SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT.

POTENCIATOR® 5 g oral solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ampoule of 10 mL contains 5 g of Arginine aspartate.

Excipients with known effect:
Saccharose, 1,3 g, Sorbitol (E-420) 2 g, methyl parahydroxybenzoate (E-218) 8 mg, propyl parahydroxybenzoate (E-216) 2 mg.

To check the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.
The solution is brown colour with caramel odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention of deficiency states of amino acids caused by an insufficient protein intake due to imbalanced or restrictive diets (weight loss, vegetarian), convalescence.
Potenciator 5 g oral solution is indicated in adults and adolescents over 12 years.

4.2 Posology and method of administration

Posology

Adults and adolescents (over 12 years of age):
The recommended dose is 1 ampoule once a day (5 g of arginine aspartate) during lunch.

Under normal circumstances, the treatment should not exceed 2 weeks.

Pediatric population
Potenciator should not be taken by children aged under 12 years due to the dosage.

Method of Administration

Oral way
Detach the ampoule, Tear the tab at the top of the ampoule with a twisting motion, after turning it upside down, press the ampoule and pour its contents in a glass.

Potenciator can be taken diluted with some water or fruit juice.

4.3 Contraindications

- Hypersensitivity to the active substance or any of the excipients included in section 6.1
- Pregnancy

Due to the Potenciator's dose (high), it is contraindicated in:

- Breastfeeding
- Children under 12 years of age.

4.4 Special warnings and precautions for use

Maintained and continued use of this preparation for long periods of time is not recommended. Do not exceed the recommended daily dose.

Special precautions should be taken in case of liver and/or kidney severe insufficiency or diabetes.
The active ingredient (arginine) could produce hyperkalemia in patients with severe liver disease or kidney disease.

People with urinary retention problems will take the drug under medical supervision.
Patients with cystic fibrosis may suffer abdominal cramps, weight loss and abdominal swelling while taking this medicine.

Warning about excipients:

This drug contains saccharose. Patients with hereditary fructose intolerance, glucose-galactose malabsorption or saccharose-isomaltase insufficiency should not take this product.

This drug contains sorbitol. Patients with hereditary fructose intolerance should not take this product.

It may cause allergic reactions (possibly delayed) because it contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E-216).

4.5 Interaction with other medicinal products and other forms of interactions

The following interactions could be produced:

- Potassium-sparing diuretics, such as amiloride, spironolactone or triamterene: arginine administration may produce hyperkalemia, especially in patients with severe liver disease treated with potassium-sparing diuretics.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no data from the use of Arginine aspartate in pregnant women.
Animal studies are insufficient with respect to reproductive toxicity.
Potenciator should not be used during pregnancy.

Lactation

The risk in newborns / infants cannot be excluded.
Potenciator should not be used during breastfeeding.

4.7 Effects on ability to drive and use machines

The influence of Potenciator on the ability to drive and use machine is nule or insignificant.

4.8 Undesirable effects.

The following side effects may occur with a frequency not known exactly:

- Blood and lymphatic system disorders:
  Some cases of thrombocytopenia and hematuria have been reported.

- Immune system disorders:
  In rare cases allergic reactions (hypersensitivity) to any component of the formulation may appear.

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 National Reporting System.

4.9 Overdose

No case of overdose has been reported. Continued or accidental intake of large doses may cause gastrointestinal discomfort (diarrhoea, nausea, vomiting).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Other alimentary tract and metabolism products. Amino acids and derivatives, ATC code: A16AA.

Arginine is a basic amino acid which is essential for growth. It is used as a supplement for

treating or preventing dietary deficiency or to help recovery in convalescence. It is orally administered as aspartate or other salts.

Arginine aspartate is a dipeptide formed by the union of two amino acids whose activity is of vital importance for cell metabolism.

L-Arginine is a nitric oxide precursor, having activity as a vasodilator, inhibitor of the platelet aggregation and modulator of immunological processes and epithelial permeability. Arginine also stimulates the release of the growth hormone (GH) from the hypophysis, presumably as a result of effects on the hypothalamus.

Arginine hydrochloride orally administered before an IV injection of growth hormone releasing hormone has been shown to significantly increase the release of the growth hormone (GH) in short prepubertal children.

5.2 Pharmacokinetic Properties

Arginine aspartate is rapidly absorbed and increases the plasmatic concentration of the two amino acids.
The bioavailability of arginine orally is of a 20% approximately. It is metabolized in the liver after hydrolysis of the guanidine group by arginase, producing ornithine and urea.
Arginine reaches it maximum concentration by oral administration at 90 minutes.

5.3 Preclinical safety Data

There are no toxicity, genotoxicity, carcinogenic potential, and toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sorbitol (E-420) (solution 70%)
Saccharose
Citric acid monohydrate
Sodium Saccharin
Caramel aroma
Caramel colouring
Potassium sorbate (E-202)
Methyl parahydroxybenzoate (E-218)
Propyl parahydroxybenzoate (E-216)
Deionised water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

3 years.

6.4 Special precautions for storage

Do not store above 25 ºC.

6.5 Nature and contents of container

Amber PVC/PVDC/PE (polyvinyl chloride/polyvinylidene chloride/polyethylene) ampoules containing 10 mL of solution.
Packs of 20 ampoules

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

FAES FARMA S.A.
Máximo Aguirre, 14
48940 Leioa (Vizcaya) SPAIN

8. MARKETING AUTHORISATION NUMBER(S)

60684

9. DATE OF FIRST AUTHORISATION

Date of first authorisation: 09 May 1995
Date of the last revalidation: 30/11/2009

10. DATE OF REVISION OF THE TEXT

July/ 2014