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February 7, 2017

Prescriber Information

Important information for prescribers of Emerade solution for injection in pre-filled pen

Bausch + Lomb continue to research and improve the use of our products. Emerade solution for injection in pre-filled pen; 150, 300 & 500 mcg shelf-life has been amended from 30 months to 18 months. There are no other changes for this product and patients should be advised to continue to use their pen as instructed. The shelf-life change will be implemented for any **future** Emerade 150, 300 & 500 mcg batches manufactured and released in UK. Kindly note that this change will be effective from February 2017.

It is important that patients should be advised to continue to carry or use your pen if required and do not need to take any further action. The shelf-life can be found on the product label (refer to EXP date).

Bausch + Lomb are committed to delivering high quality products and offering clinical value to the NHS and patients. The Marketing Authorisation Holder has taken the decision to amend the Emerade finished product shelf-life as long-term testing shows that discoloration of solution and slight precipitation may occur. This is a known characteristic of adrenaline. The safety and efficacy profile of Emerade remains the same.

As with all Adrenaline Auto-injectors, patients are advised to check their Emerade pens periodically through the inspection window to make sure the solution is clear and colourless. Patients are advised to discard and replace Emerade if the solution is discoloured or contains precipitate. Please refer your patient to the information leaflet that comes with Emerade, or **www.emerade-bausch.co.uk** for full product information and training material.

Full product information can be found at: **www.medicines.org.uk/emc/search** **Any side effects should be reported. This includes any possible side effects not listed in the package leaflet. You can report side effects directly via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard.By reporting side affects you can help provide more information on the safety of this medicine.**

Adverse events can also be reported to Bausch + Lomb directly on 01748 828864 or e-mail **Pharmacovigilance.UK@bausch.com**

For further information please visit **www.emerade-bausch.co.uk** or contact Bausch + Lomb on 01748 828864; e-mail: **Pharmacovigilance.UK@bausch.com**

Table 1 Existing Emerade stocks with 30month shelf-life

Description	Batch	Expiry date
EMERADE 150	RB0013A5A	19/08/2017
EMERADE 150	RB0013A6A	19/08/2017
EMERADE 150	RC0020A3A	19/09/2017
EMERADE 150	RD0033A6A	30/10/2017
EMERADE 150	RF0058A4F	30/11/2017
EMERADE 150	SB0015A1D	01/07/2018
EMERADE 150	SD0020A2A	01/09/2018
EMERADE 150	SH0042A1A	01/01/2019
EMERADE 300	QL0118B9B	30/05/2017
EMERADE 300	RA0009B2A	26/07/2017
EMERADE 300	RB0013B8A	19/08/2017
EMERADE 300	RC0020B1A	20/09/2017
EMERADE 300	RC0020B1C	01/09/2017
EMERADE 300	RC0020B4A	19/09/2017
EMERADE 300	RD0033B5B	13/10/2017
EMERADE 300	RA0009B2A	26/07/2017
EMERADE 300	RF0058B3F	30/11/2017
EMERADE 300	SB0015B4D	01/07/2018
EMERADE 300	SB0015B4F	01/07/2018
EMERADE 300	SB0015B5F	01/07/2018
EMERADE 300	SB0015B5C	01/07/2018
EMERADE 500	RA0009C1A	26/07/2017
EMERADE 500	RA0009C1B	26/07/2017
EMERADE 500	RA0009C3A	26/07/2017
EMERADE 500	RB0013C2A	19/08/2017
EMERADE 500	RB0013C7B	19/08/2017
EMERADE 500	RC0020C2A	19/09/2017
EMERADE 500	RD0033C4A	30/10/2017
EMERADE 500	RE0034C2A	30/11/2017
EMERADE 500	RF0058C5C	30/11/2017
EMERADE 500	SB0015C2E	01/07/2018
EMERADE 500	SD0020C3A	01/09/2018
EMERADE 500	SD0020C4A	01/09/2018
EMERADE 500	RF0058C5C	30/11/2017

Yours sincerely

Jenni White
Business Unit Head Pharmaceuticals

EMERADE 150, 300, 500 MICROGRAMS SOLUTION FOR INJECTION IN PRE-FILLED PEN
Adrenaline
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.

Contains: 0.5 ml of adrenaline solution 1 mg/ml. Emerade 150, 300, 500 micrograms delivers a single dose of 0.15, 0.3, 0.5 ml containing 150, 300, 500 micrograms of adrenaline (as tartrate) and 0.075mg, 0.15mg and 0.25mg of sodium meta-bisulphite respectively. **Main Indications, Dosage and Administration**: Emerade is indicated for 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. *Posology:* 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:* Use in children: Emerade 500 micrograms is not recommended for use in children. 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 between 15 kg and 30 kg bodyweight*: The usual dose is 150 micrograms. *Children over 30 kg bodyweight:* The usual dose is 300 micrograms. *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. In the absence of clinical improvement or if deterioration occurs, a second injection with an additional Emerade may 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. *Method of administration:* For intramuscular injection only. For single use. Emerade is given intramuscularly as soon as the symptoms of anaphylactic shock arise. A poor outcome from anaphylaxis is associated with late administration of adrenaline. Emerade must be injected in the outer side of the thigh. Massaging around the injection area accelerates absorption. The injection can be administered through clothing. The patient/carer should be informed that following each use of Emerade: They should call for immediate medical assistance, ask for an ambulance and state 'anaphylaxis' even if symptoms appear to be improving. Conscious patients should preferably lie flat with feet elevated but sit up if they have breathing difficulties. Unconscious patients should be placed on their side in the recovery position. The patient should if possible remain with another person until medical assistance arrives. **Contraindications, Precautions and Warnings**: There are no absolute contraindications to the use of Emerade in an allergic emergency. Do not remove the needle shield until ready for use. Emerade must be administrated only into the anterolateral thigh. The injection is delivered immediately after the triggering cylinder is pressed against the skin. 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. It is strongly advised also to educate the patient's immediate associates (e.g. parents, caregivers, teachers) for the correct usage of Emerade in case support is needed in the emergency situation. The patient/carer should be informed about the possibility of biphasic anaphylaxis which is characterised by initial resolution followed by recurrence of symptoms some hours later. Patients with concomitant asthma may be at increased risk of a severe anaphylactic reaction. Use with caution in patients with heart diseases including angina pectoris, cardiac arrhythmia, cor pulmonale, obstructive cardiomyopathy and atherosclerosis. There is also a risk for adverse reactions

after the administration of adrenaline to patients with hyperthyroidism, hypertension, phaeochromocytoma, glaucoma, severe renal impairment, prostate adenoma, hypercalcaemia, hypokalaemia, diabetes, and in elderly patients and pregnant women. Emerade contains sodium metabisulphite which can cause allergic reactions including anaphylaxis and bronchospasm in sensitive individuals particularly in those with a history of asthma. All those patients should be carefully instructed in which circumstances Emerade must be used. Unintentional injection in hands and feet can result in peripheral ischemia that may require treatment. Patients should be warned regarding related allergens and should be investigated whenever possible so that their specific allergens can be characterised. Emerade is essentially sodium free (contains less than 1 mmol sodium (23 mg) per dose). **Fertility, pregnancy and lactation:** There are no adequate or well-controlled studies of adrenaline during pregnancy. Adrenaline should be used in pregnancy only when the potential benefit to the mother outweighs the possible risk to the foetus. Because of its poor oral bioavailability and short half-life, any adrenaline in breast milk is unlikely to affect the nursing infant. **Undesirable effects**: Side-effects of adrenaline in general are associated with the α- and β-receptor activity of adrenaline. *Metabolic and nutrition disorders: Frequency Not known:* Hyperglycaemia, hypokalaemia, acidosis. *Psychiatric disorders: Frequency Not known:* Anxiety, hallucination. *Nervous system disorders: Frequency Not known:* Headache, dizziness, tremor, syncope. *Cardiac disorders: Frequency Not known:* Tachycardia, arrhythmia, palpitations, angina pectoris, stress cardiomyopathy. *Vascular disorders: Frequency Not known:* Hypertension, vasoconstriction, peripheral ischaemia. *Respiratory, thoracic and mediastinal disorders: Frequency Not known:* Bronchospasm. *Gastrointestinal disorders: Frequency Not known:* Nausea, vomiting. *General disorders and administration site conditions: Freequency Not known:* Hyperhidrosis, asthenia. Emerade contains sodium metabisulphite, which may rarely cause severe hypersensitivity reactions. Reporting suspected adverse reactions after authorisation of the medicinal product is important. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Adverse events should be reported to Bausch & Lomb UK on 01748 828864.

Legal Category: POM
Product licence number:
Emerade 150 micrograms: PL 33616/0013 (UK) **Basic NHS Price:** £25.99
Emerade 300 micrograms: PL 33616/0014 (UK) **Basic NHS Price:** £25.99
Emerade 500 micrograms: PL 33616/0015 (UK) **Basic NHS Price:** £26.99
Emerade 150, 300, 500 micrograms are available as single unit doses.
Marketing Authorisation Holder: PharmaSwiss Česká republika s.r.o. Jankovcova 1569/2, 170 00 Praha 7, Czech Republic
Date of Preparation: December 2016
Date of Revision: January 2017