Nootropil™
Piracetam

1. NAME OF THE MEDICINAL PRODUCT
Piracetam, 800 mg, film-coated tablet
Piracetam, 1200 mg, film-coated tablet
Piracetam, 3 g/15 ml, solution for injection
Piracetam, 12 g/60 ml, solution for infusion

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Piracetam, 800 mg, film-coated tablet
Each film-coated tablet contains 800 mg of piracetam.

Piracetam, 1200 mg, film-coated tablet
Each film-coated tablet contains 1200 mg of piracetam.

Piracetam, 3 g/15 ml, solution for injection
Each 15 ml solution for injection contains 3 g of piracetam.

Piracetam, 12 g/60 ml, solution for infusion
Each 60 ml solution for infusion contains 12 g of piracetam.

Excipients
Piracetam, 800 mg, film-coated tablet
Piracetam, 1200 mg, film-coated tablet
Macrogol 6000, Colloidal anhydrous silica, Magnesium stearate, Sodium croscarmellose, Hydroxypropylmethylcellulose, Titanium dioxyde (E171), Macrogol 400.

Piracetam, 3 g/15 ml, solution for injection
Sodium acetate, Glacial acetic acid, Water for injection.

Piracetam, 12 g/60 ml, solution for infusion
Sodium acetate, Glacial acetic acid, Sodium chloride, Water for injection.

3. PHARMACEUTICAL FORM
Piracetam, 800 mg, film-coated tablet
Piracetam, 1200 mg, film-coated tablet
White, oblong, film-coated tablet, with a bisect line, marked N/N.

Piracetam, 3 g/15 ml, solution for injection
Piracetam, 12 g/60 ml, solution for infusion
Clear colourless solution.

4. CLINICAL INFORMATION
4.1 Indications
- Film-coated tablet 800 mg and 1200 mg:
  1. Involution syndrome related to ageing: memory deficits, asthenia, adaptation disorders, and disturbed psychomotor reactions.
  2. Post traumatic syndrome: cerebral dysfunction to post traumatic sequelae
- Injection and infusion :
  Post traumatic syndrome : cerebral dysfunction to post traumatic sequelae (headache, vertigo, agitation, memory disorders, asthenia).

4.2 Dosage and Administration
- Film-coated tablet 800 mg and 1200 mg:
  Psycho-organic syndrome related to ageing:
  - Initial dose : 2,4 g (3 film-coated tablet 800 mg) per day in 3 divided doses during 6 weeks.
  - Maintenance dose : 1.2 g per day in 3 divided doses.

  Post traumatic syndrome :
  - Initial dose: 3 × 800 mg a day orally. After therapeutic effect achieved, decrease the dosage gradually until 400 mg three times a day.
  - Film-coated tablet 1200 mg are used for treatment in patients who need a high dose.
  - Usual dose: 1.2-4.8 g per day in 2-3 divided doses.

- Injection and infusion:
  - 1 g three times a day, i.v.

Renal impairment
Piracetam is contraindicated in severe renal impairment (renal creatinine clearance of less than 20 ml per minute) *(see Sections: Contraindications: Warnings and Precautions)*.

The daily dose must be individualised according to renal function. Refer to the following table and adjust the dose as indicated. To use this dosing table, an estimate of the patient's creatinine clearance (Clcr) in ml/min is needed. The Clcr in ml/min may be estimated from serum creatinine (mg/dl) determination using the following formula:

$$Clcr = \frac{[140 - age\ (years)]\ x\ weight\ (kg)}{[72\ x\ serum\ creatinine\ (\frac{mg}{dl})]\ (x\ 0.85\ for\ women)}$$

Group	Creatine Clearance (ml/min)	Posology and frequency
Normal	>80	Usually daily dose, 2 to 4 sub-doses
Mild	50 - 79	2/3 usually daily dose, 2 to 3 sub-doses
Moderate	30 - 49	1/3 usually daily dose, 2 sub-doses
Severe	<30	1/6 usually daily dose, 1 single doses
End-Stage Renal Disease	-	Contraindicated

4.3 Contraindications
Piracetam is contraindicated in:
- hypersensitivity to piracetam, other pyrrolidone derivatives or any of the excipients,
- end stage renal disease (renal creatinine clearance of less than 20 ml per minute),
- cerebral haemorrhage,
- Suffering from Huntington's chorea.

4.4 Warnings and Precautions
Effects on platelet aggregation
Due to the effect of piracetam on platelet aggregation, caution is recommended in patients with severe haemorrhage, patients at risk of bleeding such as gastrointestinal ulcer, patients with underlying disorders of haemostasis, patients with a history of haemorrhagic CVA, patients undergoing major surgery including dental surgery, and patients using anticoagulants or platelet antiaggregant drugs including low dose aspirin.

Renal insufficiency
Piracetam is eliminated via the kidneys and care should thus be taken in cases of renal insufficiency (see Section Dosage and Administration).

Excipients
Piracetam, 800 mg, film-coated tablet
Piracetam, 1200 mg, film-coated tablet
Sodium
These products contain about 2 mmol (or about 46 mg) sodium per 24 g piracetam. This should be taken into consideration by patients on a controlled sodium diet.

Piracetam, 3 g/15 ml, solution for injection
Sodium
This product contains less than 1 mmol (23mg) sodium per 24 g piracetam. This should be taken into consideration by patients on a controlled sodium diet.

Piracetam, 12 g/60 ml, solution for infusion
Sodium
This product contains about 19 mmol (or about 445 mg) sodium per 24 g piracetam. This should be taken into consideration by patients on a controlled sodium diet.

4.5 Interactions
Thyroid hormones
Confusion, irritability and sleep disorder have been reported during concomitant treatment with thyroid extract (T3+T4).

Antiepileptic drugs
At present, no interaction has been documented with the following antiepileptic medications: clonasepam, carbamazepine, phenytoin, phenobarbitone, and sodium valporate. To date, there are no known interactions with other medicines.

4.6 Pregnancy and Lactation
Fertility
There are no relevant data available.

Piracetam should not be used during pregnancy unless clearly necessary, when benefit exceeds the risks and the clinical condition of the pregnant mother requires treatment with piracetam. There are no adequate data from the use of piracetam in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or post-natal development.

Piracetam crosses the placental barrier. Drug levels in the newborn are approximately 70% to 90% of maternal levels.

Lactation
Piracetam should not be used during breastfeeding or breastfeeding should be discontinued, while receiving treatment with piracetam. A decision must be made whether to discontinue breast-feeding or to discontinue piracetam therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.
Piracetam is excreted in human breast milk.

4.7 Ability to perform tasks that require judgement, motor or cognitive skills
In view of the undesirable side effects, which were observed after the administration of the preparation, there is the possibility of influence on the ability to drive and to operate machinery and this should be taken into consideration.

4.8 Adverse Reactions
Clinical Trial and Post Marketing Data
Double-blind placebo-controlled clinical or pharmaco-clinical trials, of which quantified safety data are available (extracted from the UCB Documentation Data Bank on June 1997), included more than 3000 subjects receiving piracetam, regardless of indication, dosage form, daily dosage or population characteristics.

Adverse reactions are ranked under headings of frequency using the following convention:
Very common ≥1/10
Common ≥1/100 to <1/10
Uncommon ≥1/1000 to <1/100
Rare ≥1/10000 to <1/1000
Very rare <1/10000
Not known (cannot be estimated from the available data).

Blood and lymphatic system disorders
Not known: haemorrhagic disorder

Immune system disorders
Not known: anaphylactoid reaction, hypersensitivity

Psychiatric disorders
Common: nervousness
Uncommon: depression
Not known: agitation, anxiety, confusion, hallucination

Nervous system disorders
Common: hyperkinesia
Uncommon: somnolence
Not known: ataxia, balance disorder, epilepsy, headache, insomnia

Ear and labyrinth disorders
Not known: vertigo

Vascular disorders
Rare: thrombophlebitis (only parenteral formulations), hypotension (only parenteral formulations)

Gastrointestinal disorders
Not known: abdominal pain, abdominal pain upper, diarrhoea, nausea, vomiting

Skin and subcutaneous tissue disorders
Not known: angioedema, dermatitis, pruritus, urticaria

General disorders and administration site conditions
Uncommon: asthenia
Rare: pyrexia (only parenteral formulations), pain at the place of injection (only parenteral formulations)

Investigations
Common: weight increased

4.9 Overdosage
Symptoms and signs
No additional adverse events specifically related to overdose have been reported with piracetam.
The highest reported overdose with piracetam was oral intake of 75 g wherein bloody diarrhoea with abdominal pain, was most probably related to the extreme high dose of sorbitol contained in the used formulation.

Treatment
In acute, significant overdosage, the stomach may be emptied by induction of emesis. There is no specific antidote for overdose with piracetam. Treatment for an overdose will be symptomatic treatment and may include haemodialysis. The extraction efficiency of the dialyser is 50 to 60% for piracetam.

5. MODE OF ACTION
Piracetam is a nootropic agent.

6. PHARMACEUTICAL INFORMATION
6.1 Shelf-Life
Piracetam, 3 g/15 ml, solution for injection
Piracetam, 12 g/60 ml, solution for infusion
~~60 months.~~ 36 months 30/3/16
Piracetam, 800 mg, film-coated tablet
Piracetam, 1200 mg, film-coated tablet
48 months.

6.2 Storage
Piracetam, 3 g/15 ml, solution for injection
Store below 30°C.

Piracetam, 12 g/60 ml, solution for infusion
Store below 30°C.

Piracetam, 800 mg, film-coated tablet
Piracetam, 1200 mg, film-coated tablet
Store at temperature below 30°C.

PACKAGE

- Injection 200mg/mL, Box, 4 ampoules @ 15mL	Reg No DKI1083901143A1
- Infusion 200mg/mL, Box, bottle 60mL	Reg No DKI1233200249A1
- Film-coated tablet 800mg, Box, 4 blisters @ 15 tablets	Reg No DKI1283901409A1
- Film-coated tablet 1200mg, Box, 3 blisters @ 10 tablets	Reg No DKI1283901409B1

HARUS DENGAN RESEP DOKTER

Nootropil Injection is manufactured by:
Aesica Pharmaceuticals S.r.l.
Pianezza - Italy

Nootropil Infusion is manufactured by:
Aesica Pharmaceuticals S.r.l.
Pianezza - Italy

Nootropil Film coated-tablet is manufactured by:
UCB S.A. Pharma Sector
Braine L'alleud - Belgium

Imported by
PT. Glaxo Wellcome Indonesia
Jakarta, Indonesia

PI based on NCDS ver 01 (19 October 2011)

GlaxoSmithKline

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312 mm

226 mm