PRESCRIBING INFORMATION

FASENRA® ▼ 30MG SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE

FASENRA® ▼ 30MG SOLUTION FOR INJECTION IN PRE-FILLED PEN
(Benralizumab)

Consult Summary of Product Characteristics before prescribing.

Indication: Fasenra is indicated as an add on maintenance treatment in adult patients with severe eosinophilic asthma inadequately controlled despite high-dose inhaled corticosteroids plus long acting β agonists

Presentation: Pre-filled syringe containing 30 mg benralizumab in 1mL. Pre-filled pen containing 30 mg benralizumab in 1mL.

Dosage and Administration: Fasenra treatment should be initiated by a physician experienced in the diagnosis and treatment of severe asthma. After proper training in the subcutaneous injection technique and education about signs and symptoms of hypersensitivity reactions, patients with no known history of anaphylaxis or their caregivers may administer Fasenra if their physician determines that is appropriate, with medical follow-up as necessary. Self-administration should only be considered in patients already experienced with Fasenra treatment. The recommended dose is 30 mg of Fasenra by subcutaneous injection every 4 weeks for the first 3 doses, and then every 8 weeks thereafter. If an injection is missed on the planned date, dosing should resume as soon as possible on the indicated regimen; a double dose must not be administered. Fasenra is intended for long term treatment. A decision to continue the therapy should be made at least annually based on disease severity and level of exacerbation control and eosinophil counts. Fasenra should be injected into the thigh or abdomen. If the healthcare professional or caregiver administers the injection, the upper arm can also be used. It should not be injected into areas where the skin is tender, bruised, erythematous, or hardened. No dosing adjustment is required for elderly patients or patients with renal or hepatic impairment. Fasenra is not recommended in children aged 6 -18.

Contraindications: Hypersensitivity to the active substance or excipients.

Warnings and Precautions: Fasenra should not be used to treat acute asthma exacerbations. Patients should be instructed to seek medical advice if their asthma remains uncontrolled or worsens after initiation of treatment. Abrupt discontinuation of corticosteroids after initiation of Fasenra therapy is not recommended. Reduction in corticosteroid doses should be gradual and performed under the supervision of a physician. Acute systemic reactions including anaphylactic reactions and hypersensitivity reactions (e.g. urticaria, papular urticaria and rash) have occurred following administration of benralizumab. Such reactions may occur within hours of administration, but some may have a delayed onset (i.e. days). History of anaphylaxis unrelated to benralizumab may be a risk factor for anaphylaxis following Fasenra administration. In line with clinical practice, monitor patients for an appropriate time after administration. Fasenra should be discontinued permanently and appropriate therapy initiated in the event of a hypersensitivity reaction. Patients with pre-existing helminth infections should be treated before initiating therapy with Fasenra. If patients become infected while receiving treatment with Fasenra and do not respond to anti helminth treatment, discontinue treatment with Fasenra until infection resolves. In a conducted study, the humoral antibody responses
induced by seasonal influenza virus vaccination do not appear to be affected by benralizumab treatment. Interactions with other medicinal products is not expected.

**Pregnancy and Lactation:** Fasenra should be avoided during pregnancy and breast-feeding. Administration to pregnant or breast-feeding women should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus or child.

**Undesirable Events:** Consult SmPC for full list of side effects. **Common:** Pharyngitis, hypersensitivity reactions, headache, pyrexia and injection site reaction. **Not known** (cannot be estimated from available data): Anaphylactic reaction.

**Legal Category:** POM

**Marketing Authorisation Number:** Fasenra 30 mg solution for injection in pre-filled syringe EU/1/17/1252/001; Fasenra 30 mg solution for injection in pre-filled pen EU/1/17/1252/002

**Presentation & Basic NHS Cost:** 1 x single-use pre-filled syringe: £1955; 1 x single-use pre-filled pen: £1955.

**Marketing Authorisation Holder:** AstraZeneca AB, SE 151 85 Södertälje, Sweden

**Further Information is Available From:** AstraZeneca UK Ltd., 600 Capability Green, Luton, LU1 3LU, UK.

FASENRRA is a trade mark of the AstraZeneca group of companies.

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Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard). Adverse events should also be reported to AstraZeneca by visiting [https://aereporting.astrazeneca.com](https://aereporting.astrazeneca.com) or by calling 0800 783 0033.