ADVATE (human coagulation factor VIII (rDNA), octocog alfa)

Detailed Safety statement

Please consult the Advate Summary Product Characteristics (SPC) before prescribing, particularly in relation to dosing and treatment monitoring.

Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in SmPC section 6.1 or to mouse or hamster proteins.

Special warnings and precautions for use

The product contains traces of mouse and hamster proteins. If symptoms of hypersensitivity occur, patients should be advised to discontinue use of the product immediately and contact their physician.
Patients should be informed of the early signs of hypersensitivity reactions including hives, generalised urticaria, tightness of the chest, wheezing, hypotension and anaphylaxis.
The formation of neutralising antibodies (inhibitors) against factor VIII is a known complication in the management of individuals with haemophilia A. These inhibitors are usually IgG immunoglobulins directed against the factor VIII procoagulant activity, which are quantified in Bethesda Units (BU) per ml of plasma using the modified assay. In patients who develop inhibitors to factor VIII, the condition may manifest itself as an insufficient clinical response. In such cases, it is recommended that a specialised haemophilia centre be contacted.
In general, all patients treated with coagulation factor VIII should be carefully monitored for the development of inhibitors by appropriate clinical observations and laboratory tests. If the expected factor VIII activity plasma levels are not attained, or if bleeding is not controlled with an appropriate dose, testing for factor VIII inhibitor presence should be performed.
After reconstitution this medicinal product contains 0.45 mmol sodium (10 mg) per vial.

Adverse Reactions

Common (≥1/100 to <1/10)	Factor VIII inhibition, Headache, Pyrexia
Uncommon (≥1/1000 to <1/100)	Influenza, Laryngitis, Lymphangitis, Dizziness, Dysgeusia, Memory impairment, Migraine, Syncope, Tremor, Eye inflammation, Palpitations, Haematoma, Hot flush, Pallor, Dyspnoea, Abdominal pain upper, Diarrhoea, Nausea, Vomiting, Hyperhidrosis, Pruritus, Rash, Urticaria, Chest discomfort, Chest pain, Chills, Feeling abnormal, Peripheral oedema, Vessel puncture site haematoma, Coagulation factor VIII level decreased, Haematocrit decreased, Laboratory test abnormal, Monocyte Count increased, Post procedural complication, haemorrhage, procedural site reaction.
Not known	Anaphylactic reaction, Hypersensitivity, Fatigue, Injection site reaction, Malaise

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