Emerade 150, 300, 500 micrograms solution for injection in pre-filled pen
Prescribing Information

Please refer to Summary of Product Characteristics before prescribing. Further information about this product can be requested from the Marketing Authorisation Holder or may be found in the Summary of Product Characteristics.

Composition: The pre-filled pen contains 0.5 ml of adrenaline solution 1 mg/ml. Emerade 150, 300 and 500 micrograms deliver a single dose of 0.15, 0.3 and 0.5 ml containing 150, 300 and 500 micrograms of adrenaline (as tartrate) and 0.075mg, 0.15mg and 0.25mg of sodium meta-bisulphite respectively. **Indications**: The emergency treatment of severe acute allergic reactions (anaphylaxis) triggered by allergens in foods, medicines, insect stings or bites, and other allergens as well as for exercise-induced or idiopathic anaphylaxis. **Dosage**: The effective dose is usually within the range 5-10 micrograms per kg bodyweight but higher doses may be necessary in some cases. Paediatric population**:** *Children below 15 kg bodyweight*: A dosage below 150 micrograms cannot be administered with sufficient accuracy in children weighing less than 15 kg and use is therefore not recommended unless during a life-threatening situation and under medical advice. *Children weighing between 15 kg and 30 kg*: The usual dose is150 micrograms. *Children over 30 kg in bodyweight:* The usual dose is 300 micrograms. Emerade 500 micrograms is not recommended for use in children. *Adolescent patients over 30 kg bodyweight*: The dosage recommendations for adult patients should be followed. Adults: The recommended dose is 300 micrograms for individuals under 60 kg bodyweight. The recommended dose is 300 to 500 micrograms for individuals over 60 kg bodyweight, depending on clinical judgement. An initial dose should be administered as soon as symptoms of anaphylaxis are recognised. **Administration:** For intramuscular use. For single use. Emerade should be administered early, at the first signs of anaphylaxis. Emerade must be injected in the outer side of the thigh, through clothing if necessary. If the patient still feels unwell after the first injection, a second injection should be administered 5-15 minutes after the first injection. It is recommended that the patients are prescribed two Emerade pens which they should carry at all times. See sections 4.2 and 6.6 of the SmPC for more detail on the method of administration and detailed instructions for use. Autoinjectors without needles are available for training purposes. **Contraindications**: There are no absolute contraindications to the use of Emerade in an allergic emergency. **Warnings and precautions:** Do not remove the cap until ready for use. Emerade must be administrated only into the anterolateral thigh. Patients should be advised not to inject Emerade into the *gluteus maximus* due to the risk of accidental injection into a vein. Emerade should be used in emergency situations as life-sustaining treatment. The patient must urgently seek medical assistance for further treatment after using Emerade.
All patients who are prescribed Emerade should be thoroughly instructed to understand the indications for the use and the correct method of administration (see SmPC section 6.6). It is also strongly advised to educate the patient's immediate associates (e.g. parents, caregivers, teachers) in the correct use of Emerade for emergency situations. In patients with a thick sub-cutaneous fat layer, there is a risk of adrenaline being administered in the sub-cutaneous tissue which may result in a slower adrenaline absorption (see SmPC section 5.2) and a suboptimal effect. This may increase the need for a second Emerade injection (see SmPC section 4.2). Unintentional injection in hands and feet can result in peripheral ischemia that may require treatment. Emerade contains sodium metabisulphite which can cause allergic reactions including anaphylaxis and bronchospasm in sensitive individuals particularly in those with a history of asthma. See section 4.4 of the SmPC for more detail on special warnings and precautions for use. **Interactions:** Certain medicines can enhance the effect of adrenaline: Tricyclic antidepressants, monoamine oxidase (MAO) inhibitors, and catechol-O-methyl transferase (COMT) inhibitors. Adrenaline must be used with caution in patients receiving halogenated hydrocarbons and related medicines and drugs that may sensitize the heart to arrhythmias, e.g. digitalis, quinidine, halogenated anaesthetics. The administration of fast-acting vasodilators or α-blockers can counteract the effects of adrenaline on blood pressure. β-blockers can inhibit the stimulating effect of adrenaline. The hyperglycaemic effect of adrenaline may necessitate an increase in insulin or oral hypoglycaemic treatment in diabetic patients. **Fertility, pregnancy and lactation:** Adrenaline should be used in pregnancy only when the potential benefit to the mother outweighs the possible risk to the foetus. Any adrenaline in breast milk is unlikely to affect the nursing infant due to poor oral bioavailability and short half-life. **Ability to drive:** Patients are not recommended to drive or use machines following administration of adrenaline, since they will be affected by the anaphylactic reaction. **Undesirable effects**: Side-effects of adrenaline in general are associated with the α- and β-receptor activity of adrenaline. Metabolic and nutrition disorders: *Not known*: Hyperglycaemia, hypokalaemia, acidosis. Psychiatric disorders: *Not known*: Anxiety, hallucination. Nervous

system disorders: *Not known*: Headache, dizziness, tremor, syncope. Cardiac disorders: *Not known*: Tachycardia, arrhythmia, palpitations, angina pectoris, stress cardiomyopathy. Vascular disorders: *Not known*: Hypertension, vasoconstriction, peripheral ischaemia. Respiratory, thoracic and mediastinal disorders: *Not known*: Bronchospasm. Gastrointestinal disorders: *Unknown*: Nausea, vomiting. General disorders and administration site conditions: *Unknown*: Hyperhidrosis, asthenia. See section 4.8 of the SmPC for more detail on undesirable effects.

Legal category: POM.
Product licence number:
Emerade 150 micrograms: PL 33616/0013 (UK)
Emerade 300 micrograms: PL 33616/0014 (UK)
Emerade 500 micrograms: PL 33616/0015 (UK)
Package quantity and basic NHS price: Emerade 150, 300, 500 micrograms are available as single unit doses. Emerade 150; £26.94, Emerade 300; £26.94, Emerade 500; £28.74.
Marketing Authorisation Holder: PharmaSwiss Ceska republika s.r.o. Jankovcova 1569/2c
170 00 Prague 7 Czech Republic.
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