

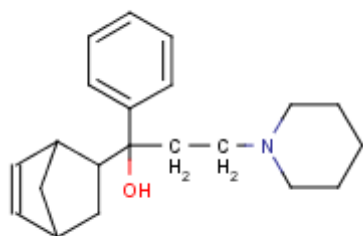
PRODUCT INFORMATION

AKINETON (biperiden hydrochloride 2 mg tablet)

NAME OF THE MEDICINE

Biperiden hydrochloride.

The structural formula for biperiden is shown below:



CAS Number: 514-65-8

DESCRIPTION

Biperiden is a white, crystalline, odourless powder, slightly soluble in water and alcohol. It is stable in air at normal temperatures. Biperiden is α -5-norbornen-2-yl- α -phenyl-1-piperidine propanol. Its molecular weight is 311.5. The molecular weight of the hydrochloride salt is 347.9.

Biperiden hydrochloride tablet 2mg is equivalent to 1.8mg biperiden. Biperiden tablets contain the following inactive ingredients: starch – maize, calcium hydrogen phosphate, cellulose – microcrystalline, povidone, lactose, talc – purified, magnesium stearate, water – purified and starch – pregelatinised potato.

INDICATIONS

Akineton is indicated for the treatment of parkinsonism, drug-induced extrapyramidal symptoms, pyramidal spasticity, closed crani-ocerebral trauma and post-concussion symptoms, trigeminal neuralgia and nocturnal cramps.

CONTRAINDICATIONS

Known hypersensitivity to biperiden hydrochloride or to any of the components in the medication, narrow angle glaucoma, mechanical stenoses of the gastrointestinal tract, in megacolon and in ileus.

PRECAUTIONS

Akineton should be administered with caution to patients with prostatic hypertrophy with accumulation of residual urine.

In a few cases, especially in patients with prostatic adenoma, Akineton may cause disturbances of micturition calling for a reduction of the dose, rarely anuria (antidote: carbachol).

Akineton should be administered with caution in conditions which may be associated with significant tachycardia or in patients who show an increased tendency to convulsion.

Depending on dose and individual sensitivity, Akineton may impair the patients' speed of reaction (e.g. fitness to drive).

Use in Pregnancy

Category B2

Drugs which have been taken by only a limited number of pregnant women and women of childbearing age without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. Studies in animals are inadequate or may be lacking, but available data show no evidence of an increased occurrence of fetal damage.

In accordance with present views on the use of drugs, prescription of Akineton should be carefully evaluated during the first 3 months of pregnancy and during lactation.

Interactions with other Medicines

After additional administration of other anti-Parkinson drugs, quinidine or tri- and tetracyclic antidepressants or neuroleptics, a possible intensification of vegetative or central effects as described above is observed; the Akineton dose should in this case be reduced according to the doctor's instructions. Concomitant intake of quinidine may enhance the anticholinergic cardiovascular effects (especially AV conduction).

When administered in combination with antihistamines and spasmolytics, there may be an enhancement of the central nervous and peripheral side effects.

As with all other drugs acting on the central nervous system the consumption of alcohol should be avoided under Akineton therapy.

Concurrent administration of levodopa and Akineton may potentiate dyskinesia. Generalised choreic movements have been reported in Parkinson's disease when biperiden is added to carbidopa/levodopa.

Tardive dyskinesia induced by neuroleptics may be intensified by Akineton. Anticholinergics can heighten the CNS side effects of pethidine.

The action of metoclopramide and compounds of similar activity in the gastrointestinal tract is antagonised by Akineton.

ADVERSE EFFECTS

Vegetative symptoms may occur such as dryness of the mouth, rarely, swelling of the salivary glands, accommodation disorders, mydriasis accompanied by photophobia, hypohidrosis, dizziness and drowsiness, fatigue, vertigo, tachycardia and, very rarely, bradycardia, nausea, gastric upset and in rare cases obstipation and increase of heart rate. Dyskinesia, ataxia, muscle twitching and speech impairment have sometimes been observed. Occasional loss of memory and, rarely, hallucinations may occur especially at higher doses. In some cases allergic skin reactions, and dyskinesia provoked by biperiden have been observed.

Feeling of unrest, confusion, or conditions similar to psychoses, are reversible symptoms of overdose which in patients with low tolerance, such as patients with cerebral arteriosclerosis, may occur even with doses falling into the therapeutic range; similar symptoms occur if Akineton doses are rapidly increased or the drug is given simultaneously with other central acting anticholinergic agent such as antidepressants or neuroleptics in high doses.

Occasionally, difficult urination especially in patients with prostatic hypertrophy and more rarely, retention of urine.

Reactions from postmarketing surveillance or clinical trials

Clinically significant adverse events seen with postmarketing surveillance or clinical trials are listed below by body system.

Immune system disorders

Hypersensitivity, including rash

Psychiatric disorders

A reduction in rapid eye movement (REM) sleep, characterised by increased REM latency and decreased percentage of REM sleep, has been reported. Tolerance to this effect has been reported.

The following adverse events are class effects of anticholinergic drugs. A cause and effect relationship may not have been established.

Psychiatric disorders

Anxiety, euphoric mood, agitation, confusion, delirium, hallucinations

Nervous system disorders

Drowsiness, memory impairment, ataxia, convulsions

Eye disorders

Mydriasis-Narrow angle glaucoma may occur. Intra-ocular pressure should be checked at regular intervals.

Cardiac disorders

Tachycardia, bradycardia.

Gastrointestinal disorders

Dry mouth, constipation

Renal and urinary disorders

Urinary retention

DOSAGE AND ADMINISTRATION

If not otherwise prescribed by the physician:

Parkinsonism

Gradual increase from ½ tablet twice daily up to the individually adjusted optimal dose which generally ranges between ½-2 tablets 3-4 times daily.

Drug-induced extrapyramidal symptoms (dyskinesia, akathisia, akinesia, parkinsonism)

Adults take orally, concomitant with the neuroleptic drug ½-1(-2) tablets 1-4 times daily, increased, as required, to a maximum of 9 tablets daily; children aged between 3-15 years receive ½-1 tablet 3 times daily.

Pyramidal spasticity

Adults:

Gradual increase from ½ tablet 2-3 times daily to 2 tablets 3 times daily.

Children:

The dose should be slowly increased, starting with ¼ to ½ tablet 1-3 times daily, until optimal effect is reached. Generally, children aged between 1 and 5 years require ¼ to ½ tablet 1-3 times daily, between 6 and 11 years ½-1 tablet 1-6 times daily, between 12 and 16 years 1 tablet 2-6 times daily.

Closed craniocerebral trauma and post-concussion symptoms

Adults:

As soon as oral medication is possible, 1-2 tablets 3(-5) times daily for a period of about 5-9 weeks. In mild craniocerebral trauma and post-concussion symptoms, 1 tablet is given 3 times daily for 2-3 weeks.

Children:

In mild craniocerebral trauma ½-1 tablet 3 times daily.

Trigeminal neuralgia

In mild cases treatment with oral doses of 1-2 tablets 3 times daily for at least 2 months.

Nocturnal cramps

Usually 2 tablets with the evening meal (alternatively 1 tablet with the evening meal and 1 tablet on retiring) for approximately 10-30 days. In severe cases the daily dosage may be increased to 6 tablets and treatment extended over many months.

Expiry date

Do not use beyond the expiry date indicated on the carton.

PRESENTATION AND STORAGE CONDITIONS

Akineton tablets are white, round, quarter scored tablets marked with the Knoll logo, supplied in a blister pack of 100 tablets. They should be stored below 30°C.

NAME AND ADDRESS OF SPONSOR

Link Medical Products Pty Ltd.
18/6A Prosperity Parade
Warriewood NSW 2102

POISON SCHEDULE OF THE MEDICINE

Prescription only medicine – S4

Date of preparation

23 June 2008
Version 01