SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

AKINETON® Injection

Biperiden lactate 5 mg/ml

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 lactate.

Each ampoule contains 5 mg/ml biperiden lactate.

The other ingredients are lactic acid, sodium hydroxide, water for injection.

2. WHAT AKINETON IS USED FOR

AKINETON is used for

- Parkinsonism
- Medicine-induced movement disorders

3. BEFORE YOU ARE GIVEN AKINETON

You should not be given AKINETON:

- if you are hypersensitive (allergic) to the active or any of the other ingredients of AKINETON;
- 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

Tell your doctor or healthcare professional before being given the injection if:

- you experience dizziness, unsteadiness, fainting, blurred vision, confusion or general weakness, as after injection low blood pressure may be observed.
- 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.

Receiving AKINETON with food and drink

AKINETON is an injection and may be given may be given 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.

Effects on the ability to drive and use 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.

Receiving 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 RECEIVE 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 receive more AKINETON than you should

Since a healthcare professional will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage. 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 receive a dose of AKINETON

Receive your missed dose as soon as you remember, within a few hours after missing a dose. Do not receive 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 ^{o}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 injection: 5 colourless type I glass ampoules, 1 ml each.

8. IDENTIFICATION OF AKINETON

Clear, colourless solution in colourless ampoule.

9. REFERENCE NUMBER

AKINETON® Injection: B1039 (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

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