

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Jext 150 micrograms solution for injection in pre-filled pen

Jext 300 micrograms solution for injection in pre-filled pen

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Jext 150 micrograms: One pre-filled pen delivers one dose of 0.15ml solution for injection containing 150 micrograms of adrenaline (as tartrate).

Jext 300 micrograms: One pre-filled pen delivers one dose of 0.30ml solution for injection containing 300 micrograms of adrenaline (as tartrate).

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

Excipients: Sodium metabisulphite (E223) and sodium chloride.

Jext contains less than 1 mmol sodium (23 mg) per dose.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection in pre-filled pen.

Clear and colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Jext is indicated in the emergency treatment of severe acute allergic reactions (anaphylaxis) to insect stings or bites, foods, drugs and other allergens as well as idiopathic or exercise induced anaphylaxis.

4.2 Posology and method of administration

Posology:

Patients between 15 kg and 30 kg in weight:

The usual dose is 150 micrograms.

A dosage below 150 micrograms cannot be administered in sufficient accuracy in children weighing less than 15 kg and use is therefore not recommended unless life-threatening situation and under medical advice. Patients over 30 kg in weight should be prescribed a Jext 300 micrograms.

Patients over 30 kg in weight:

The usual dose is 300 micrograms.

Larger adults may require more than one injection to reverse the effect of an allergic reaction.

Patients between 15 kg and 30 kg in weight should be prescribed a Jext 150 micrograms.

An initial dose should be administered as soon as symptoms of anaphylaxis are recognised.

The effective dose is typically in the range of 0.005-0.01 mg/kg but higher doses may be necessary in some cases.

In the absence of clinical improvement or if deterioration occurs, a second injection with an additional Jext may be administered 5 – 15 minutes after the first injection.

Method of administration:

For intramuscular use.

For single use.

Jext is for intramuscular administration into the anterolateral thigh.

It is designed to inject through clothing or directly through the skin.

Massage around the injection area is advised to accelerate absorption.

Please refer to section 6.6 for detailed instructions for use

4.3 Contraindications

There are no absolute contraindications to the use of Jext during an allergic emergency. Hypersensitivity to any of the excipients. Refer to section 4.4 for more information on sulphites.

4.4 Special warnings and precautions for use

Do not remove yellow cap until ready for use.

Jext should be administered into the anterolateral thigh. The injection is delivered immediately after the black needle shield of the auto-injector is pressed firmly against the skin or other surface. Patients should be advised not to inject Jext into the gluteus maximus due to the risk of accidental injection into a vein.

The patient should be instructed to seek emergency medical assistance immediately after administering the first dose in order to have close monitoring of the anaphylactic episode and further treatment as required.

Jext contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions including anaphylactic symptoms and bronchospasm in susceptible people, especially those with a history of asthma. Patients with these conditions must be carefully instructed in regard to the circumstances under which Jext should be used.

Due to an increased risk of adverse reactions following administration of adrenaline special caution should be taken in patients with cardiovascular diseases including angina pectoris, obstructive cardiomyopathy, cardiac arrhythmia, cor pulmonale, atherosclerosis and hypertension.

Special caution should also be taken in patients with hyperthyroidism, phaeochromocytoma, narrow angle glaucoma, severe renal impairment, prostatic adenoma leading to residual urine, hypercalcaemia, hypokalaemia and diabetes.

Caution should also be taken in elderly and pregnant patients.

Peripheral ischaemia following accidental injection into hands or feet may cause loss of blood flow to adjacent areas due to vasoconstriction.

All patients who are prescribed Jext should be thoroughly instructed to understand the indications for use and the correct method of administration.

There is often a prolonged period between supply of Jext and an allergic reaction requiring adrenaline. Patients should be advised to regularly check Jext and ensure it is replaced within the expiry period.

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

4.5 Interaction with other medicinal products and other forms of interaction

Caution is indicated in patients receiving drugs that may sensitise the heart to arrhythmias, including digitalis and quinidine. The effects of adrenaline may be potentiated by tricyclic antidepressants, monoamine oxidase inhibitors (MAO-inhibitors) and catechol-O-methyl transferase inhibitors (COMT inhibitors).

Adrenaline inhibits the secretion of insulin, thus increasing the blood glucose level. It may be necessary for diabetic patients receiving adrenaline to increase their dosage of insulin or oral hypoglycaemic drugs.

The alpha- and beta-stimulating effect can be inhibited by concomitant use of alpha- and beta-blocking drugs as well as sympathomimetic drugs.

4.6 Fertility, pregnancy and lactation

Clinical experience in the treatment of anaphylaxis during pregnancy is limited. Adrenaline should only be used during pregnancy if the potential benefit justifies the potential risk for the foetus.

Adrenaline is not orally bioavailable; any adrenaline excreted in breast milk would not be expected to have any effect on the nursing infant.

4.7 Effects on ability to drive and use machines

Jext has no or negligible influence on the ability to drive and use machines, however, patients are not recommended to drive or use machines following administration of adrenaline, since they will be affected by the anaphylactic reaction.

4.8 Undesirable effects

Side effects associated with adrenaline's alpha and beta receptor activity may include cardiovascular effects as well as undesirable effects on the central nervous system.

The following table is based upon post marketing experience with the use of adrenaline. The frequency cannot be estimated from the available data.

System Organ Class	Adverse Drug Reaction
Metabolism and nutrition disorders	Hyperglycaemia, hypokalaemia, metabolic acidosis
Psychiatric disorders	Anxiety, hallucination
Nervous system disorders	Headache, dizziness, tremor, syncope
Cardiac disorders	Tachycardia, arrhythmia, palpitations, angina pectoris, stress cardiomyopathy
Vascular disorders	Hypertension, vasoconstriction, peripheral ischaemia
Respiratory, thoracic and mediastinal disorders	Bronchospasm
Gastrointestinal disorders	Nausea, vomiting

General disorders and administration site conditions	Hyperhidrosis, asthenia
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Peripheral ischaemia following accidental injection of adrenaline in the hands or feet has been reported.

Jext contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions including anaphylactic symptoms and bronchospasm (see section 4.4. Special warning and precautions for use).

4.9 Overdose

Overdose or inadvertent intravascular injection of adrenaline may cause cerebral haemorrhage and ventricular arrhythmias resulting from a sharp rise in blood pressure. Myocardial ischaemias and necroses as well as renal impairment may occur. Fatalities may also result from pulmonary oedema because of peripheral vascular constriction together with cardiac stimulation.

Pulmonary oedema may be treated with alpha-blocking agents such as phentolamine. In case of arrhythmias these may be treated with beta-blocking agents.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Cardiac stimulants excl. cardiac glycosides, adrenergic and dopaminergic agents.

ATC code: C01CA24.

Adrenaline is a catecholamine which stimulates the sympathetic nervous system (both alpha and beta receptors) by which cardiac rate, cardiac output and coronary circulation is raised. Adrenaline through its action on beta receptors on bronchial smooth muscles causes bronchial smooth muscle relaxation which alleviates wheezing and dyspnoea.

5.2 Pharmacokinetic properties

Adrenaline is a naturally occurring substance produced by the adrenal medulla and secreted in response to exertion or stress. It is rapidly inactivated in the body mostly by the enzymes COMT and MAO. The liver is rich in these enzymes and is an important, although not essential, tissue in the degradation process. Much of the dose of adrenaline is accounted for by excretion of metabolites in the urine.

The plasma half-life of adrenaline is about 2.5 min. However local vasoconstriction may retard absorption, so that the effects can last longer than the half-life would predict. Massage around the injection area is advised to accelerate absorption.

5.3 Preclinical safety data

Adrenaline has been utilised in the treatment of allergic emergencies for many years. There is no preclinical data of relevance available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Chloride
Sodium Metabisulphite (E223)
Hydrochloric Acid (for pH adjustment)
Water for Injections

6.2 Incompatibilities

In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.

6.3 Shelf life

2 years

6.3 Special precautions for storage

Do not freeze.

6.5 Nature and contents of container

Pre-filled pen (single dose pen) comprising an auto-injector with a cartridge. The cartridge is made of glass (type 1), sealed with a latex free grey rubber plunger and a latex free bromobutyl rubber seal within an anodised aluminium cap. The auto-injector is made of plastic.

Pack-size: 1 pre-filled pen

6.6 Instruction for use and handling

Jext is a single-use pre-filled pen designed for easy use.

The pre-filled pen is operated by simply pressing the black injector tip against the outer thigh. This will activate a plunger, which pushes a concealed needle through the membrane on the black injector tip into the muscle and injects a dose of adrenaline. This can be done through clothing.

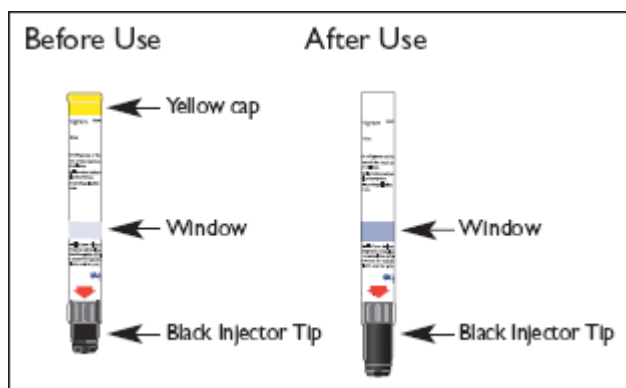
Jext 150 micrograms contains 1.4 ml of adrenaline injection 1 mg/ml which is designed to deliver a single dose (0.15 ml) of 150 micrograms adrenaline when activated. After activation of the auto-injector 1.25 ml remains in the pre-filled pen. Discard any unused solution.

Jext 300 micrograms contains 1.4 ml of adrenaline injection 1 mg/ml which is designed to deliver a single dose (0.30 ml) of 300 micrograms adrenaline when activated. After activation of the auto-injector 1.1 ml remains in the pre-filled pen. Discard any unused solution.

A small air bubble may occur in Jext. It has no influence on either the use or the efficacy of the product.

The prescriber may use a “Jext Simulator” during patient instruction. This is a pen without needle or adrenaline, which is also available for patients or carers who may wish to practise at home.

Note: the yellow cap prevents the device from activating, and should not be removed before injection is required. The black injector tip should be kept away from the hand.



	<p>1. Grasp the Jext injector in your dominant hand (the one you use to write with) with your thumb closest to the yellow cap.</p>
	<p>2. Pull off the yellow cap with your other hand.</p>
	<p>3. Place the black injector tip against your outer thigh, holding the injector at a right angle (approx 90°) to the thigh.</p>
	<p>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.</p>
	<p>5. Massage the injection area for 10 seconds. Seek immediate medical help.</p>

Any expired products should be disposed of in accordance with local requirements.

Check the solution periodically through the viewing window of the unit to make sure the solution is clear and colourless.

The solution darkens in colour upon exposure to air or light.

Replace and discard the pre-filled pen if the solution is discoloured or contains a precipitate, or at the latest before the expiry date.

The expiry date is indicated on the label and Jext should not be used after this date.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<{DD/MM/YYYY}> <{DD month YYYY}>

<[To be completed nationally]>

10. DATE OF REVISION OF THE TEXT

<{MM/YYYY}>

<[To be completed nationally]>