

# CLEAN COPY OF ENGLISH PACKAGE INSERT

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**SCHEDULING STATUS:** S4

**PROPRIETARY NAME** (and dosage form):

**EPIPEN® AUTO-INJECTOR**

**EPIPEN® Jr AUTO-INJECTOR**

**COMPOSITION:**

Each 0,3 ml of **EPIPEN®** Auto-injector contains:

Adrenaline 0,3 mg

Sodium Metabisulfite (Antioxidant)

Each 0,3 ml of **EPIPEN® Jr** Auto-injector contains:

Adrenaline 0,15 mg

Sodium Metabisulfite (Antioxidant)

**PHARMACOLOGICAL CLASSIFICATION:**

A 5.1 Adrenomimetics (sympathomimetics)

**PHARMACOLOGICAL ACTION:**

Adrenaline is a sympathomimetic agent.

**INDICATIONS:**

Use as an adjunct in the treatment of severe anaphylactic or life-threatening reactions. **EPIPEN®** and **EPIPEN® Jr** are to be used only when prescribed by a doctor for patients who are highly allergic and in danger of developing a life-threatening reaction. **EPIPEN®** and **EPIPEN® Jr** are intended as emergency treatment and should not substitute any medical care to be implemented at a later stage.

**CONTRA-INDICATIONS:**

Sensitivity to any of the ingredients including sensitivity to sulphites.

**WARNINGS:**

The Adrenaline solution should be checked every 14 days for any brown discolouration.

If there is any such discolouration or if any turbidity has formed, the solution should not be used.

Should the patient accidentally inject him or herself, in the hands, feet, fingers or toes; immediate hospitalisation together with the appropriate treatment is recommended.

## INTERACTIONS:

Interaction with monoamine oxidase inhibitors and alpha and betablockers may occur.

## DOSAGE AND DIRECTIONS FOR USE:

**EPIPEN<sup>®</sup>** or **EPIPEN<sup>®</sup> Jr** should be administered immediately in the case of the development of a life-threatening reaction.

**EPIPEN<sup>®</sup>** is intended for the treatment of adults and children with a body mass of more than 45 kg.

**EPIPEN<sup>®</sup> Jr** is intended for the treatment of children with a body mass of less than 45 kg.

**EPIPEN<sup>®</sup>** and **EPIPEN<sup>®</sup> Jr** are for single dose administration only and the unused portion must be discarded.

Never put thumb, fingers or hand over orange tip. The needle comes out of the orange tip.

Do not remove blue safety release until ready to use.

A dose of 0,3 ml (0,23 - 0,37 ml) injection fluid is automatically injected intramuscularly by the auto-injector. Grasp unit with the orange tip pointing downward, form a fist around the unit (orange tip down). With your other hand, pull off the blue safety release. Hold the orange tip near outer thigh. **DO NOT INJECT INTO BUTTOCK.** Take the shaft firmly in the hand with the orange plastic tip directed to the upper thigh whilst pushing hard against the skin until the mechanism releases the injection needle. The device should be held in position for at least 10 seconds. Remove the unit from thigh (the orange needle cover will extend to cover needle). After this the device is removed from the thigh and the injection area massaged for 10 seconds. A doctor should be consulted as soon as possible and the used device taken along.

Intravascular injection should be avoided at all costs.

Figure (1):



Figure (2):



**SIDE-EFFECTS AND SPECIAL PRECAUTIONS:**

The following side-effects have been reported and the frequencies are unknown:

*Nervous System Disorders:*

Fear, anxiety, restlessness, insomnia, confusion, irritability, headaches.

*Gastrointestinal Disorders:*

Loss of appetite, nausea, vomiting.

*Psychiatric Disorders:*

Psychotic states.

*Musculoskeletal and Connective Tissue Disorders:*

Tremors, weakness.

*Vascular Disorders:*

Cerebral haemorrhage (very rare).

*Respiratory, Thoracic and Mediastinal Disorders:*

Pulmonary oedema, dyspnoea.

*Cardiac Disorders:*

Tachycardia, cardiac arrhythmias, anginal pain, palpitations, cardiac arrest, hypotension with dizziness and fainting.

*Renal and Urinary Disorders:*

Difficulty in micturition, urinary retention.

*Endocrine Disorders:*

Hypersalivation, altered metabolism including disturbances of glucose metabolism.

**Special precautions:**

**EPIPEN®** and **EPIPEN® Jr** should be used with caution in patients with hyperthyroidism, ischaemic heart disease, arrhythmia or tachycardia, hypertension or aneurysms, diabetes mellitus or closed angle glaucoma and in patients on antihypertensive therapy.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

See under "Side-effects and Special Precautions".

Treatment of overdosage is symptomatic and supportive.

**IDENTIFICATION:**

Clear, colourless solution, free from foreign visible particles.

**PRESENTATION:**

This pre-filled disposable automatic injection device is designed to deliver a single dose. It consists of a glass cartridge, containing the drug product, sealed by a rubber plunger at one end and by a rubber diaphragm, which has been inserted into an aluminium hub with attached stainless steel needle at the other end.

**STORAGE INSTRUCTIONS:**

Store below 25°C, protected from light.

Do not refrigerate.

KEEP OUT OF REACH OF CHILDREN.

For single use only. Discard unit after use.

**EPIPEN®** Auto-injector: 27/5.1/0063

**EPIPEN® Jr** Auto-injector: 38/5.1/0278

**NAME AND BUSINESS ADDRESS OF THE APPLICANT:**

Mylan (Pty) Limited

Building 6, Greenstone Hill Office Park

Emerald Boulevard, Modderfontein, 1645

Republic of South Africa

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