

Prescribing information: AVONEX® (interferon beta-1a)

Please refer to the Summary of Product Characteristics for further information.

Indication: For the treatment of patients with relapsing multiple sclerosis or patients who have experienced a single demyelinating event with an active inflammatory process who are determined to be at high risk of developing clinically definite multiple sclerosis. **Dosage and Administration:** 30 µg injected IM once a week. **Contraindications:** Initiation of treatment in pregnancy. Patients with a history of hypersensitivity to any of the constituents. Patients with severe depression and/or suicidal ideation; **Warnings & Precautions:** Use with caution in patients with previous or current depressive disorders - depression and suicidal ideation are known to occur in increased frequency in the multiple sclerosis population in association with interferon use. Administer with caution to patients with a history of seizures, or receiving treatment with anti-epileptics, particularly if their epilepsy is not adequately controlled with anti-epileptics. Use with caution & monitor closely in patients with cardiac disease, severe renal or hepatic failure or severe myelosuppression. Routine periodic blood chemistry and haematology tests are recommended during treatment. Development of neutralizing antibodies to AVONEX may decrease efficacy. **Pregnancy & lactation:** Initiation of treatment is contraindicated during pregnancy. Women of child bearing potential should take appropriate contraceptive measures. If the patient becomes pregnant or plans to become pregnant, or breast feeding while taking AVONEX, discontinuation of therapy should be considered. **Drug interactions:** No formal interaction studies have been conducted with AVONEX in humans. Corticosteroids or ACTH can be given during relapses. Caution should be exercised in combining AVONEX with products with a narrow therapeutic index and dependent on cytochrome P450 for clearance. **Side Effects:** The most commonly reported symptoms are of the flu-like symptoms: myalgia, fever, chills, asthenia, headache and nausea. Other common events include: Investigations decreased; lymphocyte count, white blood cell count, neutrophil count, haematocrit and increased blood potassium and blood urea nitrogen. Nervous system disorders: muscle spasticity, hypoesthesia. Respiratory, thoracic and mediastinal disorders: rhinorrhoea. Gastrointestinal disorders: vomiting, diarrhoea, nausea. Skin and subcutaneous tissue disorders: rash, increased sweating, contusion. Musculoskeletal and connective tissue disorders: muscle cramp, neck pain, myalgia, arthralgia, pain in extremity, back pain, muscle stiffness, musculoskeletal stiffness. Metabolism and nutrition disorders: anorexia. Vascular disorders: flushing. General disorders and administration site conditions: flu-like symptoms, pyrexia, chills, sweating, injections site pain, injection site erythema, injection site bruising, asthenia, pain, fatigue, malaise, night sweats. Psychiatric disorders: depression, insomnia. **Legal Classification:** POM. **Pack Size and UK NHS Price:** Box containing four injections £654, box containing twelve injections £1962. Reimbursed through High Tech Scheme in Ireland. **Package Quantities:** Lyophilised Powder: 1 box containing four trays. Each tray contains a 3 ml glass vial with BIO-SET device containing a 30 µg dose of Interferon beta-1a per vial, a 1 ml pre-filled glass syringe of solvent and one needle. Pre-filled Syringe: One box of four or twelve pre-filled syringes. Each syringe is packed in a sealed plastic tray. Each tray contains a 1 ml pre-filled syringe made of glass containing 0.5 ml of solution (30 µg dose of interferon beta-1a) and one needle for intramuscular use. **Product Licence Numbers:** EU/1/97/033/002-004. **Product Licence Holder:** Biogen Idec UK Ltd., Innovation House, 70 Norden Road, Maidenhead, Berkshire SL6 4AY, United Kingdom. **Date of last revision of Prescribing Information:** July 2008.

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk or www.imb.ie Adverse events should also be reported to Biogen Idec on 0800 008 7401 (UK) or 1800 812 719 (Ireland).