

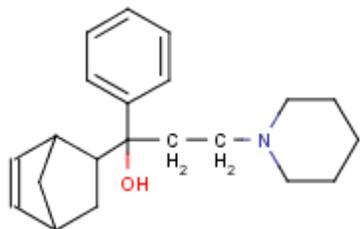
## PRODUCT INFORMATION

### AKINETON® (biperiden hydrochloride 2 mg tablets)

#### NAME OF THE MEDICINE

Non-proprietary name: biperiden hydrochloride

Structural formula (biperiden):



Chemical name (biperiden):  $\alpha$ -5-norbornen-2-yl- $\alpha$ -phenyl-1-piperidine propanol

Molecular weight: 311.5 (biperiden); 347.9 (biperiden hydrochloride)

CAS number: 514-65-8 (biperiden); 1235-82-1 (biperiden hydrochloride)

#### DESCRIPTION

Biperiden is a white, crystalline, odourless powder, slightly soluble in water and alcohol. It is stable in air at ambient temperatures.

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

#### INDICATIONS

Akineton is indicated for the treatment of Parkinsonism, drug-induced extrapyramidal symptoms, pyramidal spasticity, closed craniocerebral 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 stenosis 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.

Particular caution is required treating patients with myasthenia gravis.

Intraocular pressure should be checked at regular intervals. Caution should also be exercised in cases of existing glaucoma.

Impaired memory may arise whilst taking biperiden.

If marked dryness of the mouth occurs, this can be improved by frequently drinking small amounts of liquid or by chewing sugar-free chewing gum.

Abrupt withdrawal or abrupt reduction in dose must be avoided because of the possible occurrence of withdrawal symptoms.

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

### **Effects on fertility**

The effects of biperiden on fertility in humans are not known.

### **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."

Prescription of Akineton should be carefully evaluated during the first 3 months of pregnancy.

### **Use in lactation**

No information is available on the use of biperiden during lactation. Anticholinergic agents can hinder lactation and it is possible that biperiden may be excreted in breast milk. Breastfeeding is not recommended while taking Akineton.

### **Use in the elderly**

Elderly patients are more sensitive to anticholinergic drugs. Akineton must be administered with care in elderly patients, especially those with symptoms of organic brain disease and those exhibiting hypersensitivity to cerebral seizures.

## **INTERACTIONS WITH OTHER MEDICINES**

After additional administration of other anti-Parkinson medicines, quinidine or tri- and tetracyclic antidepressants or neuroleptics, a possible intensification of vegetative or central effects is observed. If this occurs, the dose of Akineton dose should be reduced. 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 medicines acting on the central nervous system (CNS), the consumption of alcohol should be avoided under Akineton therapy.

Anticholinergics can heighten the CNS side effects of pethidine.

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 monohydrate/levodopa.

Tardive dyskinesia induced by neuroleptics may be intensified by Akineton.

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

## **ADVERSE EFFECTS**

### **Adverse effects reported from post-marketing surveillance or clinical trials**

Clinically significant adverse effects seen during post-marketing surveillance or clinical trials are listed below by body system.

The frequency of adverse effects is listed as follows:

Very common ( $\geq 1/10$ ); common ( $\geq 1/100$  to  $< 1/10$ ); uncommon ( $\geq 1/1000$  to  $< 1/100$ ); rare ( $\geq 1/10,000$  to  $< 1/1,000$ ); very rare ( $< 1/10,000$ ), not known (cannot be estimated from the available data).

#### Cardiac disorders

Rare: tachycardia

Very rare: bradycardia

#### Eye disorders

Rare: accommodation disorders, mydriasis accompanied by photophobia

Not known: narrow angle glaucoma

#### Gastrointestinal disorders

Rare: obstipation, swelling of the salivary glands

Very rare: nausea, gastric upset

Not known: dry mouth, constipation

#### Immune system disorders

Not known: hypersensitivity, including allergic skin reactions e.g. rash

### Nervous system disorders

Rare: dizziness, drowsiness, fatigue, vertigo

Not known: dyskinesia, ataxia, muscle twitching, convulsions, speech impairment, memory impairment, loss of memory (especially at higher doses)

### Psychiatric disorders

Rare: hallucinations (especially at higher doses)

Not known: delirium, anxiety, euphoric mood, agitation, confusion

Feelings of unrest, confusion or conditions similar to psychoses, are reversible symptoms of overdosage 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 medicine is given simultaneously with other central acting anticholinergic agent such as antidepressants or neuroleptics in high doses.

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.

### Skin and subcutaneous tissue disorders

Rare: hypohidrosis

### Renal and urinary disorders

Not known: difficult urination (especially in patients with prostatic hypertrophy), urinary retention

## **DOSAGE AND ADMINISTRATION**

### **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.

## **OVERDOSAGE**

Symptoms of overdose are characterised by anticholinergic symptoms, namely, CNS symptoms (e.g. agitation, delirium, confusion, mental fog and/or hallucination) and peripheral symptoms (e.g. dilated pupils, dry mucous membranes, reddening of the face, increased heart rate, bladder atonia, intestinal atonia and elevated temperature). There is the risk of acute circulatory and respiratory failure in cases of severe poisoning.

For information on the management of overdose, contact the Poisons Information Centre on 13 11 26 (Australia).

## **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.

Store below 25°C.

## **NAME AND ADDRESS OF THE SPONSOR**

Amdipharm Mercury (Australia) Pty Ltd  
Level 9, 76 Berry Street  
North Sydney NSW 2060

## **POISON SCHEDULE OF THE MEDICINE**

Prescription only medicine – Schedule 4

## **DATE OF FIRST INCLUSION IN THE AUSTRALIAN REGISTER OF THERAPEUTIC GOODS (THE ARTG)**

8 October 1991

**DATE OF MOST RECENT AMENDMENT**

9 June 2017

Amdipharm Mercury (Australia) Pty Ltd is licensed to use the trademark Akineton.