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 this leaflet about?

1. What Emerade is and what it is used for

Emerade is an auto-injector that contains adrenaline in a solution for injection. 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.

Emerade is an auto-injector that contains adrenaline. 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 only 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.

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 is therefore not recommended unless during a life-threatening situation and under medical advice.

Other medicines and Emerade

Tell your doctor 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.

Driving and using machines

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.

Can you breast feed after you have used Emerade?

You should not breast feed because it contains important information for you. It may harm them, even if their signs of illness are the same as yours.

What to do in an emergency situation

Emerade should only be used during an allergic emergency. You should store Emerade in the original packaging and use the 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 body weight.

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, caregivers or teachers are also instructed in the correct use of Emerade. Emerade should only be used for injection in the outer thigh. 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).

Holding Emerade
1. Remove the needle shield.
2. Place and press Emerade against the outer side of the thigh. You will hear a click when the injection goes into the muscle.
3. Hold Emerade against the thigh for about 5 seconds. Lightly massage the injection site afterwards. Seek immediate medical help.

The needle in Emerade is protected before, during and after the injection. When the injection is completed, the plunger is visible in the inspection window by lifting the label. 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 more than one Emerade 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 more than one Emerade with you at all times.

Emerade is designed as emergency treatment. You should always get medical help immediately after using Emerade. Dial 999 and ask for an ambulance. State ‘anaphylaxis’ even if symptoms appear to be improving. 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 auto-injector 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. Ask someone to stay with you until the ambulance arrives in case you feel unwell again. Unconscious patients should be placed on their side in the recovery position.

Do not remove the needle shield unless injection is required.
Some liquid remains in the auto-injector after the injection. The needle in Emerade is protected before, during and after the injection.

What Emerade looks like and contents of the pack
What Emerade contains
The active substance is adrenaline as tartrate.
Emerade 150 micrograms delivers 150 micrograms of adrenaline in 0.3 ml of solution.
Emerade 300 micrograms delivers 300 micrograms of adrenaline in 0.6 ml of solution.
Emerade 500 micrograms delivers 500 micrograms of adrenaline in 0.7 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 a 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
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