

## PACKAGE LEAFLET: INFORMATION FOR THE USER

Jext 150 micrograms solution for injection in pre-filled pen  
Jext 300 micrograms solution for injection in pre-filled pen

Adrenaline

**Read all of this leaflet carefully before you start using this medicine.**

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

**In this leaflet:**

1. What Jext is and what it is used for
2. Before you use Jext
3. How to use Jext
4. Possible side effects
5. How to store Jext
6. Further information

### **1. WHAT JEXT IS AND WHAT IT IS USED FOR**

Jext contains a sterile solution of adrenaline within an auto-injector for emergency injection of a single dose of adrenaline into the outer part of the thigh muscle (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. BEFORE YOU USE JEXT**

There are no medical reasons not to use Jext 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: Important information about some of the ingredients of Jext.

Do not use Jext

- There are no medical reasons not to use Jext during an allergic emergency.

### **Take special care with 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 (phaeochromocytoma)
- 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
- and/or if you are elderly, pregnant or the child weighs less than 15 kg as there is a greater risk of getting side effects.

Make sure that you discuss this with your doctor if any of the above conditions apply to you.

You should have been 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.

### **Warning**

Accidental injection into the hands or fingers 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.

### **Taking other medicines**

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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.
- Alpha and beta blocking medicines for heart disease or medicines to treat disorders of the nervous system as they can reduce the effect of adrenaline.

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

### **Pregnancy and breast-feeding**

Ask your doctor or pharmacist for advice before taking any medicine.

There is limited experience of the use of adrenaline during pregnancy. If you are pregnant, do not hesitate to use Jext in an emergency, since you and your baby's life may be in danger.

Jext would not be expected to have any effect on the nursing infant. Discuss this with your doctor if you are pregnant or breast-feeding.

### **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 an anaphylactic reaction. If affected, do not drive.

### **Important information about some of the ingredients of Jext**

Jext contains sodium metabisulphite, which may rarely cause severe allergic reactions (hypersensitivity) or breathing difficulty (bronchospasm). Your doctor must instruct you under which circumstances Jext should be used.

Jext contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially sodium free.

## **3. HOW TO USE JEXT**

Always use Jext exactly as your doctor has told you. Make sure you understand in what situations you should use Jext. You should check with your doctor or pharmacist if you are not sure.

### **Dosage**

The dose will be decided by your doctor, who will adjust it individually for you.

**Adults and Children over 30kg** – the usual dose for allergic emergencies is 300 micrograms adrenaline for injection into the outer thigh muscle (intramuscular use).

**Children between 15kg and 30kg** - the usual dose 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 an allergic reaction. For this reason, your doctor may prescribe more than one Jext for you. Repeated injections may be administered after 5-15 minutes if the symptoms are still present and your doctor has told you that you can do this. 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 against 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 the 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.

Jext should **only** be injected into the outer thigh.  
**It should not be injected into the buttock (your bottom).**

### Instructions for use

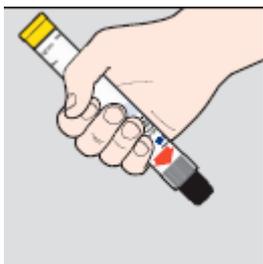
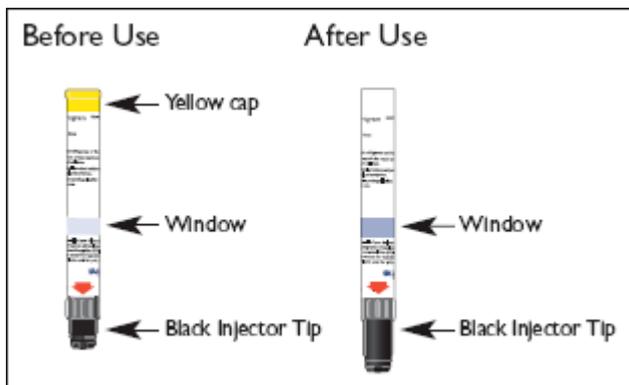
Before you ever need to use it you should, fully familiarise yourself with Jext, when and how it should be used. During instruction in correct use of Jext, your doctor may use a Jext Simulator to ensure that you and any other family members or carers are confident in what to do when an allergic emergency happens.

Follow these directions only when ready to use.

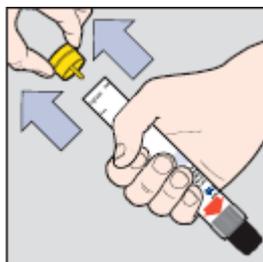
- Never put thumb, fingers or hand over the black needle shield as this is where the needle comes out.

- Do **not** remove yellow cap until you need to use Jext.

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



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



2. Pull off the yellow cap with your other hand.



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

4. Push the black tip firmly into your outer thigh until you hear a 'click' confirming the injection has started, then keep it pushed in. Hold the injector firmly in place against the thigh for 10 seconds (a slow count to 10) then remove. The black tip will extend automatically and hide the needle.

5. Massage the injection area for 10 seconds. Seek immediate medical help.

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.

**As Jext is designed as emergency treatment only, you should always seek medical help immediately after using Jext, by reporting to your doctor, nearest hospital or by calling an ambulance.** Make sure that you inform the healthcare professional that you have received an intramuscular injection of adrenaline and hand over the used Jext for safe disposal.

#### **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. Overdose 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.

#### **4. POSSIBLE SIDE EFFECTS**

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

Usual side effects include: irregular heartbeat (including palpitations and rapid heartbeats), high blood pressure, chest pain (angina pectoris), narrowing of the blood vessels, sweating, nausea, vomiting, difficulty breathing, headache, dizziness, weakness, tremor or anxiety. Hallucinations, fainting, changes in your blood such as increased blood sugar levels, decreased potassium levels in your blood, harmful collection of acid in the body and heart problems (stress cardiomyopathy).

Accidental injection of the adrenaline into hands or fingers 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.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

## **5. HOW TO STORE JEXT**

Keep out of the reach and sight of children.

Do not use Jext after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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 if 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.**

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

## **6. FURTHER INFORMATION**

### **What Jext contains**

The active substance is adrenaline.

1 ml solution contains 1 mg adrenaline (as tartrate).

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

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

Pack size: 1 pre-filled pen.

**Marketing Authorisation Holder and Manufacturer**

ALK-Abelló A/S, Bøge Allé 6-8, DK-2970 Hørsholm

**This medicinal product is authorised in the following Member States of the EEA under the name of Jext 150 micrograms and Jext 300 micrograms:**

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

**This leaflet was last approved in {MM/YYYY}.**