

AKINETON LP4 mg

Biperiden

30 film-coated tablets – Oral route

Parkinson's disease. Parkinsonism syndromes secondary to neuroleptic drug therapy.

FORMS and PRESENTATIONS

Prolonged release film-coated tablet (white): pack of 30 in thermoformed blisters.

COMPOSITION

Per tablet

Biperiden (INN) hydrochloride 4 mg

Excipients: Core: corn starch, magnesium stearate, lactose monohydrate, povidone, microcrystalline cellulose, hypromellose, purified water. Film-coating: talc, anhydrous colloidal silica, titanium dioxide (E171), hypromellose, hydroxypropylcellulose, macrogol, sodium docusate, yellow iron oxide (E 172), carnauba wax.

INDICATIONS

Parkinson's disease.

Parkinsonism syndromes secondary to neuroleptic drug therapy.

DOSAGE AND ADMINISTRATION

Restricted to adults.

1 to 2 tablets daily in a single morning dose, away from meals.

Daily treatment cost: €0.128 to €0.256.

CONTRAINDICATIONS

Particular sensitivity to anticholinergic agents.

Risk of angle closure glaucoma.

Risk of urinary retention related to urethroprostatic disorders.

Decompensated heart disease.

Children under 15 years of age.

WARNINGS AND PRECAUTIONS FOR USE

In the elderly, who may be more susceptible to the action of parasympatholytic agents, the dosage should be titrated very carefully.

If the patient shows signs of intolerance, reduce the dose or temporarily discontinue the treatment.

Do not discontinue treatment abruptly, as this may result in decompensation of the disease.

Possible exacerbation of intellectual impairment in dementia patients, particularly those with parkinsonism.

Concomitant administration of two anticholinergic antiparkinsonism agents should be avoided since this may only increase the side effects without increasing the therapeutic efficacy.

INTERACTIONS

Drug interactions:

Requiring precautions for use:

Lisuride: risk of mental confusion. Frequent clinical monitoring.

To be taken into consideration:

Atropine and other atropinic substances (imipramine antidepressants, sedative H1 antihistamines, atropinic antispasmodics, other anticholinergic antiparkinsonism agents, mequitazine, disopyramide, phenothiazine neuroleptics): additive atropinic side effects such as urinary retention, constipation, dry mouth, etc.

PREGNANCY and LACTATION

Pregnancy:

Data from animal studies are insufficient to draw any conclusions.

During the first trimester of pregnancy, clinical data on biperiden available to date, while limited, do not suggest an increased risk of fetal malformation.

Treatment with biperiden in late pregnancy may give rise, in the neonate, to effects related to its atropinic properties (tachycardia, hyperexcitability, urinary retention, delayed passage of meconium).

In light of these data, it is preferable to avoid using biperiden during pregnancy, regardless of the term.

If the use of biperiden during pregnancy is absolutely necessary, the aforementioned effects should be taken into account during neonatal monitoring.

Lactation:

This medicinal product is not recommended for breastfeeding women due to decreased production of breast milk and a risk of anticholinergic effects in the infant (tachycardia, constipation, thickening of bronchial secretions).

DRIVING and USING MACHINES

Patients and especially those who drive or use machines should be warned that this medicinal product may cause drowsiness.

UNDESIRABLE EFFECTS

Those of atropinic agents: dry mouth, decreased lacrimal secretion, blurred vision, risk of acute angle closure glaucoma, ocular hypertonia, micturition disorders, urinary retention, constipation, hallucinations, drowsiness, mental confusion or agitation in elderly subjects.

These effects regress after reduction of the dosage.

OVERDOSE

Symptoms: those of acute anticholinergic intoxication: mydriasis, agitation, mental confusion, hallucinations, convulsions, hyperventilation, tachycardia and hyperthermia. Treatment: symptomatic therapy in a specialized hospital setting with cardiac and respiratory monitoring.

PHARMACODYNAMICS

Biperiden: central and peripheral anticholinergic agent.

PHARMACOKINETICS

Anticholinergic antiparkinsonism agent (N: central nervous system).

Biperiden: central and peripheral anticholinergic agent.

PRESCRIPTION/SUPPLY/REIMBURSEMENT

Marketing Authorization No. 314 988.9 (1976/97 revised 18. 05. 2006).

Price: €3.83 (30 tablets).

65% reimbursement by national health insurance. Healthcare establishments.

Accepted for use by Public Hospitals of the Paris area and by *Assistance Publique* (welfare services).