

## SCHEDULING STATUS

**S4**

## PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

### AKINETON® Tablets

Biperiden hydrochloride 2 mg

### Read all of this leaflet carefully before you receive AKINETON

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- AKINETON has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

### 1. WHAT AKINETON CONTAINS

The active substance is biperiden hydrochloride

Each tablet contains 2 mg of biperiden hydrochloride.

The other ingredients are Calcium hydrogen phosphate dihydrate, copovidone (copolyvidone), lactose monohydrate, magnesium stearate, maize starch, microcrystalline cellulose, potato starch, talc.

Contains sugar: lactose monohydrate.

### 2. WHAT AKINETON IS USED FOR

AKINETON is used for

- Parkinsonism
- Medicine-induced movement disorders

### 3. BEFORE YOU TAKE AKINETON

#### Do not take AKINETON:

- if you are hypersensitive (allergic) to the active or any of the other ingredients of AKINETON;
- if you are lactose intolerant;
- if you are suffering from an eye disorder called narrow angle glaucoma;

- if you have been told that you have a narrow stomach or bowels, or any other bowel problem;
- if you are suffering from abnormal dilation of the colon (also called the large bowel);
- if you are suffering from a disease, injury or physical disorder that causes impaired brain function;
- if you are pregnant or breast feeding;
- if you suffer from myasthenia gravis.

### **Take special care with AKINETON**

- if you had a disease, injury or physical disorder that causes decreased brain function;
- If you have low tolerance to the medicine (e.g. patients with cerebral arteriosclerosis (thickening and hardening of the walls of the arteries in the brain));
- If you have an enlarged prostate;
- If you are suffering from heart failure or fast-heart beat or fits;
- If you are an alcoholic;
- If you have glaucoma. Your doctor may check the pressure in your eye at regular intervals;
- AKINETON can cause addiction if used for longer durations than prescribed.

### **Taking AKINETON with food and drink**

AKINETON may be taken at any time of the day, with or without food.

### **Pregnancy and Breastfeeding**

The safety of AKINETON during pregnancy and breastfeeding has not been established.

If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare professional for advice before being given this medicine.

### **Driving and using machinery**

Since side effects such as tiredness, dizziness, sleepiness, confusion, hallucination (an experience involving the apparent perception of something not present), nervousness, extreme arousal, elevated mood, blurred vision, dilation of the pupil of the eye, extreme sensitivity to light, and eye disorders (narrow-angle glaucoma) may occur in patients receiving AKINETON, you should not drive, use machinery or perform any tasks that require concentration, until you are certain that AKINETON does not adversely affect your ability to do so (see

POSSIBLE SIDE EFFECTS), especially if used with other medicines that affect the central nervous system or alcohol. In these situations, impaired decision making could lead to accidents.

### **Important information about some of the ingredients in AKINETON**

AKINETON tablets contain lactose monohydrate. Patients with lactose intolerance should not take AKINETON. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking AKINETON.

### **Taking other medicines with AKINETON**

Always tell your healthcare professional if you are taking any other medicines. (This includes complementary or traditional medicines).

Combining AKINETON with other medicines having similar effects may increase its undesirable effects. Such medicines include:

- Antiparkinson medicines (e.g. levodopa, carbidopa): medicines used to treat disease of the brain affecting movements;
- Tricyclic antidepressants (e.g. amitriptyline, imipramine):
- medicines used to treat depression;
- Quinidine: medicine used to treat irregular heartbeats;
- Alcohol; the effects of alcohol may be increased during treatment with AKINETON.

## **4. HOW TO TAKE AKINETON**

Do not share medicines prescribed for you with any other person.

Always receive AKINETON exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

Your doctor will decide on the dose that is suitable for you.

Your doctor will tell you how long your treatment with AKINETON will last.

Do not stop treatment early because your condition may get worse. Withdrawal should be done gradually.

If you have the impression that the effect of AKINETON is too strong or too weak, tell your doctor or pharmacist

### **If you take more AKINETON than you should**

The symptoms for overdose are:

- slow response of pupil of the eye;
- dilated pupils;
- slowing of movements;
- reddening of face;
- dryness of mucous membranes (cavities of the body);
- increased heart rate;
- pain in abdominal area;
- increased temperature;
- excitation;
- confusion;
- extreme arousal;
- mental fog;
- hallucination (an experience involving the apparent perception of something not present);
- In case of massive overdose there is a risk of circulatory failure and central respiratory paralysis (life-threatening condition).

**In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.**

### **If you forget to take a dose of AKINETON**

Take your missed dose as soon as you remember, within a few hours after missing a dose. Do not take a double dose to make up for forgotten individual doses.

### **Effects when treatment with AKINETON is stopped**

An abrupt withdrawal or abrupt reduction in doses must be avoided because your condition may get worse. Upon stopping of treatment or reduction of the dose, sleeplessness develops. Abrupt withdrawal can lead to the following symptoms: feeling sick, sweating, and urinary urgency.

## 5. POSSIBLE SIDE-EFFECTS

AKINETON can have side effects.

Not all side effects reported for AKINETON are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while receiving AKINETON, please consult your doctor, pharmacist or other healthcare professional for advice.

**If any of the following happens, stop receiving AKINETON and tell your doctor immediately or go to the casualty department at your nearest hospital:**

- allergic reactions such as rash

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to AKINETON. You may need urgent medical attention or hospitalisation.

**Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:**

- abnormally slow heart rate;
- increased heart rate

These are all serious side effects. You may need urgent medical attention.

**Tell your doctor if you notice any of the following:**

- confusion;
- hallucination (an experience involving the apparent perception of something not present);
- delirium
- sleeplessness;
- nervousness;
- headache;
- dyskinesia (movement disorders that are characterized by involuntary muscle movements);
- the loss of full control of bodily movements;
- speech disorder;
- memory impairment;
- constipation;
- obstipation;
- abdominal discomfort/disorder;

- feeling sick;
- difficulty passing urine;

*Frequency unknown:*

- extreme arousal;
- elevated mood;
- depersonalisation;
- derealisation;
- laziness;
- increased risk of fits;
- change in ability of eye to maintain a clear image or focus on an object;
- blurred vision;
- dilation of the pupil of the eye;
- extreme sensitivity towards light;
- eye disorder called narrow-angle glaucoma and angle closure glaucoma may occur. therefore, pressure of the eye should be checked at regular intervals;
- vertigo (a sensation of whirling and loss of balance, associated particularly with looking down from a great height, or caused by disease affecting the inner ear or the vestibular nerve; giddiness);
- dryness of mouth;
- hypohidrosis (abnormal lack of sweat in response to heat);
- tiredness;
- fever;
- hot skin;
- blood pressure decrease

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

## **6. STORING AND DISPOSING OF AKINETON**

Store at or below 25 °C.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

## 7. PRESENTATION OF AKINETON

**AKINETON:** Blister packs with 10 tablets per blister and 5 blisters per pack.

## 8. IDENTIFICATION OF AKINETON

Scored, almost white tablet marked with a double score line on one side.

## 9. REFERENCE NUMBER

**AKINETON**<sup>®</sup> Tablets: B1042 (Act 101/1965)

## 10. NAME AND ADDRESS OF REGISTRATION HOLDER

Pharmaco Distribution (Pty) Ltd.

3 Sandown Valley Crescent,

South Tower, 1st Floor,

Sandton 2196,

South Africa

Ethical assistance Line: +27 (0)11 784 0077

## 11. DATE OF PUBLICATION

Date of Registration: 4 March 1975

Date of last revision: 02 November 2020

<b>AKINETON</b> Tablets NAMIBIA: NS2 Reg. No.: 14/5.4.1/0195	<b>AKINETON</b> Injection NAMIBIA: NS2 Reg. No.: 14/5.4.1/0196	<b>AKINETON</b> Tablets BOTSWANA: S2 Reg. No.: B9305380	<b>AKINETON</b> Injection BOTSWANA: S2 Reg. No.: BOT1803351
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