Jext®

150 micrograms
300 micrograms

Package leaflet: Information for the patient
Jext 150 micrograms, solution for injection in pre-filled pen
Jext 300 micrograms, solution for injection in pre-filled pen

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:
1. What Jext is and what it is used for
2. What you need to know before you use Jext
3. How to use Jext
4. Possible side effects
5. How to store Jext
6. Contents of the pack and other information

1. What Jext is and what it is used for

Jext contains a sterile solution of adrenaline (intramuscular injection).

Jext is to be used for the emergency treatment of sudden life threatening allergic reactions (anaphylactic shock) to insect stings or bites, foods or drugs or exercise.

Symptoms that signal the onset of an anaphylactic shock occur within minutes of exposure to the allergen and include: itching of the skin; raised rash (like a nettle rash); flushing; swelling of the lips, throat, tongue, hands and feet; wheezing, hoarseness; shortness of breath; nausea; vomiting; stomach cramps and in some cases, loss of consciousness.

2. What you need to know before you use Jext

Jext can always be used during an allergic emergency. If you are allergic (hypersensitive) to sodium metabisulphite or to any of the other ingredients of Jext, your doctor will need to instruct you under which circumstances Jext should be used. For further information on hypersensitivity to sulphites please look in the section: Jext contains sodium metabisulphite and sodium chloride.

Warnings and precautions:

Talk to your doctor when you are prescribed Jext:
• if you have heart disease
• if you have an overactive thyroid
• if you have high blood pressure
• if you have diabetes
• if you have a tumour on the adrenal gland (parathyroïd gland)
• if you have increased pressure in the eye (glaucoma)
• if you have renal or prostate disease
• if you have low potassium levels or high calcium levels in your blood
• if you are elderly, pregnant or the child weighs less than 15 kg as there is a greater risk of getting side effects.

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.

You should be carefully instructed by your doctor or nurse when and how to correctly use Jext.

The instructions for use must be carefully followed in order to avoid accidental injection.

Jext 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.

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.

Laceration may occur if the injection is given by someone other than the patient and the patient’s leg is not immobilised during injection. To prevent injuries, the instructions for use given in section 3 must be carefully followed.

Other medicines and Jext:

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is especially important if you take any of the following medicines:

- Medicines that may increase the effect of adrenaline: Antidepressants such as tricyclic antidepressants or monoamine oxidase inhibitors (MAO inhibitors).
- Medicines for treatment of Parkinson’s disease such as catechol-O-methyl transferase inhibitors (COMT inhibitors) and levodopa.
- Medicines that make the heart sensitive to uneven beats (arrhythmias), such as digitalis and quinidine.
- Medicines for thyroid disease (levothyroxine).
- Medicines that make you breathe more easily; used for asthma (theophylline).

- Medicines used in labour (e.g. oxytocin).
- Medicines used to treat allergies such as diphenhydramine, chlorpheniramine (first generation antihistamines).
- Medicines that may reduce the effect of adrenaline: Alpha and beta blocking medicines for heart disease.
- Medicines that act on the parasympathetic nervous system which regulates the body’s unconscious functions such as heart beat and lung function (parasympatholytics, parasympathomimettics).

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

Jext with alcohol:

Alcohol can increase the effect of adrenaline.

Pregnancy, breast-feeding and fertility:

• Medicines used in labour (e.g. oxytocin).
• Medicines that may make the heart sensitive to uneven beats (arrhythmias), such as digitalis and quinidine.
• Antidepressants such as tricyclic antidepressants or monoamine oxidase inhibitors (MAO inhibitors).
• Medicines that act on the parasympathetic nervous system which regulates the body’s unconscious functions such as heart beat and lung function (parasympatholytics, parasympathomimettics).

The instructions for use of Jext given below must be carefully followed. The pen is for single use only and cannot be reused.

Follow these directions only when ready to use:

- Never put thumb, feet or hand over the black needle shield as this is where the needle comes out.
- Do not remove the yellow cap until you need to use Jext.

For correct administration, look at the diagrams and follow these steps:

Before Use After Use

Yellow cap

Remove the yellow cap until you:

- The window is visible in window after use (white in Jext 300 and blue in Jext 150).

Coloured plastic rod

Black Injector Tip

The instructions for use must be carefully followed.

3. How to use Jext

Always use this medicine exactly as your doctor or pharmacist have told you. Make sure you understand in what situation you should use Jext. Check with your doctor or pharmacist if you are not sure.

Doseage

Adults and Children over 30kg - the recommended dose for allergic emergencies is 300 micrograms adrenaline for injection into the outer thigh muscle (intramuscular use). Children between 15kg and 30kg - the recommended dose of adrenaline for allergic emergencies is 150 micrograms adrenaline for injection into the outer thigh muscle (intramuscular use). Remember: the correct dose of Jext depends on bodyweight. The dose will need to be increased as your child develops and will need to be discussed with your doctor.

If you notice the signs of an acute allergic reaction, use Jext immediately, through your clothing if necessary.

After use some liquid will remain in the auto-injector but this cannot be reused.

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 Jext 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 Jext with you at all times.

Method of administration

Jext has been designed to inject through the clothes or directly through the skin of the outer thigh. Jext should be pushed firmly into the outer portion of the thigh into the largest part of the thigh muscle. When you push Jext firmly into your thigh, a spring activated plunger will be released, which pushes the hidden needle through a seal at the end of the black needle shield, into the thigh muscle and injects a dose of adrenaline. The instructions for use of Jext given below must be carefully followed.
Dial 999, ask for ambulance, state anaphylaxis. 

Grasp the Jext injector in your dominant hand (the one you use to write with) with your thumb closest to the yellow cap.

Pull off the yellow cap with your other hand.

Place the black injector tip against your outer thigh. Grip the injector at a right angle (approx 90°) to the thigh.

Massage the injection area for 10 seconds (a slow count to replace the used Jext as soon as possible.

If you use more Jext than you should

In case of overdose or accidental injection of the adrenaline, you should always seek immediate medical help. You should see your doctor to replace the used Jext as soon as possible.

Your blood pressure may rise sharply. Over-dose may cause a sudden increase in blood pressure, irregular heartbeat, abnormal kidney function, reduced blood flow and accumulation of fluid in the lungs. If you have any further questions on the use of this product, ask your doctor or pharmacist.

Possible side effects

Like all medicines this medicine can cause side effects, although not everybody gets them. The following side effects are based on experience with the use of adrenaline (frequency not known: frequency cannot be estimated from the available data).

- Heart problems such as irregular and rapid heartbeat, feeling your heartbeat, chest pain
- High blood pressure, narrowing of the blood vessels
- Sweating
- Nausea, vomiting
- Difficulty breathing
- Headache, dizziness, fainting
- Weakness, tremor
- Anxiety, hallucinations
- Changes in your blood such as increased blood sugar levels, decreased potassium levels and harmful collection of acid in the body

Accidental injection of the adrenaline into hands or feet has been reported and may result in lack of blood supply to these areas. In case of accidental injection, always seek immediate medical help. Jext contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions including difficult breathing.

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 the MHRA Yellow Card Scheme at www.mhra.gov.uk/yelllowcard (UK) or the HPRA Pharmacovigilance Section at HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971, Fax: +353 1 6762517.

Website: www.hpra.ie, e-mail: websafety@hpra.ie (Ireland). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Jext

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store below 25°C.

Do not freeze.

Please remember to check the contents of the glass cartridge in Jext through the window in the label from time to time to make sure the liquid is still clear and colourless. Replace Jext by the expiry date or earlier. Do not use this medicine if you notice the solution is discoloured or contains a precipitate (solid particles). You may find it useful to put the expiry date in your calendar or diary to ensure that you replace Jext in time.

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 protect the environment.

6. Contents of the pack and further information

What Jext contains

The active substance is adrenaline. 1 ml solution contains 1 mg of adrenaline (as tartrate).

Jext 150 micrograms injects one single dose of 150 micrograms adrenaline in 0.15 ml solution for injection.

Jext 300 micrograms injects one single dose of 300 micrograms adrenaline in 0.3 ml solution for injection.

The other ingredients are:

- Sodium chloride,
- Sodium metabisulphite (E223),
- Hydrochloric acid.

Water for injections.

What Jext looks like and contents of the pack

Jext is a solution for injection in a pre-filled pen. It contains a clear and colourless solution inside a glass cartridge with latex free rubber seals.

Exposed needle length:

Jext 150 micrograms: 13 mm
Jext 300 micrograms: 15 mm

Pack size: Single pack with 1 pre-filled pen. Multipack with 2 pre-filled pens. Not all pack sizes may be marketed.

Marketing Authorisation Holder

ALK-Abello A/S, Bågsvej Afd 6, DK-2970 Hørsholm

Manufacturer

ALK-Abello S.A., Miguel Fleta 19, ES-28037 Madrid

This medicinal product is authorised in the Member States of the EEA under the name:

Austria, Belgium, Denmark, Finland, France, Germany, Iceland, Ireland, Italy, Luxembourg, The Netherlands, Norway, Slovakia, Spain, Sweden, United Kingdom.

This leaflet was last revised in June 2018

Other sources of information

Detailed and updated information on this product is available by scanning the QR Code included in the PIL with a smartphone. The same information is also available on the following URL:

https://itunes.apple.com/gb/app/jext/id608836531?mt=8


and the www.mhra.gov.uk website.

and www.mhr.a.gov.uk

Other pack sizes may be marketed.

22.05.2018 Version No. 2

The inspection window in the label is filled by a coloured plastic rod (white in Jext 300 and blue in Jext 150) to confirm that the auto-injector has activated and the adrenaline solution has been injected.

A small air bubble may be present in Jext. It does not affect the way the product works. Even though most of the liquid remains in Jext after use, it cannot be reused.

Pack size: Single pack with 1 pre-filled pen. Multipack with 2 pre-filled pens. Not all pack sizes may be marketed.

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