# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Akineton Retard 4 mg prolonged release tablets

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 4 mg of biperiden hydrochloride.

Excipients with known effect:
Each tablet contains 252 mg of lactose monohydrate
For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Prolonged-release, film-coated tablets
Yellowish oblong tablets, scored on both sides.
The score line is not intended for breaking the tablet.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Akineton Retard is indicated in adults for the management of:
- Parkinsonian syndromes, especially to counteract muscular rigidity and tremor;
- Extrapyramidal symptoms such as early dyskinesia, akathisia and parkinsonism provoked by neuroleptics and similarly acting drugs.

### 4.2 Posology and method of administration

Posology
Treatment with Akineton is normally initiated with small incremental doses, depending on the therapeutic effect and side effects.

Unless otherwise prescribed by the physician, 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 4 mg prolonged release tablets.

*Adults*

Experience has shown that the average dose for adults is 4-8 mg (one to two tablets), to a maximum of 12 mg (three tablets) daily.

The total daily dose should be spread over the day, with the first tablet always being taken in the morning. The tablets should be taken whole with some liquid, either with or immediately after meals.

*Special Populations*

Elderly
Cautious dosing is necessary in elderly patients, especially those with symptoms of organic brain disease.

Paediatric population

The safety and efficacy of Akineton Retard in children and adolescents have not been established.
No data are available.

Method of administration

Oral use.
The tablets are best taken during a meal with some water. In case of very dry mouth, the tablets can be taken after the meal.

**4.3 Contraindications**

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1. Akineton is contra-indicated in the presence of untreated narrow-angle glaucoma, mechanical stenoses in the gastrointestinal tract, paralytic ileus, megacolon, prostatic adenoma and diseases that can lead to perilous tachycardia.

**4.4 Special warnings and precautions for use**

Akineton Retard should only be used with caution in the elderly, and in patients with thyrotoxicosis, cardiac failure, tachycardia, prostatic adenoma or patients who show an increased tendency to convulsions.

Central excitation effects are frequently seen in patients with symptoms of a cerebral deficiency and can necessitate a decrease in the dosage (see Sections 4.2, 4.8). There have been reports of temporarily reduced REM sleep (sleeping phase with rapid eye movements), characterised by an increase in the time needed to reach this stage and a percentage decrease in the length of this phase in the total sleep (see Section 4.8).

The dose should be gradually changed not abruptly; the treatment should be initiated or discontinued gradually.

Excipients
This medicine contains lactose as lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take this medicine.

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

**4.5 Interaction with other medicinal products and other forms of 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 effect (especially AV conduction).

The concurrent administration of levodopa and Akineton may potentiate dyskinesia. Generalised choreic movements have been reported in Parkinson's disease following concurrent administration of carbidopa/levodopa and Akineton (biperiden). 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 effect of metoclopramide and compounds with similar activity on the gastrointestinal tract is attenuated by anticholinergics such as Akineton.

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

**4.6 Fertility, pregnancy and lactation**

Akineton should only be used during pregnancy or lactation if considered essential by the physician. There is no information available on animal reproductive studies and no reports of use during pregnancy or lactation in man.

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

Akineton may cause drowsiness. Patients being treated should not drive or operate machinery unless it has been shown not to affect physical or mental ability.

**4.8 Undesirable effects**

Side-effects may occur particularly at the beginning of treatment and if the dosage is increased too quickly (see Section 4.2). Due to the unknown number of users, the percentage frequency of spontaneously recorded side-effects cannot be determined exactly.

The following frequencies are used as the basis in the evaluation of side-effects:
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)

Infections and infestations
Not known: Parotitis.

Immune system disorders
Very rare: Hypersensitivity.

Psychiatric disorders
Rare: In higher doses excitement, agitation, fear, confusion, delirious syndromes, hallucinations, sleeplessness.
Central excitation effects are frequently seen in patients with symptoms of a cerebral deficiency and can necessitate a decrease in the dosage.
There have been reports of temporarily reduced REM sleep (sleeping phase with rapid eye movements), characterised by an increase in the time needed to reach this stage and a percentage decrease in the length of this phase in the total sleep.
Very rare: Nervousness, euphoria.

Nervous system disorders
Rare: Fatigue, dizziness and disturbance of memory.
Very rare: Headache, dyskinesia, ataxia and speaking disorder, increased disposition to cerebral seizures and convulsions.

Eye disorders
Very rare: Disturbance of accommodation, mydriasis, and photosensitivity. Closed-angle glaucoma might occur (controlling of intraocular pressure).

Cardiac disorders
Rare: Tachycardia
Very rare: Bradycardia. A fall in blood pressure may occur following parenteral administration.

Gastrointestinal disorders
Rare: Dryness of mouth, nausea, gastric disorder.
Very rare: Constipation

Skin and subcutaneous tissue disorders
Very rare: Reduced perspiration, allergic rash.

Musculoskeletal and connective tissue disorders
Rare: Muscle twitching.

Renal and urinary disorders
Very rare: Voiding disorders, especially in patients with prostate adenoma (dose reduction), more seldom: urinary retention.

General disorders and administration site conditions
Rare: Drowsiness.

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 HPRA Pharmacovigilance, Website: www.hpra.ie.

**4.9 Overdose**

*Symptoms*:
The symptoms of overdose are anticholinergic effects such as mydriasis, dryness of mucous membranes, flushing, rise in heart rate, reduction of bowel motility, reduction in ureter and bladder tone, increased temperature, excitation, confusion, clouding of consciousness and/or hallucinations. In severe overdose, cardiac and respiratory depression may occur.

*Treatment*:
Gastric lavage or emesis should be considered. As antidote, acetylcholinesterase inhibitors are recommended. Vital signs should be closely monitored and appropriate supportive measures taken. Artificial ventilation, reduction of fever, and application of a bladder emptying catheter may be necessary. In the event of cardiac depression, a cardiac stimulant drug, such as dobutamine, may be considered.

**5 PHARMACOLOGICAL PROPERTIES**

**5.1 Pharmacodynamic properties**

Pharmacotherapeutic group: Anti-parkinson drugs, anticholinergic agents, biperiden.
ATC code: N04AA02.
Akineton is an anticholinergic agent with a marked effect on the central nervous system which is important for its therapeutic application and, unlike atropine, has weak peripheral vegetative effects.

**5.2 Pharmacokinetic properties**

None.

**5.3 Preclinical safety data**

None.

**6 PHARMACEUTICAL PARTICULARS**

**6.1 List of excipients**

Core
Lactose Monohydrate
Maize Starch
Povidone
Microcrystalline cellulose
Hypromellose
Magnesium stearate

Film coating
Hypromellose
Hydroxypropylcellulose
Polyethylene glycol
Docusate sodium
Titanium dioxide (E171)
Yellow iron oxide (E172)
Talc
Colloidal anhydrous silica
Carnauba wax

**6.2 Incompatibilities**

Not applicable.

**6.3 Shelf life**

3 years.

**6.4 Special precautions for storage**

This medicinal product does not require any special storage conditions.

**6.5 Nature and contents of container**

PVC/PVDC/Al blister packs (20 tablets per blister sheet) in boxes of 100 tablets

**6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7 MARKETING AUTHORISATION HOLDER**

Laboratorio Farmaceutico SIT, Srl
Via Cavour 70
27035 MEDE (PV)
Italy

**8 MARKETING AUTHORISATION NUMBER**

PA1253/002/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 01 April 1979

Date of last renewal: 01 April 2009

**10 DATE OF REVISION OF THE TEXT**

December 2020