

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

EpiPen 300 micrograms, solution for injection in pre-filled pen.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 1 mg adrenaline (epinephrine). A single dose (0.3 ml) contains 300 micrograms (0.3 mg) adrenaline.

Excipient: Sodium Metabisulfite (E223) 0.5 mg/dose, sodium chloride 1.8 mg/dose.

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection in pre-filled pen (Auto-Injector).
Clear and colourless solution .

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The Auto-Injectors are indicated in the emergency treatment of a severe anaphylactic shock or allergic reaction to allergens e.g. insect stings or bites, foods or drugs.

4.2 Posology and method of administration

Posology

Paediatric population:

Children and adolescents over 30 kg in weight:

The usual dose is 300 micrograms for intramuscular use.

Children between 15 kg and 30 kg in weight*:

The usual dose is 150 micrograms for intramuscular use.

*For these patients EpiPen Jr. Auto-Injector containing 150 micrograms adrenaline per dose is available.

Children below 15 kg in weight:

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 in a life-threatening situation and under medical advice.

Adults:

The usual dose is 300 micrograms for intramuscular use.

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

In the absence of clinical improvement or if deterioration occurs after the initial treatment, a second injection with an additional EpiPen Auto-Injector may be necessary. The repeated injection may be administered after about 5 – 15 min.

The patient must consult a physician after injection in order to have relevant actions taken for further evaluation and/or treatment.

The physician prescribing an EpiPen Auto-Injector must ensure that the patient understands the indications for use and the correct method of application. Therefore, the physician should discuss the patient information leaflet, the correct handling of the Auto-Injector and the possible symptoms of an anaphylactic shock in detail with the patient.

Method of administration

For intramuscular administration into the anterolateral thigh, not the buttock. It is designed to inject through clothing or directly through the skin.

See section "6.6 Special precautions for disposal and other handling".

The patient/carer should be informed that following each use of EpiPen:

- They should call for immediate medical assistance, ask for an ambulance and state “anaphylaxis” **even if symptoms appear to be improving (see section 4.4)**.
- Conscious patients should preferably lie flat with feet elevated but sit up if they have breathing difficulties. Unconscious patients should be placed on their side in the recovery position.
- The patient should if possible remain with another person until medical assistance arrives.

4.3 Contraindications

There are no known absolute contraindications to the use of EpiPen during an allergic emergency.

4.4 Special warnings and precautions for use

The patient should be instructed to dial 112, ask for ambulance, state anaphylaxis 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.

The Auto-Injectors should be injected into the anterolateral aspect of the thigh. Patients should be advised not to inject into the buttock.

Adrenaline is ordinarily administered with extreme caution to patients who have a heart disease. Adrenaline should only be prescribed to those patients, but also those suffering from diabetes, hyperthyroidism, hypertension and elderly individuals if the potential benefit justifies the potential risk. There is a risk of adverse reactions following epinephrine administration in patients with high intraocular pressure, severe renal impairment, prostatic adenoma leading to residual urine, hypercalcaemia and hypokalaemia. In patients with Parkinson’s disease, epinephrine may be associated with a transient worsening of Parkinson symptoms such as rigidity and tremor.

The patient/carer should be informed about the possibility of biphasic anaphylaxis which is characterised by initial resolution followed by recurrence of symptoms some hours later.

Patients with concomitant asthma may be at increased risk of a severe anaphylactic reaction.

Accidental injection into hands or feet resulting in peripheral ischaemia has been reported. Patients may need treatment following the accidental injection. In patients with thick sub-cutaneous fat layer, there is a risk for adrenaline not reaching the muscle tissue resulting in a suboptimal effect.

EpiPen contains sodium metabisulfite 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 care-fully instructed in regard to the circumstances under which EpiPen should be used.

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

Patients should be warned regarding related allergens and should be investigated whenever possible so that their specific allergens can be characterised.

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), thyroid hormones, theophylline, oxytocin, parasympatholytics, certain antihistamines (diphenhydramine, chlorpheniramine), levodopa and alcohol.

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.

Observe. The β -stimulating effect can be inhibited by simultaneous treatment with β -blocking drugs.

4.6 Fertility, pregnancy and lactation

Pregnancy

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

Breast-feeding

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

Fertility

As adrenaline is a substance that naturally occurs in the body, it is unlikely that this drug would have any detrimental effects on fertility.

4.7 Effects on ability to drive and use machines

It is not recommended that patients should drive or use machines following administration of adrenaline, since patients will be affected by symptoms of the anaphylactic shock.

4.8 Undesirable effects

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

Evaluation of undesirable effects is based on the following frequency information:

- Very common ($\geq 1/10$)
- Common ($\geq 1/100$ to $< 1/10$)
- Uncommon ($\geq 1/1\ 000$ to $< 1/100$)
- Rare ($\geq 1/10\ 000$ to $< 1/1\ 000$)
- Very rare ($< 1/10\ 000$)
- Not known (Frequency cannot be estimated from the available data).

Organ System	Frequency	Adverse drug reaction
Psychiatric disorders	Frequency not known	Anxiety
Nervous system disorders	Frequency not known	Headache, dizziness, tremor
Cardiac disorders	Rare	Stress cardiomyopathy
	Frequency not known	Tachycardia, cardiac arrhythmia
Vascular disorders	Frequency not known	Hypertension, peripheral ischaemia following accidental injection of the pens in hands or feet
Gastrointestinal disorders	Frequency not known	Nausea, vomiting
Skin and subcutaneous tissue disorders	Frequency not known	Hyperhidrosis
General disorders and administration site condition	Frequency not known	Asthenia

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via <[the national reporting system listed in Appendix V*]/ [to be completed nationally]>.

4.9 Overdose

Overdose or inadvertent intravascular injection of adrenaline may cause cerebral haemorrhage resulting from a sharp rise in blood pressure. Fatalities may also result from pulmonary oedema because of peripheral vascular constriction together with cardiac stimulation. Pulmonary oedema may be treated with α -blocking agents such as phentolamine. In case of arrhythmias these may be treated with β -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. Adrenaline is rapidly inactivated and much of the dose of adrenaline is accounted for by excretion of metabolites in the urine.

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, by subcutaneous or intramuscular routes, local vasoconstriction retards absorption, so that the effects occur insidious and last much longer than the half-life would predict. Massage around the injection area is advised.

5.3 Preclinical safety data

There is no preclinical data of importance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Incompatibilities

Adrenaline and its salts are rapidly destroyed in solution with oxidising agents. Oxidation can be inhibited by addition of anti-oxidants. The solution darkens in colour upon exposure to air or light.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Keep container in the outer carton in order to protect from light. Do not store above 25°C. Do not refrigerate or freeze.

Check the solution periodically through the viewing window of the unit to make sure the solution is clear and colourless. Discard and replace the Auto-Injector if the solution is discoloured or contains a precipitate, or at the latest by expiration date. The expiry date is indicated on the label and the Auto-Injector should not be used after this date.

6.5 Nature and contents of container

The immediate container/closure system consists of a glass cartridge sealed by a rubber plunger at one end and by rubber diaphragm which has been inserted into an aluminium hub with attached stainless steel needle at the other end. The glass cartridge contains the product.

The Auto-Injector administration device:

Glass cartridge container:

Type I, Borosilicate Glass

Diaphragm - Stopper:

PH 701/50/Black (butyl rubber plunger)

Needle - Hub - Sheath:

Needle: Siliconised Type 304 stainless steel

Hub: Anodised 3003 aluminium alloy

Sheath: Synthetic polyisoprene

The Auto-Injector contains 2 ml solution for injection. Each Auto-Injector delivers one single dose (0.3 ml) of 300 micrograms adrenaline.

Pack sizes:

1 Auto-Injector.

6.6 Special precautions for disposal and other handling

For single use only. The Auto-Injectors must be discarded immediately after use.

During instruction of the patient in correct use of the EpiPen the prescribing doctor may use a “EpiPen® TRAINER” (contains no solution for injection and no needle).

The EpiPen Auto-Injector contains 2 ml of adrenaline injection 1 mg/ml which is designed to deliver a single dose (0.3 ml) of 300 micrograms adrenaline when activated. After activation of the Auto-Injector 1.7 ml remains in the Auto-Injector.

Do not remove blue safety cap until ready for use.

Under no circumstances place the orange end of the EpiPen Auto-Injector on or near your thumbs, fingers or hands. Accidental injection into hand or finger resulting in peripheral ischaemia has been reported. See section 4.4. The EpiPen Auto-Injector should be used on the outer thigh. The injection is activated immediately once the orange end of the EpiPen Auto-Injector comes into contact with any skin or other surface.

The EpiPen Auto-Injectors are designed for easy use by the lay person and has to be considered as a first aid. The Auto-Injector should simply be jabbed firmly against the outer portion of the thigh from a distance of approximately 10 cm. There is no need for more precise placement in the outer portion of the thigh. When EpiPen Auto-Injector is jabbed against the thigh, it releases a spring activated plunger, pushing concealed needle into the thigh muscle and expelling a dose of adrenaline:

1. Grasp EpiPen Auto-Injector in dominant hand, with thumb closest to blue safety cap.
2. With the other hand pull off blue safety cap.
3. Hold the EpiPen Auto-Injector in a distance of approximately 10 cm away from the outer thigh. The orange tip should point towards the outer thigh.
4. Jab firmly into the outer thigh, so that the EpiPen Auto-Injector is at a right angle to (at a 90 degree angle) the outer thigh.
5. Hold firmly in place for 10 seconds. The injection is now complete and the window of the Auto-Injector is obscured. The EpiPen Auto-Injector should be removed (the orange needle cover will extend to cover needle) and safely discarded.
6. Massage the injection area for 10 seconds.

A small bubble may occur in the EpiPen Auto-Injector. It has no influence on either the use or the efficacy of the product.

Instruction for use is enclosed in the package.

See Section 4.2 for instruction to be conveyed to the patient/carer regarding actions to be taken following each use of EpiPen Auto-Injector.

7. MARKETING AUTHORISATION HOLDER

<[to be completed nationally]>

8. MARKETING AUTHORISATION NUMBER

<[to be completed nationally]>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<[to be completed nationally]>

10. DATE OF REVISION OF THE TEXT

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

EpiPen Jr. 150 micrograms, solution for injection in pre-filled pen

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 500 micrograms adrenaline (epinephrine). A single dose (0.3 ml) contains 150 micrograms (0.15 mg) adrenaline.

Excipients with known effect: Sodium Metabisulfite (E223) 0.5 mg/dose, sodium chloride 1.8 mg/dose.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection in pre-filled pen (Auto-Injector).
Clear and colourless solution .

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The Auto-Injectors are indicated in the emergency treatment of a severe anaphylactic shock or allergic reaction to allergens e.g. insect stings or bites, foods or drugs.

4.2 Posology and method of administration

Posology

Paediatric population:

Children and adolescents over 30 kg weight*:

The usual dose is 300 micrograms for intramuscular use.

*For these patients EpiPen 300 micrograms, Auto-Injector containing 300 micrograms adrenaline per dose is available.

Children between 15 kg and 30 kg in weight:

The usual dose is 150 micrograms for intramuscular use.

Children below 15 kg in weight:

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 in a life-threatening situation and under medical advice.

Usual paediatric dose for allergic emergencies is 150 micrograms adrenaline for intramuscular use depending upon the body weight of the patient (0.01 mg/kg body weight). However, the prescribing physician has the option of prescribing more or less than these amounts based on careful assessment of each individual patient and recognizing the life-threatening nature of reactions for which this is being described. The physician should consider using other forms of injectable adrenaline if lower doses are felt to be necessary for small children.

Adults

The usual dose is 300 micrograms for intramuscular use.

An initial dose should be administered as soon as symptoms of anaphylaxis are recognized. In the absence of clinical improvement or if deterioration occurs after the initial treatment, a second injection with an additional EpiPen Jr. Auto-Injector may be necessary. The repeated injection may be administered after about 5 – 15 min.

The patient must consult a physician after injection in order to have relevant actions taken for further evaluation and/or treatment.

The physician prescribing an EpiPen Jr. Auto-Injector must ensure that the patient understands the indications for use and the correct method of application. Therefore, the physician should discuss the patient information leaflet, the correct handling of the Auto-Injector and the possible symptoms of an anaphylactic shock in detail with the patient.

Method of administration

For intramuscular administration into the anterolateral thigh, not the buttock. It is designed to inject through clothing or directly through the skin.

See section “6.6 Special precautions for disposal and other handling”.

The patient/carer should be informed that following each use of EpiPen Jr.

- They should call for immediate medical assistance, ask for an ambulance and state “anaphylaxis” **even if symptoms appear to be improving (see section 4.4)**.
- Conscious patients should preferably lie flat with feet elevated but sit up if they have breathing difficulties. Unconscious patients should be placed on their side in the recovery position.
- The patient should if possible remain with another person until medical assistance arrives.

4.3 Contraindications

There are no known absolute contraindications to the use of EpiPen Jr. during an allergic emergency.

4.4 Special warnings and precautions for use

The patient should be instructed to dial 112, ask for ambulance, state anaphylaxis 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.

The Auto-Injectors should be injected into the anterolateral aspect of the thigh. Patients should be advised not to inject into the buttock.

Adrenaline is ordinarily administered with extreme caution to patients who have a heart disease. Adrenaline should only be prescribed to those patients, but also those suffering from diabetes, hyperthyroidism, hypertension and elderly individuals if the potential benefit

justifies the potential risk. There is a risk of adverse reactions following epinephrine administration in patients with high intraocular pressure, severe renal impairment, prostatic adenoma leading to residual urine, hypercalcaemia and hypokalaemia. In patients with Parkinson's disease, epinephrine may be associated with a transient worsening of Parkinson symptoms such as rigidity and tremor.

The patient/carer should be informed about the possibility of biphasic anaphylaxis which is characterised by initial resolution followed by recurrence of symptoms some hours later.

Patients with concomitant asthma may be at increased risk of a severe anaphylactic reaction.

Accidental injection into hands or feet resulting in peripheral ischaemia has been reported. Patients may need treatment following the accidental injection.

In patients with thick sub-cutaneous fat layer, there is a risk for adrenaline not reaching the muscle tissue resulting in a suboptimal effect.

EpiPen Jr. contains sodium metabisulfite 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 EpiPen Jr. should be used.

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

Patients should be warned regarding related allergens and should be investigated whenever possible so that their specific allergens can be characterised.

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), thyroid hormones, theophylline, oxytocin, parasympatholytics, certain antihistamines (diphenhydramine, chlorpheniramine), levodopa and alcohol.

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.

Observe. The β -stimulating effect can be inhibited by simultaneous treatment with β -blocking drugs.

4.6 Fertility, pregnancy and lactation

Pregnancy

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

Breast feeding

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

Fertility

As adrenaline is a substance that naturally occurs in the body, it is unlikely that this drug would have any detrimental effects on fertility.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

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

Evaluation of undesirable effects is based on the following frequency information:

- Very common ($\geq 1/10$)
- Common ($\geq 1/100$ to $< 1/10$)
- Uncommon ($\geq 1/1\ 000$ to $< 1/1\ 00$)
- Rare ($\geq 1/10\ 000$ to $< 1/1\ 000$)
- Very rare ($< 1/10\ 000$)
- Not known (Frequency cannot be estimated from the available data)

Organ System	Frequency	Adverse drug reaction
Psychiatric disorders	Frequency not known	Anxiety
Nervous system disorders	Frequency not known	Headache, dizziness, tremor
Cardiac disorders	Rare	Stress cardiomyopathy
	Frequency not known	Tachycardia, cardiac arrhythmia
Vascular disorders	Frequency not known	Hypertension, peripheral ischaemia following accidental injection of the pens in hands or feet
Gastrointestinal disorders	Frequency not known	Nausea, vomiting
Skin and subcutaneous tissue disorders	Frequency not known	Hyperhidrosis
General disorders and administration site condition	Frequency not known	Asthenia

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare

professionals are asked to report any suspected adverse reactions via <[the national reporting system listed in Appendix V*] / [to be completed nationally]>.

4.9 Overdose

Overdose or inadvertent intravascular injection of adrenaline may cause cerebral haemorrhage resulting from a sharp rise in blood pressure. Fatalities may also result from pulmonary oedema because of peripheral vascular constriction together with cardiac stimulation. Pulmonary oedema may be treated with α -blocking agents such as phentolamine. In case of arrhythmias these may be treated with β -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.

Adrenaline is rapidly inactivated and much of the dose of adrenaline is accounted for by excretion of metabolites in the urine.

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, by subcutaneous or intramuscular routes, local vasoconstriction retards absorption, so that the effects occur insidious and last much longer than the half-life would predict. Massage around the injection area is advised.

5.3 Preclinical safety data

There is no preclinical data of importance to the prescriber.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Chloride

Sodium Metabisulfite (E223)

Hydrochloric Acid (for pH adjustment)
Water for Injections

6.2 Incompatibilities

Adrenaline and its salts are rapidly destroyed in solution with oxidising agents. Oxidation can be inhibited by addition of anti-oxidants. The solution darkens in colour upon exposure to air or light.

6.3 Shelf life

18 months

6.4 Special precautions for storage

Keep container in the outer carton in order to protect from light. Do not store above 25°C. Do not refrigerate or freeze.

Check the solution periodically through the viewing window of the unit to make sure the solution is clear and colourless. Discard and replace the Auto-Injector if the solution is discoloured or contains a precipitate, or at the latest by expiration date. The expiry date is indicated on the label and the Auto-Injector should not be used after this date.

6.5 Nature and contents of container

The immediate container/closure system consists of a glass cartridge sealed by a rubber plunger at one end and by rubber diaphragm which has been inserted into an aluminium hub with attached stainless steel needle at the other end. The glass cartridge contains the product.

The Auto-Injector administration device:

Glass cartridge container:

Type I, Borosilicate Glass

Diaphragm - Stopper:

PH 701/50/Black (butyl rubber plunger)

Needle - Hub - Sheath:

Needle: Siliconised Type 304 stainless steel

Hub: Anodised 3003 aluminium alloy

Sheath: Synthetic polyisoprene

The Auto-Injector contains 2 ml solution for injection. Each Auto-Injector delivers one single dose (0.3 ml) of 150 micrograms adrenaline.

Pack sizes:

1 Auto-Injector.

6.6 Special precautions for disposal and other handling

For single use only. The Auto-Injectors must be discarded immediately after use.

During instruction of the patient in correct use of the EpiPen Jr. the prescribing doctor may use a “EpiPen® TRAINER” (contains no solution for injection and no needle).

The EpiPen Jr. Auto-Injector contains 2 ml of adrenaline injection 500 micrograms/ml which is designed to deliver a single dose (0.3 ml) of 150 micrograms adrenaline when activated. After activation of the Auto-Injector 1.7 ml remains in the Auto-Injector.

Do not remove blue safety cap until ready for use.

Under no circumstances place the orange end of the EpiPen Jr. Auto-Injector on or near your thumbs, fingers or hands. Accidental injection into hand or finger resulting in peripheral ischaemia has been reported. See section 4.4. The EpiPen Jr. Auto-Injector should be used on the outer thigh. The injection is activated immediately once the orange end of the EpiPen Jr. Auto-Injector comes into contact with any skin or other surface.

The EpiPen Jr. Auto-Injectors are designed for easy use by the lay person and has to be considered as a first aid. The Auto-Injector should simply be jabbed firmly against the outer portion of the thigh from a distance of approximately 10 cm. There is no need for more precise placement in the outer portion of the thigh. When EpiPen Jr. Auto-Injector is jabbed against the thigh, it releases a spring activated plunger, pushing concealed needle into the thigh muscle and expelling a dose of adrenaline:

1. Grasp EpiPen Jr. Auto-Injector in dominant hand, with thumb closest to blue safety cap.
2. With the other hand pull off blue safety cap.
3. Hold the EpiPen Jr. Auto-Injector in a distance of approximately 10 cm away from the outer thigh. The orange tip should point towards the outer thigh.
4. Jab firmly into the outer thigh, so that the EpiPen Jr. Auto-Injector is at a right angle to (at a 90 degree angle) the outer thigh.
5. Hold firmly in place for 10 seconds. The injection is now complete and the window of the Auto-Injector is obscured. The EpiPen Jr. Auto-Injector should be removed (the orange needle cover will extend to cover needle) and safely discarded.
6. Massage the injection area for 10 seconds.

A small bubble may occur in the EpiPen Jr. Auto-Injector. It has no influence on either the use or the efficacy of the product.

Instruction for use is enclosed in the package.

See section 4.2 for instructions to be conveyed to the patient/carer regarding actions to be taken following each use of EpiPen Jr. Auto-Injector.

7. MARKETING AUTHORISATION HOLDER

<[to be completed nationally]>

8. MARKETING AUTHORISATION NUMBER

<[to be completed nationally]>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
<[to be completed nationally]>

10. DATE OF REVISION OF THE TEXT