3. Possible side effects

- If you get any side effects talk to your doctor or pharmacist. This includes any side effects that are not listed in this leaflet. See section 4.

- Possible side effects include:
  - 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.
  - If you have asthma you may be at increased risk of a serious allergic reaction. If you are pregnant or breast feeding, think before you plan to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

4. Contra indications

- Medicines that act on the parasympathetic nervous system which regulates the body’s unconscious functions such as heart beat and lung function (parasympatholytics, parasympathomimetics).

5. Pregnancy and breast feeding

- Pregnancy: This medicine has been prescribed for you as the risks from the use of this medicine are less than the possible risks from the condition itself. Do not breast feed while using this medicine.

- Breast feeding: This medicine contains ingredients which may easily pass into breast milk. If you breast feed, consult your doctor or pharmacist before using this medicine.

6. 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.

- 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.

- 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 (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
  - If you are elderly, pregnant or the child weighs less than 15 kg as there is a greater risk of getting side effects.

- Jext contains sodium metabisulphite and sodium chloride. It should only be injected into the outer thigh. It should not be injected into the buttock (the bottom).

- Jext contains sodium metabisulphite to prevent oxidation of related substances.
- Medicines that make you breathe more easily, used for asthma (theophylline).
- 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, parasympathomimetics).

- Diabetic patients should carefully monitor their blood glucose levels. The correct dose of Jext adrenaline can increase the blood glucose level.

- Jext with alcohol

- Alcohol can increase the effect of adrenaline.

- Pregnancy, breast-feeding and fertility

- If you are pregnant or breast feeding, think before you plan to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Jext contains sodium metabisulphite and sodium chloride. It should only be injected into the outer thigh. It should not be injected into the buttock (the bottom).

- 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:
  - 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 selegiline.
  - Medicines that may make the heart sensitive to uneven beats (arrhythmias), such as digitals and quinidine.
  - Medicines for thyroid disease (levothyroxine).

- Medicines have 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

- What is Jext and what is it used for

- Jext contains a sterile solution of adrenaline injected via a pre-filled pen for use in 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 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 sulpha drugs please look in the section: Jext contains sodium metabisulphite and sodium chloride.

- Warnings and precautions

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

- If you get 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?

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- 1. What Jext is and what it is used for

- Jext contains a sterile solution of adrenaline injected via a pre-filled pen for use in emergency treatment of sudden life threatening allergic reactions (anaphylactic shock) to insect stings or bites, foods or drugs or exercise.
**Jext**

Jext is designed as emergency treatment. You should always get medical help immediately after using Jext. Dial 999, ask for an ambulance and 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.

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.

Inform the healthcare professional that you have received an intramuscular injection of adrenaline. You can also 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 the medicine can cause side effects, although not everybody gets them.

The following side effects are based upon 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, abnormal kidney function, reduced blood flow and accumulation of fluid in the lungs.
- 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/yellowcard (UK) or the HPRA Pharmacovigilance Section at HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2, Tel: +353 1 6764971, Fax +33 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 of the pack.

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 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 prefilled 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-Abelló A/S,
Bøge Allé 6-8,
DK-2970 Harsholm

**Manufacturer**

ALK-Abelló S.A.
Miguel Pica 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 October 2018

Other sources of information

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

