opportunistic infections. Physicians should review the immunization status of patients, follow the current regional vaccination recommendations and administer important booster shots before starting treatment with Ocrevus. Vaccinations should be completed at least 6 weeks prior to first administration of Ocrevus. Due to potential B-cell depletion in neonates and infants of mothers who have received Ocrevus during pregnancy, infants must be monitored for B-cell depletion. Cases of malignancy were reported in clinical trials. **Pregnancy and Lactation:** Treatment must not be initiated during pregnancy. It is not known whether Ocrevus is excreted in human milk or has any effect on the breastfed child or on milk production. Animal studies have shown excretion of Ocrevus in the milk. **Adverse reactions:** The most important and frequently reported adverse reactions were IRRs (34.3%, 40.1% in RMS and PPMS, respectively) and infections (58.5%, 72.2% in RMS and PPMS, respectively). The safety profile of Ocrevus solution for injection was consistent with the known safety profile of intravenous Ocrevus. The frequency categories are defined as very common (≥1/10), common (≥1/100 to <1/10). Very common: Upper respiratory tract infection (RMS: 15.2%; PPMS: 12.1%), nasopharyngitis (PPMS: 24.1%; RMS: 14.9%), influenza (PPMS: 11.7%; RMS: 4.6%), IgM serum levels decreased (RMS: 16.5%, PPMS: 15.5%), Infusion-related reactions (PPMS: 40.1%; RMS: 34.3%) Common: Bronchitis, sinusitis, gastroenteritis, viral infection, oral herpes, respiratory tract infection, cellulitis, herpes zoster, conjunctivitis, Neutropenia, cough, catarrh, IgG serum levels decreased Legal Category: Medicinal product subject to restricted medical prescription. **Ref:** Ocrevus Subcutaneous GCC Label April 2024 **Date of Preparation**: October 2024

Full prescribing information is available upon request
In case of any adverse event occurring with any of Roche products, please forward details to gulf.safety@roche.com
In case of any medical query regarding any of Roche products, please forward details to e-mail: kuwait.medinfogulf@roche.com
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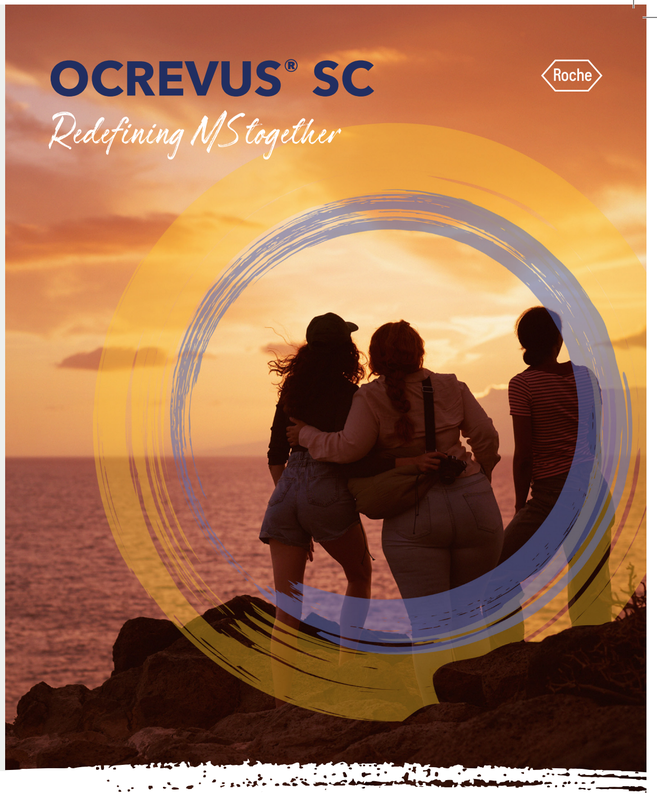
OCREVUS® ocrelizumab Subcutaneous injection



OCREVUS® ocrelizumab Subcutaneous injection