

**PAMPHLET : INFORMATION FOR THE USER**  
**Adrenalina Level 1mg/ml injectable solution**  
**Epinefrina**

**Please read the whole information pamphlet carefully before starting to use this medicine.**

- Do not throw this pamphlet away as you may need to reread it.
- If you have any doubts please consult your doctor or a pharmacist.
- This medicine has been prescribed for you and you must not give it to other people, even if they have the same symptoms, as this could be prejudicial to them.
- If you consider that any of the side effects is serious, or you appreciate an adverse effect that is not mentioned in this pamphlet inform your doctor or pharmacist.

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**1. What is Adrenalina Level and what is it used for?**

Adrenalina Level belongs to the group of medicines known as cardiac stimulants excluding cardiac glucosides: adrenergic agents and dopaminergics. It is indicated for the following cases:

- Treatment of sudden and involuntary muscular contraction in the respiratory passages in strong asthma attacks (a sudden feeling of breathlessness).
- Rapid relief from allergic reactions to medicines or other substances.
- Treatment of emergency shock as a result of an allergic reaction.
- Cardiac arrest and cardio-lung reanimation (at first it is necessary to apply physical measures).

**2. Before using Adrenalina Level.**

**Do not use Adrenalina Level**

- If you are allergic (hypersensitive) to adrenaline, to sympathomimetics (medicines which stimulate the central nervous system) or any of the other components of Adrenalina Level.
- If you suffer from cardiac dilatation, coronary insufficiency, cardiac arrhythmias or cardiac insufficiency (problems in the working of the heart).
- If you suffer from organic cerebral injuries, such as cerebral atherosclerosis (chronic inflammation of the brain's arteries with a tendency to their obstruction).

- If you have closed angle glaucoma (affliction of the eyes characterised by an increase of intraocular tension).
- If you suffer from arterial hypertension, hyperthyroidism (alteration of the thyroid glands) or pheochromocytoma (medullar super renal tumour).
- Giving birth
- If you have received general anaesthetic with halogen hydrocarbons (chloroform, trichloroethylene) or ciclopropanene, as the combination with adrenaline could provoke serious arrhythmias (alteration of the heartbeat).

However, in cases of extreme seriousness there are no absolute counter indications.

### **Be especially careful with Adrenalina Level**

If you suffer or have suffered from a stroke (affliction of the brain's blood vessels), cardiac illness (like angina pectoris myocardial infarction), chronic pulmonary illness or urinary difficulty due to a hypertrophic prostate (alteration of the prostate).

If you are taking any other medicine which can produce a loss of potassium, such as corticosteroids (medicines used for their anti inflammatory and immunosuppressant properties), diuretics (they facilitate urination), aminophaline (a medicine used to facilitate respiration) or theophylline (anti asthma, helps urination), you will have to check the level of potassium in your blood.

If you are diabetic you must take special care due to the possible side effects that can appear, above all related to metabolic alterations as it is necessary to check the dose.

This medicine can be used by older patients but special care is recommended.

The repeated administration of local injections can lead to necrosis in the area injected due to vascular vasoconstriction (contraction of the blood vessels). The point of injection must be alternated.

Consult your doctor, even if only one of the aforementioned circumstances has happened to you.

### **Use of other medicines**

Inform your doctor or pharmacist if you are using or have recently used other medicines, even those acquired without a prescription, homeopathic products, medicinal plants and other health related products as it may be necessary to interrupt the treatment or adjust the dose of some of them.

Adrenergic blockers (drugs that act on the neurons and modify the physiology of organs and tissues) antagonise some of the effects of adrenaline. They are used as therapy in cases of adrenaline intoxication.

If this drug is administered in conjunction with digitalis glycosides (medicines for the heart) cardiac arrhythmias can appear (alteration of the heartbeat).

If this drug is administered in conjunction with certain anti depressive medicines or with guanethidine (an anti hypertension agent) an intense rise in the arterial tension can occur.

If this medicine is administered in conjunction with COMT or MAO inhibitors (medicines which act on the metabolic systems responsible for the elimination of adrenaline), this medicine will be less effective.

Adrenalina Level can reduce the effectiveness of glucose lowering drugs (those which lower the level of sugar in the blood).

#### Interference with analytic tests

If you are going to have an analytic test (blood or urine analysis) inform your doctor that you are in treatment with adrenaline, as this medicine can alter the results of the level of sugar in the blood, bilirubin, cholesterol, lactates, uric acid and insulin. In urine, adrenaline can alter the results of vanillylmandelic and catecholamine acids.

#### **Pregnancy and when breastfeeding**

Consult your doctor or pharmacist before using any medicine.

If you are pregnant you will receive adrenaline only if your doctor considers it absolutely necessary for your treatment.

This medicine is excreted with maternal milk, consequently it is recommended to suspend breast feeding or avoid using this medicine.

#### **Driving and the use of machines**

This is not appropriate in the context of treatment with this medicine.

#### **Important information about some of the components of Adrenalina Level**

This medicine can produce serious allergic reactions and bronchospasms (a sudden feeling of breathlessness) because it contains the sodium acid sulphite (E-222).

This medicine contains less than 23mg (1 mmol/l) of sodium per dose (1ml), as a result it is considered essentially 'sodium free'.

#### **Use by sportsmen/women**

This medicine contains adrenaline which can produce a positive result in doping tests.

The use of adrenaline when administered in association with local anaesthetics or with agents for local administration, for example for nasal or ophthalmologic administration.

### 3. How to use Adrenalina Level

Adrenalina level will be administered by qualified health personnel in the case that it be administered intravenously or intracardiacy.

Adrenalina Level can be administered subcutaneously intramuscularly or intravenously. Only in cases of extreme gravity and if the intravenous method is not possible can it be administered via the intracardiac method. The intravenous and intracardiac methods can only be used via previous dilution in water for injection, 0.9% sodium chloride solution, glucose 5% in a 0.9% solution of sodium chloride, this must be done in hospitals and under cardiac monitoring.

The lowest dose that produces relief. After prolonged use it may be necessary to increase the dose due to the development of resistance to the action of adrenaline.

**Intramuscular injection in the groin area must be avoided**, as it can produce gas gangrene (a diffuse gangrene of the tissue under the skin with the production of gases), as well as peripheral areas such as fingers and toes, ear lobules, the nose or penis.

#### Sharp asthma attacks, allergic reactions and anaphylactic shock

-Adults: the usual dose for the treatment of **sharp asthma attacks and allergic reactions is of 0.3-0.5 mg (0.3-0.5 ml) intramuscularly or subcutaneously, the intramuscular method is the quickest and most effective**. If necessary the treatment can be repeated after 20 minutes and then every 4 hours. In the case of anaphylactic shock the intramuscular method must be used, or in very serious cases the intravenous method, if adrenaline is administered intravenously then this must be done in a hospital. In serious cases the dose can be raised up to 1 mg if necessary.

-Children: the usual dose is **0.01mg (0.01ml) per kg of body weight either intravenously or subcutaneously up to a maximum dose of 0.5mg (0.5ml)**. If necessary the treatment can be repeated 15 – 20 minutes later and then every 4 hours. It cannot be administered to children weighing less than 20kg as the minimum dose allowed by the syringe is 0.2ml.

The dosage is the same for elderly patients as it is for adults, though special care is needed.

#### Cardiac arrest and cardiopulmonary reanimation

In the treatment of cardiac arrest and cardiopulmonary reanimation the recommended dose of adrenaline is 1mg intravenously which must be administered after previously diluting it at 1:10.000 and it can be repeated as many times as necessary every 3-5 minutes.

In children the standard dose is 0.01mg/kg administered intravenously, this can be repeated every 5 minutes if necessary.

It cannot be administered to children with a weight of less than 20kg, as the minimum dose allowed by the syringe is 0.2ml.

In the case that the intravenous method is not possible the intracardiac method method can be used (using the same diluted solution). However, it must be remembered that this

method presents important risks and should only be used in the case that the intravenous path is persistently inaccessible.

#### Rules for the correct administration of Adrenalina Level

Separate the protective sleeve from the cone point of the syringe with a rotating movement. Expulse the air and the syringe will be ready to use.

This syringe must be used once and then be destroyed. Shared use constitutes risk of infection.

#### **If you use more Adrenalina Level than you should**

An overdose of adrenaline can produce sharp rises in the arterial tension and tachycardia (acceleration of the hearts rhythm), this can occur after a first transitory phase of bradycardia (abnormal slowness of the heart's rhythm). Potentially fatal arrhythmias can also appear (alteration of the heartbeat).

The duration of the adverse effects of adrenaline is brief due to its rapid inactivation by the body, as a result the treatment of these adverse effects is of support. To correct adverse effects on the arterial tension and the hearts rhythm some medicines like phentolamine and propanole can be administered. If a sharp rise in the arterial pressure occurs then vasodilatory medicines such as nitrates can be administered. Angina attacks are treated with trinitrine sublingually, whereas in the case of ventricular fibrillation (abnormal contraction of the heart) the electric defibrillator must be used.

In the case of overdosing or accidental injection immediately consult your pharmacist or doctor, or phone the Toxicological Information Service on 915620420 (indicating the medicine and the amount injected).

#### **4. Possible side effects**

As with all medicines Adrenalina Level can produce adverse effects, though not all people may suffer them.

It must be remembered that the appearance and severity of these effects is linked to the how the drug is administered, the subcutaneous and intramuscular methods causing less incidences than the intravenous and intracardiac methods.

-Frequent (>1/100, <1/10)

Disturbances in the nervous system: fear, anxiety, puling headache, breathing difficulty, sweating and nausea, vomiting, trembling and dizziness.

Cardiovascular disturbances: tachycardia, palpitations, paleness, slight rise in blood pressure.

These symptoms are not serious and disappear with the relaxation and tranquilising of the patient.

Infrequent (>1/1000, <1/100)

Cardiovascular disturbances (heart and blood vessels: hypertension, which could lead to a cerebral haemorrhage or acute cardiac insufficiency with pulmonary edema (infiltration of liquid in the lungs), angina pectoris (even with the doses common in patients with coronary insufficiency), ventricular arrhythmias (alteration of the heartbeat), tachycardia (acceleration of the rhythm) and ventricular fibrillation (abnormal contraction of the heart), which can be mortal.

Some cases of difficulty urinating, necrosis at the point of injection metabolic acidosis and renal failure have been observed.

If you consider any of the side effects to be serious or if you notice any side effect not mentioned in this pamphlet, inform your doctor or pharmacist.

## **5. Conservation of Adrenalina Level**

Keep out of sight and reach of children.

Do not use Adrenalina Level after the expiry date that appears on the container. The date of expiry is the last day of the month indicated.

You do not need to take any special care of Adrenalina Level. Conserve it in its original container.

Adrenalina Level must be used immediately after opening the syringe. Discard any residual liquid.

Do not use Adrenalina Level if you notice that the solution presents colouration or sedimentation.

Medicines must not be disposed of in the drains or thrown away. Ask your pharmacist how to dispose of any containers or unneeded medicines. This way you will help look after the environment.

## **6. Additional information**

### **Composition of Adrenalina Level**

-The principal ingredient is epinephrine (adrenaline). Each millilitre of solution contains 1 milligram of epinephrine.

-The remaining ingredients are sodium chloride, acid sulphite of sodium (E-222), hydrochloric acid (to adjust the pH) and water for injection.

### **Appearance of Adrenalina Level**

Adrenalina Level is a transparent watery solution with a slightly yellow colour which is presented in pre-prepared Type I glass syringes with a capacity of 1 millilitre.

Size of container: box of 1 or 50 units.

**Holder of the authorisation for the commercialisation and fabrication of the product.**

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