n°. 22952/74

Important information, please read carefully!

Akineton® retard

Active ingredient: biperiden hydrochloride
Sugar-coated tablets
Anticholinergic, antiparkinsonian agent

Composition
1 tablet contains 4 mg biperiden hydrochloride.

Indications
a) parkinsonian syndromes, especially to counteract muscular rigidity and tremor;
b) extrapyramidal symptoms such as early dyskinesia, akathisia and parkinsonoid provoked by neuroleptics and similarly acting drugs.

Dosage and administration
Treatment with Akineton retard is normally initiated with small incremental doses, depending on the therapeutic effect and side effects.
Cautious dosing is necessary in elderly patients, especially those with symptoms of organic brain disease.
Parkinsonism and drug-induced movement disorders: unless otherwise prescribed, treatment is normally initiated with Akineton tablets, gradually incremented to determine the most suitable dosage for each individual; patients are then switched to Akineton retard, sugar-coated tablets.
Experience has shown the average dose for adults to be 1-2, at most 3 sugar-coated tablets daily. The total daily amount should be spread over the day, with the first sugar-coated tablet always being taken in the morning.

Contraindications
Akineton is absolutely contraindicated in the presence of untreated narrow-angle glaucoma, mechanical stenoses in the gastrointestinal tract and in megacolon.
Prostatic adenoma and diseases that can lead to perilous tachycardia are relative contraindications.
Akineton retard is not intended for paediatric use; children are given Akineton tablets of 2 mg.

Use in pregnancy and lactation:
There is no evidence to suggest that Akineton presents a particular teratogenic risk. In view of lacking experience with the use of Akineton in pregnancy, caution should be exercised in such cases, especially during the first three months. Anticholinergic agents can inhibit lactation. No data on this subject is available for Akineton. Akineton is excreted in human milk, and concentrations equal to those found in the maternal plasma may be reached. Since the type and extent of metabolization in neonates are not known and since pharmacological-toxicological effects cannot be excluded, ablactation is generally recommended.

Side effects
Central nervous side effects may take the form of fatigue, dizziness and drowsiness, mainly at higher dosages restlessness and confusion, occasionally impairment of memory and in rare cases hallucinations. Peripheral side effects include dry mouth, disturbances of accommodation, hypohidrosis, constipation, gastric symptoms and an increase in heart rate, very rarely a decrease in heart rate. Allergic skin rash and dyskinesia have also been observed occasionally following the administration of Akineton.
In some cases, especially in patients with prostatic adenoma, Akineton may cause micturition difficulties (a dose reduction is recommended) and, more rarely, retention of urine (antidote: carbachol).

Interactions
The administration of Akineton in combination with other anticholinergic psychotropic drugs, antihistamines, antiparkinsonian drugs and antispasmodics can potentiate the CNS and peripheral side effects. The concomitant intake of quinidine may potentiate the anticholinergic effects (especially AV conduction). The concurrent administration of levodopa and Akineton may potentiate dyskinesia. Tardive dyskinesia induced by neuroleptics may be intensified by Akineton. Parkinsonian symptoms in the presence of existing tardive dyskinesia are occasionally so serious as to mandate continued anticholinergic therapy.
The effects of alcohol may be increased during therapy with Akineton.
The action of metoclopramide and compounds with similar activity on the gastrointestinal tract is antagonized by Akineton.

Warnings
Side effects occur especially in early stages of treatment and if the dose is increased too rapidly. Except in the case of vital complications, abrupt discontinuation of the drug is to be avoided due to the risk of excessive counterregulation. Elderly patients, particularly those with cerebral lesions of a vascular or degenerative nature, may frequently exhibit increased sensitivity even to therapeutic doses of the drug.
As the results of animal studies have demonstrated, centrally acting anticholinergic drugs like Akineton may lead to an increased tendency to cerebral seizure. This should be taken into account in the management of predisposed persons.
Abuse of Akineton has been observed.
Especially when Akineton is taken in combination with other centrally acting drugs, anticholinergics or alcohol, central nervous and peripheral side effects may impair the ability to drive and to operate machinery.

Expiry date
The medicinal product should no longer be used after the stated expiry date.

Original packs
20 and 50 sugar-coated tablets

Other commercial packs
Trade packs containing 20 and 50 Akineton tablets of 2 mg of biperiden hydrochloride
Trade pack containing 5 ampoules, 1 ml biperiden lactate each

Store medicinal products carefully! Keep out of the reach of children!

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