Basic Succinct Statement

BONSPRI® 20 mg/0.4 mL solution for injection

Important note: Before prescribing, consult full prescribing information.

Presentation:

20 mg/0.4 mL Solution for injection in a pre-filled syringe

Each pre-filled syringe contains 20 mg ofatumumab solution for injection (0.4 mL of 50 mg/mL solution).

Indications:

BONSPRI is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

Dosage and administration:

Adults: The recommended dose is 20 mg BONSPRI administered by subcutaneous injections with initial dosing at weeks 0, 1 and 2, followed by subsequent monthly dosing, starting at week 4.

Contraindications:

History of confirmed hypersensitivity to BONSPRI.

Warnings and precautions:

♦Injection site reaction (local) symptoms observed in clinical studies include erythema, swelling, itching and pain. ♦Systemic injection-related reactions (SIRRs) occurred predominantly with the first injection. Symptoms observed include fever, headache, myalgia, chills and fatigue and were predominantly (99.7%) non-serious and mild to moderate in severity. ♦Additional SIRRs reported in the post-marketing setting include rash, urticaria, dyspnea, angioedema (e.g., tongue, pharyngeal or laryngeal swelling), and rare cases which were reported as anaphylaxis. Most of the cases were non-serious and occurred with first injection. While there were some cases which were serious and resulted in discontinuation of BONSPRI treatment, there were also serious cases where patients were able to continue BONSPRI treatment without further incidents. ♦Some SIRR symptoms may be clinically indistinguishable from Type 1 acute hypersensitivity reactions (IgE-mediated). ♦Inform patients that injection-related reactions generally occur within 24 hours and predominantly following the first injection. SIRRs can be managed with symptomatic treatment, should they occur. ♦A hypersensitivity reaction may present with any injection, although typically would not present with the first injection. For subsequent injections, more severe symptoms than previously experienced, or new severe symptoms, should prompt consideration of a potential hypersensitivity reaction. Patients with known IgE mediated hypersensitivity to BONSPRI must not be treated. ♦First injection should be performed under the guidance of an appropriately trained healthcare professional. ♦It is recommended to evaluate the patient's immune status prior to initiating therapy. BONSPRI has the potential for an increased risk of infections.

BONSPRI administration should be delayed in patients with active infection until the infection is resolved. ♦Vigilance is advised for clinical symptoms or MRI findings that may be suggestive of progressive multifocal leukoencephalopathy (PML). If PML is suspected, treatment with BONSPRI should be suspended. ♦ BONSPR**I** treatment should not be initiated in patients with active hepatitis B (HBV) infection until the infection has been adequately treated. Perform HBV screening in all patients before initiation of treatment with BONSPRI. Patients with positive serology should consult liver disease experts before start of treatment. ♦Vaccinations: Administer all required immunizations at least 4 weeks prior to initiation of BONSPRI for live or live-attenuated vaccines and, whenever possible, at least 2 weeks prior to initiation of BONSPRI for inactivated vaccines. BONSPR**I** may interfere with the effectiveness of inactivated vaccines. Administering live or live-attenuated vaccines to neonates and infants exposed to ofatumumab in utero should be avoided until B-cell recovery occurs.

Pregnancy, lactation, females and males of reproductive potential

Pregnancy: There are no or limited amount of data from the use of BONSPRI in pregnant women. BONSPRI may cause fetal B-cell depletion.

Lactation: Published data suggest that antibodies in breast milk do not enter the neonatal and infant circulations in substantial amounts. The potential for absorption of ofatumumab to lead to B-cell depletion in the infant is unknown. The developmental and health benefits of breast-feeding should be considered along with the mother's clinical need for BONSPRI and any potential adverse effects on the breast-fed infant from BONSPRI.

Females and males of reproductive potential: Women of childbearing potential should use effective contraception while receiving BONSPRI and for 6 months after the last treatment of BONSPRI.

Adverse drug reactions:

- ***Very common (≥10%)****:* upper respiratory tract infections, injection-related reactions (local) injection-related reactions (systemic)
- ***Common (≥1 to <10%)****:* back pain, blood immunoglobulin M decreased.
- ***Unknown:*** hypersensitivity reaction, liver injury

Interactions:

The risk of additive immune system effects should be considered when coadministering immune-modulating or immunosuppressive therapies with BONSPRI. When switching from drugs with prolonged immune effects, such as ocrelizumab, cladribine, fingolimod, natalizumab, teriflunomide, mitoxantrone or dimethyl fumarate, the duration and mode of action of these drugs should be considered because of potential additive immunosuppressive effects when initiating BONSPRI.

Packs Bonspri 20mg/0.4ml solution for injection in pre-filled syringe – 1 pre-filled syringe per pack.

Before prescribing, please consult full prescribing information available from Novartis Healthcare Private Limited**,** Inspire BKC, 7th Floor, Bandra Kurla Complex, Bandra (E) Mumbai 400051, Maharashtra, India. Tel +91 22 50243000

WARNING: To be sold by retail on the prescription of a Registered Neurologist only.

India BSS dated 26 Jul 2024, revised on 10 Mar 2026 based on the International BSS dated 09 Aug 2023, effective from 10 Mar 2026.