SUMMARY OF PRODUCT CHARACTERISTICS
1. NAME OF THE MEDICINAL PRODUCT

Piracetam Mylan, 800 mg, film-coated tablets
Piracetam Mylan, 1200 mg, film-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 800 mg tablet contains: 800 mg of piracetam
Each 1200 mg tablet contains: 1200 mg of piracetam

Excipients with known effect:
This product contains 0.0168 g of lactose monohydrate per dose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film-coated tablet.

800 mg: white to off-white film-coated biconvex capsule-shaped tablet, debossed with “PM” and “8” on either side of a score line on one side of the tablet and “M” on one side of a score line on the other side of the tablet. The tablet dimensions are approximately 19 mm x 8 mm. The tablet can be divided into equal doses.

1200 mg: white to off-white film-coated biconvex capsule-shaped tablet, debossed with “PM” and “12” on either side of a score line on one side of the tablet and “M” on one side of a score line on the other side of the tablet. The tablet dimensions are approximately 21 mm x 9 mm. The tablet can be divided into equal doses.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Piracetam Mylan is indicated for
- adult patients suffering from myoclonus of cortical origin
- symptomatic treatment of cognitive and memory disorders caused by organic disorders except neurodegenerative dementias, such as Alzheimer’s disease
- treatment of vertigo
- treatment of dyslexia in children from 8 years old and adolescents in combination with appropriate measures, such as speech therapy (logopaedics).

4.2 Posology and method of administration

Posology

Adults
Symptomatic treatment of cognitive and memory disorders caused by organic disorders.
The recommended daily dose ranges from 2.4 g up to 4.8 g, in two or three sub-doses. The therapy should be initiated with 4.8 g/day dose for the first few weeks. Subsequently the dose should be gradually lowered to 2.4 g/day in 1.2 g/day steps.
Treatment of myoclonus of cortical origin
The daily dosage should begin at 7.2 g increasing by 4.8 g every three to four days up to a maximum of 24 g, in two or three sub-doses. Treatment with other anti-myoclonic medicinal products should be maintained at the same dosage. Depending on the clinical benefit obtained, the dosage of other such medicinal products should be reduced, if possible.
Once started, treatment with piracetam should be continued for as long as the original cerebral disease persists. In patients with an acute episode, spontaneous evolution may occur over time and an attempt should be made every 6 months to decrease or discontinue the medicinal treatment. This should be done by reducing the dose of piracetam by 1.2 g every two days (every three or four days in the case of a Lance and Adams syndrome, in order to prevent the possibility of sudden relapse or withdrawal seizures).

Treatment of vertigo
The recommended daily dose ranges from 2.4 g up to 4.8 g, in two or three sub-doses, for 8 weeks.

Paediatric population
Treatment of dyslexia in combination with speech therapy
In children from 8 years old and adolescents, the recommended daily dose is about 3.2 g, in two sub-doses.

Elderly
Adjustment of the dose is recommended in elderly patients with compromised renal function (see ‘Dosage adjustment in patients with renal impairment’ below). For long term treatment in the elderly, regular evaluation of the creatinine clearance is required to allow dosage adaptation if needed.

Patients with renal impairment
The daily dose must be individualized 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 (CL cr) in ml/min is needed.

The CL cr in ml/min may be estimated from serum creatinine (mg/dl) determination using the following formula:

\[
\text{Cl cr} = \left( \frac{[140 - \text{age (years)}] \times \text{weight (kg)}}{72} \times \text{serum creatinine (mg/dl)} \times 0.85 \right) \text{ for women}
\]

<table>
<thead>
<tr>
<th>Group</th>
<th>Creatinine Clearance (ml/min)</th>
<th>Posology and frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>&gt;80</td>
<td>usual daily dose, 2 to 4 sub-doses</td>
</tr>
<tr>
<td>Mild</td>
<td>50-79</td>
<td>2/3 usual daily dose, 2 or 3 sub-doses</td>
</tr>
<tr>
<td>Moderate</td>
<td>30-49</td>
<td>1/3 usual daily dose, 2 sub-doses</td>
</tr>
<tr>
<td>Severe</td>
<td>&lt;30</td>
<td>1/6 usual daily dose, 1 single intake</td>
</tr>
<tr>
<td>End-stage renal disease</td>
<td>--</td>
<td>contraindicated</td>
</tr>
</tbody>
</table>

Patients with hepatic impairment
No dose adjustment is needed in patients with solely hepatic impairment. In patients with hepatic impairment and renal impairment, adjustment of dose is recommended (see ‘Dosage adjustment in patients with renal impairment’ above).

Method of administration
Piracetam should be administered orally, and may be taken with or without food. The tablet(s) should be swallowed with liquid. It is recommended to take the daily dose in two to four sub-doses.
4.3 Contraindications

- Hypersensitivity to piracetam or other pyrrolidone derivatives or any of the excipients listed in section 6.1.
- Cerebral haemorrhage
- End stage renal disease
- Huntington's Chorea.
- Haemorrhagic stroke.

4.4 Special warnings and precautions for use

Effects on platelet aggregation
Due to the effect of piracetam on platelet aggregation (see section 5.1), 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 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 4.2).

Elderly
For long-term treatment in the elderly, regular evaluation of the creatinine clearance is required to allow dosage adaptation, if needed (see section 4.2).

Discontinuation
Abrupt discontinuation of treatment should be avoided in myoclonic patients as this may induce sudden relapse or withdrawal seizures as this may induce myoclonic or generalised seizures in some myoclonic patients.

Piracetam Mylan contains lactose
Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Pharmacokinetics interactions
The drug interaction potential resulting in changes of piracetam pharmacokinetics is expected to be low because approximately 90% of the dose of piracetam is excreted in the urine as unchanged drug.

In vitro, piracetam does not inhibit the human liver cytochrome P450 isoforms CYP 1A2, 2B6, 2C8, 2C9, 2C19, 2D6, 2E1 and 4A9/11 at concentrations of 142, 426 and 1422 µg/ml.
At 1422 µg/ml, minor inhibitory effects on CYP 2A6 (21%) and 3A4/5 (11%) were observed. However, the Ki values for inhibition of these two CYP isoforms are likely to be well in excess of 1422 µg/ml. Therefore, metabolic interaction of piracetam with other drugs is unlikely.

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

Acenocoumarol
In a published single-blind study on patients with severe recurrent venous thrombosis, piracetam 9.6 g/day did not modify the doses of acenocoumarol necessary to reach INR 2.5 to 3.5, but compared with the effects of acenocoumarol alone, the addition of piracetam 9.6 g/day significantly decreased platelet aggregation, β-thromboglobulin release, levels of fibrinogen and von Willebrand's factors (VIII : C; VIII : vW : Ag; VIII : vW : RCo) and whole blood plasma viscosity.
**Antiepileptic drugs**

A 20 g daily dose of piracetam over 4 weeks did not modify the peak and trough serum levels of antiepileptic drugs (carbamazepine, phenytoin, phenobarbitone, valproate) in epileptic patients who were receiving stable doses.

**Alcohol**

Concomitant administration of alcohol had no effect on piracetam serum levels and alcohol levels were not modified by a 1.6 g oral dose of piracetam.

### 4.6 Fertility, pregnancy and lactation

**Pregnancy**

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 (see section 5.3).

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

**Breast-feeding**

Piracetam is excreted in human breast milk. Therefore, piracetam should not be used during breast-feeding or breast-feeding 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.

**4.7 Effects on ability to drive and use machines**

In clinical studies, at dosages between 1.6 - 15 grams per day, hyperkinesia, somnolence, nervousness and depression were reported more frequently in patients on piracetam than on placebo. There is no experience on driving ability in dosages between 15 and 20 grams daily. **Given the adverse events observed with the drug, an influence on driving and using machines is possible and should be taken into account. Caution should therefore be exercised by patients intending to drive or use machinery whilst taking piracetam.**

**4.8 Undesirable effects**

Summary of safety profile

Double-blind placebo-controlled clinical or pharmacoclinical trials, of which quantified safety data are available, included more than 3000 subjects receiving piracetam, regardless of indication, dosage form, daily dosage or population characteristics.

Tabulated list of adverse reactions

Undesirable effects reported in clinical studies and from post-marketing experience are listed in the following table per System Organ Class and per frequency. The frequency is defined as follows: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data).

Data from post-marketing experience are insufficient to support an estimate of their incidence in the population to be treated.

<table>
<thead>
<tr>
<th>Very Common</th>
<th>Common</th>
<th>Uncommon</th>
<th>Rare</th>
<th>Very rare</th>
<th>Not known</th>
</tr>
</thead>
</table>

6
<table>
<thead>
<tr>
<th>Very Common</th>
<th>Common</th>
<th>Uncommon</th>
<th>Rare</th>
<th>Very rare</th>
<th>Not known</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood and lymphatic system disorders</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Haemorrhagic disorder</td>
</tr>
<tr>
<td>Immune system disorders</td>
<td></td>
<td></td>
<td></td>
<td>Anaphylactoid reaction, hypersensitivity</td>
<td></td>
</tr>
<tr>
<td>Psychiatric disorders</td>
<td>Nervousness</td>
<td>Depression</td>
<td></td>
<td>Agitation, anxiety, confusion, hallucination</td>
<td></td>
</tr>
<tr>
<td>Nervous system disorders</td>
<td>Hyperkinesia</td>
<td>Somnolence</td>
<td></td>
<td>Ataxia, balance impaired, epilepsy aggravated, headache, insomnia</td>
<td></td>
</tr>
<tr>
<td>Ear and labyrinth disorders</td>
<td></td>
<td></td>
<td></td>
<td>Vertigo, dizziness</td>
<td></td>
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<tr>
<td>Gastrointestinal disorders</td>
<td></td>
<td></td>
<td></td>
<td>Abdominal pain, upper abdominal pain, diarrhoea, nausea, vomiting</td>
<td></td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td></td>
<td></td>
<td></td>
<td>Angioneurotic oedema, dermatitis, pruritus, urticaria</td>
<td></td>
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<tr>
<td>General disorders and administration site conditions</td>
<td></td>
<td></td>
<td></td>
<td>Asthenia</td>
<td></td>
</tr>
<tr>
<td>Investigations</td>
<td></td>
<td></td>
<td></td>
<td>Weight increased</td>
<td></td>
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</tbody>
</table>

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 [to be completed nationally].

4.9 Overdose

Symptoms
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. Bloody diarrhoea with abdominal pain was most probably related to the extreme high dose of sorbitol contained in the used formulation.

Management of overdose
In acute, significant overdosage, the stomach may be emptied by gastric lavage or 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. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Psychostimulant (nootropics, analeptics). ATC code: N06B X03.

The active substance is piracetam which is a pyrrolidone compound (2-oxo-1-pyrrolidine acetamide), the cyclic derivative of the gamma amino butyric acid (GABA).
Mechanism of action

Available data suggest that piracetam’s basic mechanism of action is neither cell nor organ specific. Piracetam binds physically in a dose-dependent manner to the polar head of phospholipids membrane models, inducing the restoration of the membrane lamellar structure characterized by the formation of mobile drug phospholipid complexes. This probably accounts for an improved membrane stability, allowing the membrane and transmembrane proteins to maintain or recover the 3-dimensional structure or folding essential to exert their function.

Piracetam has neuronal and vascular effects.

At the neuronal level, piracetam exerts its membrane activity in various ways. In animals, piracetam enhances a variety of types of neurotransmission, primarily through postsynaptic modulation of receptor density and activity. In both animals and human, the functions involved in cognitive processes, e.g., learning, memory, attention and consciousness, were enhanced in the normal subject as well as in deficiency states without the development of sedative or psychostimulant effects. Piracetam protects and restores cognitive abilities in animals and human after various cerebral damage, e.g., hypoxia, intoxications and electroconvulsive therapy. It protects against hypoxia-induced changes in brain function and performance as assessed by electroencephalograph (EEG) and psychometric evaluations.

Pharmacodynamic effects

Piracetam exerts its haemorrhheological effects on the platelets, red blood cells and vessel walls by increasing erythrocyte deformability and by decreasing platelet aggregation, erythrocyte adhesion to vessel walls and capillary vasospasm.

- Effects on the red blood cells:

In patients with sickle cell anaemia, piracetam improves the deformability of the erythrocyte membrane, decreases blood viscosity and prevents rouleaux formation.

- Effects on platelets:

In open studies in healthy volunteers and in patients with Raynaud's phenomenon, increasing doses of piracetam up to 12 g was associated with a dose-dependent reduction in platelet functions compared with pre-treatment values (tests of aggregation induced by ADP, collagen, epinephrine and ßTG release), without significant change in platelet count. In these studies, piracetam prolonged bleeding time.

- Effects on blood vessels:

In animal studies, piracetam inhibited vasospasm and counteracted the effects of various spasmogenic agents. It lacked any vasodilatory action and did not induce “steal” phenomenon, nor low or no reflow, nor hypotensive effects.

In healthy volunteers, piracetam reduced the adhesion of RBCs to vascular endothelium and possessed also a direct stimulant effect on prostacycline synthesis in healthy endothelium.

- Effects on coagulation factors:

In healthy volunteers, compared with pre-treatment values, piracetam up to 9.6 g reduced plasma levels of fibrinogen and von Willebrand's factors (VIII : C; VIII R : AG; VIII R : vW) by 30 to 40 %, and increased bleeding time.

In patients with both primary and secondary Raynaud phenomenon, compared with pre-treatment values, piracetam 8 g/day during 6 months reduced plasma levels of fibrinogen and von Willebrand's factors (VIII : C; VIII R : AG; VIII R : vW (RCF)) by 30 to 40 %, reduced plasma viscosity and increased bleeding time.
Another study in healthy volunteers did not show any statistically significant difference between piracetam (up to 12 g twice daily) and placebo regarding effects on coagulation parameters and bleeding time.

5.2 Pharmacokinetic properties

The pharmacokinetic profile of piracetam is linear and time-dependent with low intersubject variability over a large range of doses. This is consistent with the high permeability, high solubility, and minimal metabolism of piracetam. Plasma elimination half-life of piracetam is 5 hours. It is similar in adult volunteers and in patients. It is increased in the elderly (primarily due to impaired renal clearance) and in subjects with renal impairment. Steady-state plasma concentrations are achieved within 3 days of dosing.

Absorption
Piracetam is rapidly and extensively absorbed following oral administration. In fasted subjects, the peak plasma concentrations are achieved 1 hour after administration. The absolute bioavailability of piracetam oral formulations is close to 100%. Food does not affect the extent of absorption of piracetam but it decreases $C_{max}$ by 17% and increases $t_{max}$ from 1 to 1.5 hours.

Peak concentrations are typically 84 mcg/mL and 115 mcg/mL following a single oral dose of 3.2 g and repeat dose of 3.2 g three times daily, respectively.

Distribution
Piracetam is not bound to plasma proteins and its volume of distribution is approximately 0.6 L/kg. Piracetam crosses the blood brain barrier as it has been measured in cerebrospinal fluid following IV administration. In the cerebrospinal fluid, the $t_{max}$ was achieved about 5 hours post-dose and the elimination half-life was about 8.5 hours. In animals, piracetam highest concentrations in the brain were cerebral cortex (frontal, parietal and occipital lobes), in the cerebellar cortex and in the basal ganglia.

Piracetam diffuses to all tissues except adipose issues, crosses placental barrier and penetrates the membranes of isolated red blood cells.

Biotransformation
Piracetam is not known to be metabolized in the human body. This lack of metabolism is supported by the long plasma half-life in anuric patients and the high recovery of parent compound in urine.

Elimination
In adults the plasma half-life is approximately 5 hours after oral administration. Total clearance is 80–90 mL/min. Piracetam is mainly excreted with urine (80–100% of the dose). Piracetam is excreted by glomerular filtration in the kidney.

Linearity/non-linearity
The pharmacokinetics of piracetam are linear over the dose range of 0.8–12 g. Pharmacokinetic variables, like half-life and clearance, are not changed with respect to the dose and the duration of treatment.

Special populations

Gender:
In a bioequivalence study comparing formulations at a dose of 2.4 g, $C_{max}$ and AUC were approximately 30% higher in women (N=6) compared to men (N=6). However, clearances adjusted for body weight were comparable.

Race:
Formal pharmacokinetic studies of the effect of race have not been conducted. Moreover, cross study comparisons involving Caucasians and Asians show that pharmacokinetics of piracetam were comparable between the two races. Because piracetam is primarily renally excreted and there are no important racial differences in creatinine clearance, pharmacokinetic differences due to race are not expected.
Elderly
In elderly population the elimination half-life of piracetam is longer due to the typical decline of the renal function at this population (see section 4.2).

Paediatric population
Pharmacokinetic of piracetam in children is not established.

Renal impairment
Piracetam clearance is correlated to creatinine clearance. It is therefore recommended to adjust the daily dose of piracetam based on creatinine clearance in patients with renal impairment (see section 4.2). In anuric end-stage renal disease subjects, the elimination half life of piracetam is increased up to 59 hours. The fractional removal of piracetam was 50-60% during a typical 4-hr dialysis session.

Hepatic impairment:
The influence of hepatic impairment on the pharmacokinetics of piracetam has not been evaluated. Because 80-100% of the dose is excreted in the urine as unchanged drug, hepatic impairment solely would not be expected to have a significant effect on piracetam elimination.

5.3 Preclinical safety data
The preclinical data indicate that piracetam has a low toxicity potential. Single doses of piracetam yielded LD_{50} values at 26 g/kg in mice but LD_{50} values were not reached in rats. In dogs, clinical signs after acute oral dosing were mild and lethality was not observed at the maximum tested dose of 10 g/kg.

Repeated oral treatment for up to 1 year in dogs (10 g/kg) and 6 months in rats (2 g/kg) was very well tolerated: no target organ toxicity or signs of (irreversible) toxicity were clearly demonstrated. Safe dose levels represent a multiple of the maximum intended human daily dose of 0.4 g/kg. Mild GI effects (emesis, change in stool consistency, increased water consumption) were observed in dogs when piracetam was administered orally for 1 year at a dose increasing from 1-10 g/kg/day. Similarly, IV administration of up to 1 g/kg/day for 4-5 weeks in rats and dogs did not produce toxicity.

In terms of exposure (C_{max}) safe levels obtained in the rat and the dog represent respectively 8 fold and 50 fold of the maximum human therapeutic level. AUC levels obtained in the same animals were a multiple of the human AUC level at the maximum intended daily dose.

The only change which might eventually be attributed to chronic treatment in male, but not in female, rats was an increase of the incidence over control animals of progressive glomerulonephrosis at the dose of 2.4 g/k/day given for 112 weeks.

Although piracetam crosses the placenta into the foetal circulation, no teratogenic effects were observed at dose levels up to 4.8 g/kg/day (mice, rats) and 2.7 g/kg/day (rabbits). Furthermore, the compound affects neither fertility nor the peri- or postnatal development of the pregnancy at doses up to 2.7 g/kg/day. Piracetam was found to be devoid of any mutagenic or clastogenic activity and does not represent any genotoxic or carcinogenic risk to man.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core ingredients
Silica, Colloidal Anhydrous
Povidone (K-30)
Povidone (K-90)
Crosccarmellose Sodium
Magnesium Stearate

*Film-coat*
Hypermellose
Lactose monohydrate
Talc
Macrogol 6000
Propylene glycol
Titanium Dioxide (E171)

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
2 years

6.4 Special precautions for storage
This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container
HDPE bottle with white opaque polypropylene screw cap with induction sealing liner and desiccant (HDPE canister with 2 g of silica gel, inserted in the HDPE bottle) containing 60 and 90 tablets.
OPA/Aluminium/PVC/Aluminium blisters containing, 60 and 90 tablets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling
No special requirements

7. MARKETING AUTHORISATION HOLDER
<To be completed nationally>

8. MARKETING AUTHORISATION NUMBER(S)
<To be completed nationally>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
<To be completed nationally>

10. DATE OF REVISION OF THE TEXT
<To be completed nationally>
LABELLING
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<th>PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING</th>
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<tbody>
<tr>
<td>Carton for blisters and bottles</td>
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<table>
<thead>
<tr>
<th>1. NAME OF THE MEDICINAL PRODUCT</th>
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<tbody>
<tr>
<td>Piracetam Mylan, 800 mg, film-coated tablets</td>
</tr>
<tr>
<td>piracetam</td>
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<tr>
<th>2. STATEMENT OF ACTIVE SUBSTANCE(S)</th>
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<tbody>
<tr>
<td>Each tablet contains 800 mg of piracetam</td>
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<tr>
<th>3. LIST OF EXCIPIENTS</th>
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</thead>
<tbody>
<tr>
<td>Also contains lactose. See package leaflet for further information.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>4. PHARMACEUTICAL FORM AND CONTENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Film-coated tablet</td>
</tr>
<tr>
<td>60 film-coated tablets</td>
</tr>
<tr>
<td>90 film-coated tablets</td>
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</table>

<table>
<thead>
<tr>
<th>5. METHOD AND ROUTE(S) OF ADMINISTRATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>For oral use. Read the package leaflet before use.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN</th>
</tr>
</thead>
<tbody>
<tr>
<td>Keep out of the sight and reach of children.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>7. OTHER SPECIAL WARNING(S), IF NECESSARY</th>
</tr>
</thead>
</table>

<table>
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<tr>
<th>8. EXPIRY DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXP</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>9. SPECIAL STORAGE CONDITIONS</th>
</tr>
</thead>
</table>


10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
   <To be completed nationally>

12. MARKETING AUTHORISATION NUMBER(S)
   <To be completed nationally>

13. BATCH NUMBER
   Lot

14. GENERAL CLASSIFICATION FOR SUPPLY
   <To be completed nationally>

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE
   Piracetam 800 mg Tablets
PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

Bottle Label

1. **NAME OF THE MEDICINAL PRODUCT**

Piracetam Mylan, 800 mg, film-coated tablets

piracetam

2. **STATEMENT OF ACTIVE SUBSTANCE(S)**

Each tablet contains 800 mg of piracetam

3. **LIST OF EXCIPIENTS**

Also contains lactose. See package leaflet for further information.

4. **PHARMACEUTICAL FORM AND CONTENTS**

Film-coated tablet

- 60 film-coated tablets
- 90 film-coated tablets

5. **METHOD AND ROUTE(S) OF ADMINISTRATION**

For oral use. Read the package leaflet before use.

6. **SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN**

Keep out of the sight and reach of children.

7. **OTHER SPECIAL WARNING(S), IF NECESSARY**

Caution: This bottle contains a canister of desiccant labelled *Do not eat*. Do not attempt to eat or swallow the canister.

*Note: highlighted text is written in English.*

8. **EXPIRY DATE**

EXP

9. **SPECIAL STORAGE CONDITIONS**
10. **SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE**

11. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER**

   <To be completed nationally>

12. **MARKETING AUTHORISATION NUMBER(S)**

   <To be completed nationally>

13. **BATCH NUMBER**

   Lot

14. **GENERAL CLASSIFICATION FOR SUPPLY**

   <To be completed nationally>

15. **INSTRUCTIONS ON USE**

16. **INFORMATION IN BRAILLE**
**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

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<thead>
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<th>1. NAME OF THE MEDICINAL PRODUCT</th>
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<tbody>
<tr>
<td>Piracetam Mylan, 800 mg, film-coated tablets</td>
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<tr>
<td>piracetam</td>
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<th>2. NAME OF THE MARKETING AUTHORISATION HOLDER</th>
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<tbody>
<tr>
<td>&lt;To be completed nationally&gt;</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. EXPIRY DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>EXP</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. BATCH NUMBER, DONATION AND PRODUCT CODES</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. OTHER</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>
**PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING**

Carton for blisters and bottles

<table>
<thead>
<tr>
<th>1. NAME OF THE MEDICINAL PRODUCT</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Piracetam Mylan, 1200 mg, film-coated tablets</td>
<td></td>
</tr>
<tr>
<td>Piracetam</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2. STATEMENT OF ACTIVE SUBSTANCE(S)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Each tablet contains 1200 mg of piracetam</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>3. LIST OF EXCIPIENTS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Also contains lactose. See package leaflet for further information.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4. PHARMACEUTICAL FORM AND CONTENTS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Film-coated tablet</td>
<td></td>
</tr>
<tr>
<td>60 film-coated tablets</td>
<td></td>
</tr>
<tr>
<td>90 film-coated tablets</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>5. METHOD AND ROUTE(S) OF ADMINISTRATION</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>For oral use. Read the package leaflet before use.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>6. SPECIAL WARNING THAT THE MEDICINAL PRODUCT MUST BE STORED OUT OF THE SIGHT AND REACH OF CHILDREN</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Keep out of the sight and reach of children.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>7. OTHER SPECIAL WARNING(S), IF NECESSARY</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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<tr>
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<tr>
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</table>

<table>
<thead>
<tr>
<th>9. SPECIAL STORAGE CONDITIONS</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

11. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
   <To be completed nationally>

12. MARKETING AUTHORISATION NUMBER(S)
   <To be completed nationally>

13. BATCH NUMBER
    Lot

14. GENERAL CLASSIFICATION FOR SUPPLY
    <To be completed nationally>

15. INSTRUCTIONS ON USE

16. INFORMATION IN BRAILLE
    Piracetam 1200 mg Tablets
## PARTICULARS TO APPEAR ON THE OUTER PACKAGING AND THE IMMEDIATE PACKAGING

### Bottle Label

<table>
<thead>
<tr>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
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<td>piracetam</td>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Caution: This bottle contains a canister of desiccant labelled ‘Do not eat’. Do not attempt to eat or swallow the canister.</td>
<td></td>
</tr>
</tbody>
</table>

*Note: highlighted text is written in English.*

<table>
<thead>
<tr>
<th><strong>8. EXPIRY DATE</strong></th>
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</thead>
<tbody>
<tr>
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</table>

| **9. SPECIAL STORAGE CONDITIONS** |  |
10. SPECIAL PRECAUTIONS FOR DISPOSAL OF UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS DERIVED FROM SUCH MEDICINAL PRODUCTS, IF APPROPRIATE

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   Lot

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<th>MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS</th>
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<tr>
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<td>5. OTHER</td>
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Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet
1. What Piracetam Mylan is and what it is used for
2. What you need to know before you take Piracetam Mylan
3. How to take Piracetam Mylan
4. Possible side effects
5. How to store Piracetam Mylan
6. Contents of the pack and other information

1. What Piracetam Mylan is and what it is used for

Piracetam Mylan contains the active substance piracetam. Piracetam belongs to the nootropic drugs which support cognitive processes like: learning, concentration of attention and awareness. Piracetam protects and restores the cognitive abilities (functions) in patients with various brain lesions, e.g. caused by lack of oxygen or intoxication, prevents changes in brain function and efficiency as a result of lack of oxygen.

Piracetam Mylan is used in adults for:
- Treatment of myoclonus of cortical origin (involuntary muscles twitches)
- Symptomatic treatment of cognitive and memory disorders caused by organic disorders except neurodegenerative dementias, such as, Alzheimer’s disease –brain function disorder, such as memory loss, concentration disorders and lack of motivation
- Treatment of vertigo (feeling of spinning of either yourself or your surrounding), except for dizziness caused by mental, emotional, or behavioural factors.

Piracetam Mylan is used in children from 8 years old and adolescents for:
- Treatment of dyslexia (disorder when child has speech disorder and problems with reading that are not expression of intelligence disability) in combination with appropriate measures, such as speech therapy (logopaedics).

You must talk to a doctor if you do not feel better or if you feel worse after taking Piracetam Mylan.

2. What you need to know before you take Piracetam Mylan

Do not take Piracetam Mylan if:
- You are allergic to the active ingredient piracetam or other derivative of pyrrolidone
- You are allergic to any of the other ingredients of Piracetam Mylan (these are listed in Section 6)
- You suffer from end-stage renal failure
- You suffer from Huntington’s Disease (also known as Huntington’s Chorea)
- You have ever experienced a brain haemorrhage.
If any of the above applies to you, do not take Piracetam Mylan and talk to your doctor or pharmacist.

**Warning and precautions**
Talk to your doctor or pharmacist before taking Piracetam Mylan if:
- you have kidney problems. Piracetam is excreted by the kidneys, in patients with renal impairment the dose may be lowered
- you have ever had any kind of bleeding disorders or gastric ulceration
- you have to undergo surgery or have recently had surgery, including extensive dental intervention.

**Other medicines and Piracetam Mylan**
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor or pharmacist if you are taking any of the following medicines:
- Thyroid extract (T3 and T4) or thyroxine
- Anticoagulants such as warfarin or acenocoumarol
- Low dose aspirin.

**Pregnancy and breast-feeding**
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

If you are taking this medicine, use contraception to avoid becoming pregnant. If you are taking Piracetam Mylan and you think you may be pregnant, consult your doctor immediately.

Piracetam is excreted in human milk. Therefore, you should avoid the use of piracetam when breast-feeding or stop breast-feeding during treatment with piracetam.

**Driving and using machines**
Piracetam Mylan may cause drowsiness and shakiness. If this happens to you, do not drive or operate machinery.

**Piracetam Mylan contains lactose**
Piracetam Mylan tablets contain lactose (milk sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. **How to take Piracetam Mylan**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

**Adults**
Treatment of cognitive and memory disorders caused by organic disorders except neurodegenerative dementias, such as, Alzheimer’s disease

The recommended daily dose ranges from 2.4 g to 4.8 g (3-6 tablets of 800 mg or if available 2-4 tablets of 1200 mg) in two or three divided doses. **The therapy should be initiated with 4.8 g/day dose for the first few weeks. Subsequently the dose should be gradually lowered to 2.4 g/day in 1.2 g/day steps.**

**Treatment of myoclonus of cortical origin**
The recommended starting dose is 7.2 g (9 tablets of 800 mg or if available 6 tablets of 1200 mg) in two or three divided doses, increasing by 4.8 g every three to four days. Maximum daily dose is 24 g. In combination with other antimyoclonic drugs the doses of the other products should be administered within recommended dosage range.

In the case of acute events, please contact your doctor.
Treatment of vertigo
The recommended daily dose is 2.4 g to 4.8 g (3-6 tablets of 800 mg or if available 2-4 tablets of 1200 mg) in two or three divided doses for 8 weeks.

The tablet can be divided into equal doses.

Use in children from 8 years old and adolescents
Treatment of dyslexia in combination with speech therapy
In children from 8 years old and adolescents, the recommended daily dose is 3.2 g, i.e. 2 tablets of 800 mg twice daily.

Use in older people and in patients with kidney problems
If you are elderly or have kidney problems your doctor may reduce dose of your medicine.

Method of Administration
Piracetam Mylan may be taken with or without food. The tablet should be swallowed with a glass of water. The tablet can be divided into equal doses.

If you take more Piracetam Mylan than you should
If you accidentally take too much, immediately go to the nearest hospital casualty department or to your doctor.

If you forget to take Piracetam Mylan
Do not take a double dose to make up for a forgotten dose.

If you stop taking Piracetam Mylan
Do not stop taking Piracetam Mylan without speaking to your doctor or pharmacist first. Abruptly stopping your medicine may cause twitching and jerking.

If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects
Like all medicines, this medicine can cause side effects, although not everybody gets them.

If any of the following happen, do not take more Mylan. Tell your doctor immediately or go to the casualty department at your nearest hospital:

Not known (frequency cannot be estimated from the available data):
- anaphylactoid reaction (reaction similar to allergic reaction), hypersensitivity
- swelling of the skin.

Other side effects reported:

Common (may affect up to 1 in 10 people):
- nervousness
- hyperkinesia (abnormal movements)
- increased body weight.

Uncommon (may affect up to 1 in 100 people):
- depression
- somnolence (feeling sleepy)
- asthenia (general feeling of weakness).

Not known (frequency cannot be estimated from the available data):
• haemorrhagic disorder (bleeding disorder)
• agitation, anxiety, confusion, hallucination
• ataxia (unsteadiness when walking), vertigo, dizziness, balance impaired, epilepsy aggravated, headache, insomnia (difficulty sleeping)
• abdominal pain, upper abdominal pain, diarrhoea, nausea, vomiting
• dermatitis, itching, urticaria (hives).

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via [to be completed nationally]. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Piracetam Mylan

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after abbreviation used for expiry date (EXP). The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Piracetam Mylan contains
The active substance is piracetam.
Each 800 mg tablet of Piracetam Mylan contains 800 mg of piracetam.
Each 1200 mg tablet of Piracetam Mylan contains 1200 mg of piracetam.

The other ingredients:
*Tablet core:* silica, colloidal anhydrous, povidone (K-30), povidone (K-90), croscarmellose sodium, magnesium stearate.

*Tablet coating:* hypromellose, lactose monohydrate, talc, macrogol 6000, propylene glycol and titanium dioxide (E171).

What Piracetam Mylan looks like and contents of the pack

800 mg: white to off-white film-coated biconvex capsule-shaped tablet, debossed with “PM” and “8” on either side of score break line on one side of the tablet and “M” on one side of score break line on the other side of the tablet

1200 mg: white to off-white film-coated biconvex capsule-shaped tablet, debossed with “PM” and “12” on either side of score break line on one side of the tablet and “M” on one side of score break line on the other side of the tablet

Piracetam Mylan is available in blister packs of 60 and 90 tablets and in HDPE bottles (with inserted inside desiccant - HDPE canister with 2 g of silica gel) of 60 and 90 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
This medicinal product is authorised in the Member State of the EEA under the following names:

This leaflet was last revised in {MM/YYYY}