SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Medicinal product

GAMALATE B6 oral solution

2. Qualitative and quantitative composition.

Each 5 ml of oral solution contains:
Magnesium glutamate hydrobromide (MGH).....100 mg
γ-amino-butyric acid (GABA).....100 mg
γ–amino-β-hydroxy-butyric acid (GABOB)..... 50 mg
Vitamin B6.....50 mg

List of excipients, see section 6.1.

3. Pharmaceutical form

Oral solution

4. Clinical particulars.

4.1 Therapeutical indications.

Decrease of intellectual performance in children.
Behavior disorders (hyperactivity) in children with mild to moderate intellectual impairment.
Decrease of the intellectual performance in adults.
Somatic symptoms related to anxiety.

4.2 Posology and method of administration.

Gamalate B6 oral solution is administrated by oral route.

Adults: 10 ml 2 or 3 times daily.
Children up to 2 years: 2.5 ml 3 times daily.
From 2-4 years: 5 ml 3 times daily.
From 4-7 years: 10 ml 2 times daily.
Over 7 years: 10 ml 2-3 times daily.

4.3 Contraindications.

In case of hypersensitivity to any of the components.

4.4 Special Warnings and precautions for use.

GAMALATE B6 oral solution contains Sorbitol (E-420) as excipient, because of that patients with rare hereditary problems of fructose intolerance should not take this medicine.

GAMALATE B6 oral solution contains Propyl parahydroxybenzoate and Methyl parahydroxybenzoate as excipients, because of that it may cause allergic reactions

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Date 01.10.15

(possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction.

Not known

4.6 Pregnancy and lactation

The safety of medicine during pregnancy and lactation has not been established. In pregnant women or women that can be pregnant or during the lactation period, it should be administrated in case the expected therapeutic benefit is considered to outweigh any possible risk.

4.7 Effects on the ability to drive and use machines.

Not applicable.

4.8 Undesirable effects.

When used in high doses can provoke dyspepsia, which disappears with the dose adjustment. It is possible the appearance of allergic reactions.

4.9 Overdose.
Given the scarce of the preparation, poisoning is not foreseen, even by accident.
Symptoms can be the intensification of undesirable effects and should be treated symptomatically.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapautic group: Psychoanaleptics. Other psychostimulants and nootropics.
ATC-code: N06BX

Gamma-aminobutyric acid or GABA acts as a post-synaptic inhibitor. Metabolized in the brain, via transamination and decarboxylation, becomes succinic acid, incorporated into the Krebs cycle.
Factors affecting the contents or conditions of GABA in the brain have a remarkable influence on brain activities. Thus the GABA level would depend on the activity of glutamic acid decarboxylase, which would form GABA, and transaminase which would eliminate GABA. In situations of hyperarousal, anomalies are detected at the level of synaptic transmission. The levels required for the enzymatic transformation of glutamic acid into GABA are decreased in these circumstances, so that the levels of glutamic acid and GABA, the modulator of neurotransmission, increase.
Administration of Gamalate B_6 is an attempt to correct the deficit of GABA immediately by external administration and additionally normalize metabolic biochemical processes of its production at synaptic level. Thanks to its content of GABA and GABOB (GABAs precursor) it is corrected immediately decreased level of GABA in states of hyperarousal. Thanks to its content of BMG, that acts as an agonist of glutamate receptors, blocking them and inhibits the erousal produced by this. Also, pyridoxine, a coenzyme necessary for the transformation of glutamic acid into GABA, helps to activate this metabolic conversion.

5.2 Pharmacokinetic properties.

Gamalate B_6 oral solution is well absorbed after oral administration.

5.3 Preclinical safety data.

LD_{50} was determined for Gamalate B_6 oral solution in Wistar albino rats with 180-220g, which was administered by gastric gavage 12% solution with distilled water. At a dose of 6g/kg only one death was recorded in 24 hours, this being the maximum administered dose, which would correspond to 100 cc of solution per kilogram, which can be considered that the LD 50 in this animal model is indeterminable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients.

Each 5ml contains:
Saccharin sodium 5mg; citric acid 5mg; methyl parahydroxybenzoate 6.75mg; propyl parahydroxybenzoate 0.75mg; raspberry essence 8mg; sunset yellow 0.05mg; sorbitol 3g and purified water q.s 5ml.

6.2. Incompatibilities.

Not known

6.3 Shelf life.

5 years

6.4 Special precautions for storage

Store at temperature below 30 ºC

6.5 Nature and contents of container

Amber glass bottle with screw cap containing 80 ml of oral solution.

6.6 Special precautions for disposal

Not applicable

7. Manufacturer
FERRER INTERNACIONAL, S.A. (Central Office)
Gran Via Carlos III, 94
08028 Barcelona
SPAIN

FERRER INTERNACIONAL, S.A. (Manufacturing Site)
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SPAIN

8. Marketing authorization holder

FERRER INTERNACIONAL, S.A. (Central Office)
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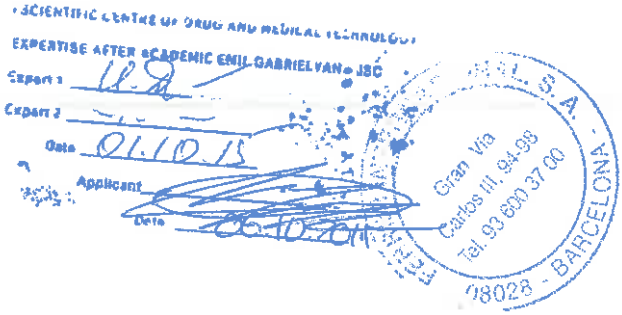

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