Graphics&Packing Technology Section ICN POLFA RZESZÓW S.A.	**ULOTKA PIL**			
Nazwa produktu Product Name	**EMERADE 150µg/300µg/500µg** */adrenaline/*	Kolor nadruku Colours		
		Cyan	Black	-	-
Kraj Country (ISO)	**UK/IE**	Nr wykrojnika Spec No	-	
Opracowane przez Designed by	**Monika Walczuk monika.walczuk@ bauschhealth.com**	Kod Wytwórcy Manufacturer code	**601554**	
Nr korekty Proof No	**2** Data **2022-08-03**	Kod farmaceutyczny Pharmacode	-	
Kod wersji Valeant version code	**P9UKIE10**	Inny kod Other code	-	
Rozmiar czcionki Font size	**minimum 9 pt**	Wymiar ulotki PIL size	**220 x 320 mm**	
Krój czcionki Font used	**Times New Roman font family**	Gramatura papieru Paper weight	-	

Komentarze Comments (Reason for the change)

- Amend PIL to add QR code for Emerade UK website
- packing site: Rechon
- PMR_ICN-22-0752

proof #02 - ZTM

Akceptacja Techniczna Technical Approval

Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval

601554

Package leaflet: Information for the user
Emerade® 150 micrograms solution for injection in pre-filled pen
Emerade® 300 micrograms solution for injection in pre-filled pen
Emerade® 500 micrograms solution for injection in pre-filled pen

adrenaline

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Emerade is and what it is used for

Emerade is an auto-injector that contains adrenaline in a solution for injection into the muscle (intramuscular).
Adrenaline counteracts the fall of blood pressure in anaphylactic reactions. It also stimulates the heart and facilitates breathing.

Emerade is used for emergency treatment of severe allergic reactions (anaphylaxis) caused by allergens in foods, medicines, insect stings or bites and other allergens as well as triggered by exercise or unknown causes.

2. What you need to know before you use Emerade

Your doctor should have explained when and how you should use Emerade. If you are not completely sure or you have questions you must contact your doctor.

Warnings and precautions
Emerade can always be used during an allergic emergency. If you are allergic (hypersensitive) to sodium metabisulphite or to any of the other ingredients of Emerade, your doctor will need to instruct you under which circumstances Emerade should be used.

Talk to your doctor before using Emerade if you have
- heart disease,
- high blood pressure,
- an overactive thyroid,
- diabetes,
- a tumour on the adrenal gland,
- increased pressure in the eye,
- reduced kidney function,
- prostate disease,
- low potassium levels or high calcium levels in your blood.

If you have asthma you may be at increased risk of a severe allergic reaction.

Anyone who has an episode of anaphylaxis should see their doctor about testing for substances they may be allergic to, so these can be strictly avoided in future. It is important to be aware that an allergy to one substance can lead to allergies to a number of related substances.
If you have food allergies it is important to check the ingredients in everything you ingest (including medicines) as even small amounts can cause severe reactions.

There is also a greater risk of getting side effects if you are elderly or pregnant.

The instructions for use must be carefully followed in order to avoid accidental injection.
Emerade should be injected intramuscularly into the outer thigh. It should not be injected into the buttock due to the risk of accidental injection into a vein.

Warnings
Accidental injection into the hands or feet may result in reduced blood supply to these areas. If there is an accidental injection into these areas, you should go immediately to the nearest hospital emergency department for treatment.

If you have a thick sub-cutaneous fat layer, there is a risk that a single dose of Emerade may not be sufficient. This may increase the need for a second Emerade injection. Carefully follow the instructions for use given in section 3.

Children
Emerade should not be used in children under 15 kg.
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.

Other medicines and Emerade
Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

This is especially important if you take any of the following:
- Antidepressants such as tricyclic antidepressants or monoamine oxidase inhibitors (MAO inhibitors), since the effects of adrenaline may be increased.
- Medicines for treatment of Parkinson's disease such as catechol-O-methyl transferase inhibitors (COMT inhibitors), since the effect of adrenaline may be increased.
- Medicines that may make the heart sensitive to uneven beats (arrhythmias), such as digitalis and quinidine.
- Medicines for heart disease or medicines to treat disorders of the nervous system called alpha and beta blocking medicines as they can reduce the effect of adrenaline.

Diabetic patients should carefully monitor their glucose levels after use of Emerade as adrenaline can increase the blood glucose level.

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.
The experience of using adrenaline during pregnancy is limited. If you are pregnant you should however not avoid using Emerade in an emergency situation because your life can be in danger.

You can breast feed after you have used Emerade.

Driving and using machines
The ability to drive and use machines is unlikely to be affected by the administration of an adrenaline injection, but may be affected by a severe allergic reaction. If affected, do not drive.

Emerade contains sodium metabisulphite
Sodium metabisulphite may rarely cause severe hypersensitivity reactions and breathing difficulty (bronchospasm). If you are allergic (hypersensitive) to sodium metabisulphite your doctor must instruct you under which circumstances Emerade should be used.

Emerade contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'.

3. How to use Emerade

Always ensure that you have been trained in the use of Emerade and use Emerade exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Check the expiry date on your adrenaline auto-injectors and ask your doctor or nurse to prescribe you new ones before they expire. Out-of-date injectors may not work.

Use Emerade immediately if signs or symptoms of an acute allergic reaction (anaphylaxis) begin. Reactions can arise in a few minutes after the contact with the allergen and the symptoms can be, for example, rash, flush or swelling. More severe reactions also affect blood circulation and breathing.

Before you need to use Emerade, make sure you understand in what situations you should use Emerade. It is important that you always carry two adrenaline pens with you at all times if you are at risk of anaphylaxis. You should store Emerade in the original outer carton, however while carrying by patient/carer it is acceptable to store in the specially designed case provided. You must always keep the pen in this case to ensure protection of the pen and its label showing how to use the pen in an emergency situation. Always keep this information leaflet in the case.

Dosage
The dose will be decided by your doctor, who will adjust it individually for you for example depending on your bodyweight.

Adults

Adults below 60 kg
The usual dose is 300 micrograms.

Adults over 60 kg
The usual dose is 300 to 500 micrograms.

Children and adolescents
Emerade 500 micrograms is not recommended for use in children.

Children between 15 kg and 30 kg
The usual dose is 150 micrograms.

Children over 30 kg
The usual dose is 300 micrograms.

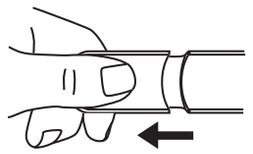
Adolescents over 30 kg
The dosage recommendations for adult patients should be followed.

How Emerade® is given
The instructions for use must be carefully followed in order to avoid accidental injection.

It is recommended that your family members, carers or teachers are also instructed in the correct use of Emerade.

Emerade should only be used for injection in the outer thigh at the first signs of a severe allergic reaction. The injection occurs when Emerade is pressed into the thigh. It can be administered through clothing. It should not be injected into the buttock (your bottom).

If your Emerade pen fails to activate, immediately you should use an increased force when pressing the pen against the intended injection site.
If your injection is not successful you should use a second pen immediately.



1. Remove the cap.

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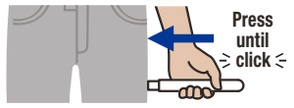

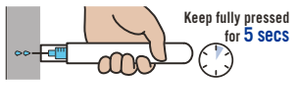

2. Place Emerade against the outer side of the thigh at a 90° angle and press firmly so that the needle cover is depressed. You will hear a click when the device has activated and the needle has penetrated the thigh.

and

Hold Emerade fully pressed against the thigh for 5 seconds. Lightly massage the injection site afterwards.

3. Seek immediate medical help.

The needle in Emerade is protected before, during and after the injection.

When the injection is completed, the needle cover of the Emerade pen is visibly longer and the plunger is visible in the inspection window by lifting the label.

Key messages:

- Sometimes a single dose of adrenaline may not be sufficient to completely reverse the effects of a serious allergic reaction. For this reason, your doctor is likely to prescribe two Emerade pens for you.
- If your symptoms **have not improved or have deteriorated within 5-15 minutes after the first injection, either you or the person with you should give a second injection**. For this reason you should carry two Emerade pens with you at all times.
- Emerade is designed as emergency treatment. **You should always get medical help immediately after using Emerade.** Ask someone to stay with you until the ambulance arrives in case you feel unwell again.
- **Call 999, ask for an ambulance and state 'anaphylaxis' (pronounced "anna-fill-axis"), even if you start to feel better.** You will need to go to hospital for observation and further treatment as required. This is because the reaction may happen again at some time later. Take the used pen with you.
- While waiting for the ambulance **you should lie down with your feet raised unless this makes you breathless** in which case you should sit up.
- Unconscious patients should be placed on their side in the recovery position.

After using of Emerade pen following the instructions, you can verify that your pen is activated. Pictures below (Fig.1-Fig.2) apply to all doses of Emerade (150 micrograms, 300 micrograms and 500 micrograms).

Fig. 1

The unused Emerade pen (before activation) has needle cover in its normal position (Fig. 1).

Fig. 2

Emerade pen that has been activated, will have an extended needle cover (Fig. 2).

If the needle cover has not extended, the pen has not activated.

An Emerade pen that has activated, and has successfully delivered a dose of adrenaline, will show a coloured plunger in the inspection window (revealed by peeling back the label on the pen):

150 micrograms: yellow

300 micrograms: green

500 micrograms: blue.

If the inspection window still shows clear liquid (adrenaline solution), the pen has not successfully delivered a dose of adrenaline. **The arrow on the pen label indicates where the label can be lifted up in order to reveal the inspection window.**

Do not remove the cap unless injection is required.

Some liquid remains in the auto-injector after the injection. The auto-injector cannot be re-used.

Auto-injectors without needles (trainer pens) are available for training purposes.

Please ask your doctor for more details.

If you use more Emerade than you should

If you have taken a too large dose, or if you have accidentally injected Emerade into a blood vessel or into a hand, you must **immediately** seek medical help.

Your blood pressure may rise sharply. Overdose may cause a sudden increase in blood pressure, irregular heartbeat and accumulation of fluid in the lungs which can make it difficult to breathe.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects are based upon experience with the use of adrenaline but the frequency of side effects cannot be estimated:

- heart problems such as irregular and rapid heartbeat, chest pain,
- high blood pressure, narrowing of the blood vessels,
- sweating,
- nausea, vomiting,
- difficulty breathing,
- headache, dizziness,
- weakness, shaking,
- anxiety, hallucinations,
- fainting,
- changes in your blood values such as increased blood sugar, decreased potassium and increased acid.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

United Kingdom

Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard
or search for MHRA Yellow Card in the Google Play or Apple App Store.

Ireland

HPRA Pharmacovigilance
Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Emerade

Keep this medicine out of the sight and reach of children.
Store in the plastic, protective case provided. The plastic case containing the pen/pens can be kept in the outer carton.
Store below 25°C. Do not freeze.

Do not use this medicine after the expiry date which is stated on the label and on the outer carton. The expiry date refers to the last day of that month. Discard and replace Emerade after the expiry date.
Check the solution periodically through the inspection window of the unit by lifting the label to make sure the solution is clear and colourless. Discard and replace Emerade if the solution is discoloured or contains precipitate.

Inspect the auto-injector if dropped. Replace if you notice damage or leakage.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Emerade contains

The active substance is adrenaline as tartrate.
Emerade 150 micrograms delivers 150 micrograms of adrenaline in 0.15 ml of solution.
Emerade 300 micrograms delivers 300 micrograms of adrenaline in 0.3 ml of solution.
Emerade 500 micrograms delivers 500 micrograms of adrenaline in 0.5 ml of solution.

The other ingredients are: sodium chloride, sodium metabisulphite (E223), disodium edetate, hydrochloric acid and water for injection.

What Emerade looks like and contents of the pack

Emerade is an auto-injector that delivers one single dose of adrenaline. Emerade is a clear and colourless solution for injection inside a glass syringe. Emerade is latex free.
The device is a white cylinder in which a needle shield covers the needle and the triggering mechanism.

Exposed needle length
Emerade 150 micrograms: 16 mm
Emerade 300 micrograms and Emerade 500 micrograms: 23 mm
Pack sizes: 1 or 2 pre-filled pens.
All pack sizes may not be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
PharmaSwiss Česká republika s.r.o
Jankovcova 1569/2c, 170 00 Prague 7, Czech Republic

Manufacturer
Rechon Life Science AB
Soldattorpsvagen 5, SE-216 13 Limhamn, Sweden

This leaflet was last revised on July 2022

For more information please refer to the instructional video by scanning the QR code with a smartphone/device. The same information is also available on the following website: www.emerade-bausch.co.uk

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