PACKAGE LEAFLET: INFORMATION FOR THE USER

Akineton 2 mg tablets
biperiden hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. WHAT AKINETON IS AND WHAT IT IS USED FOR

The name of your tablets is Akineton 2 mg tablets.
The active ingredient in Akineton is biperiden hydrochloride. Each tablet contains 2 mg of biperiden hydrochloride.

Akineton belongs to a group of medicines called anticholinergic agents.

Akineton can be used to treat Parkinson's disease by relaxing muscle spasms and controlling muscle twitching. It can also be used to control muscle twitching and spasms caused by some medicines.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE AKINETON

Do not take Akineton:
- If you are allergic (hypersensitive) to biperiden hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from glaucoma.
- If you have an abnormal heartbeat or any other heart problems.
- If your doctor has told you that you have a narrowing of your stomach or bowels, or any other bowel problem.
- If you are male, and you have benign tumour of the prostate.

Warnings and precautions

Talk to your doctor or pharmacist before taking Akineton:
- If you suffer from thyroid problems.
- Some people may be more senstitive to the effects of Akineton and may need closer monitoring. These include the frail elderly (particularly those who have had a disease, injury or physical disorder that cause decreased brain function), and patients who have heart failure, quicker heartbeat, benign tumour of the prostate or patients who have epilepsy.

Children and adolescents

Experience with Akineton 2 mg in paediatric use is limited, please ask your doctor.

Other medicines and Akineton

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
If you are taking any of the following medicines (this list includes medicines that may be prescribed by a doctor and also some medicines which are available without a prescription, such as cough/ cold medication and indigestion remedies) tell your doctor or pharmacist before you start to take Akineton tablets:

- Any other medicines for the treatment of movement disorders (e.g. levodopa)
- Any other anti-Parkinson drugs
- Any treatment for nervous disorders
- Any medicines that treat indigestion and stomach pains caused by muscle spasms, or medicines used to treat nausea and vomiting (e.g. metoclopramide)
- Antihistamines (sometimes used to treat allergies such as hay fever and skin rashes)
- Quinidine (sometimes used to treat abnormal heart rhythms)

If you are unsure if any of the list applies to you, ask your doctor before you start to take your tablets.

Akineton with food, drink and alcohol

Avoid alcohol whilst taking Akineton.

Pregnancy and Breast feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Akineton should only be used during pregnancy or lactaton if considered essential by the doctor.

Driving and using machines

Akineton can make you feel drowsy, particularly if you are taking some other medicines (see ” Other medicines and Akineton” and “Akineton with food, drink and alcohol”). Do not drive, operate machinery or do anything that requires you to be alert until you know how the tablets affect you.

Akineton contains lactose monohydrate

Akineton tablets contain lactose as lactose monohydrate (see section 6). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE AKINETON

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults: The number of tablets that you will need to take will be decided by your doctor and will depend upon your symptoms. The starting dose is usually half a tablet twice a day. This may be increased slowly by your doctor to a maximum of two tablets taken three or four times a day.

Elderly: Caution is necessary when dosing. Your doctor will choose the right dosage for you.

Children ages 3-15 years: Half to one tablet taken up to three times a day.

The tablets are best taken during a meal with a little water. If you have a very dry mouth, it may help if you take your tablets just after your meal.

If you take more Akineton than you should

If you take more than the stated dose (an overdose), you should contact a doctor immediately or go to the nearest hospital casualty department. Show them your tablets.

If you forget to take Akineton

If you forget to take a dose, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Akineton

It is important that you keep taking these tablets until your doctor tells you to stop. Don't stop just because you feel better. If you stop taking the tablets without your doctor's advice, your condition may get worse. Withdrawal of this product should be gradual.
If you have any further questions on the use of this medicines, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.
If you experience any of the following serious side effects, stop taking this medication and seek urgent medical attention immediately:

Hypersensitivity (allergic reactions, which may include difficulty in breathing, swelling of the lips or face, rash or itching)
Increased tendency to suffer from convulsions and seizures
Involuntary disorders of movement
Disturbed coordination of movement and speech disturbances
An increase in the pressure within the eye, called glaucoma (closed-angle glaucoma), is possible. The value of this pressure should be checked regularly by a specialist.
Slowing of the heart rate
Difficulties emptying the urinary bladder, in particular in patients with an enlarged prostate gland (prostate adenoma).

Side-effects may occur particularly at the beginning of treatment and if the dosage is increased too quickly. In patients with brain deficits, excitation is frequently seen. In these cases, it can be necessary to reduce the dosage.

The following side effects have been reported:

<u>Rare (may affect up to 1 in 1,000 people):</u>
In higher doses excitement, agitation, fear, confusion, mental delusions (delirious syndromes and hallucinations), sleeplessness.
Influence on sleep phases.
Fatigue, dizziness and disturbance of memory.
Accelerated pulse (palpitations).
Dryness of mouth (marked dryness of the mouth can be improved by frequently drinking small amounts of liquid or by chewing sugar-free chewing gum).

Gastric disorder.
Nausea.
Muscle twitching.
Drowsiness.

Very rare (may affect up to 1 in 10,000 people):
Nervousness, unnaturally elevated mood (euphoria).
Headache.
Visual disturbances.
Pupil dilatation with sensitivity to light.
Constipation.
Reduced perspiration.
Allergic skin rash.
Difficulty in passing urine (urinary retention).

Not known (frequency cannot be estimated from the available data):
Swelling or inflammation of the salivary glands.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE AKINETON

Keep this medicine out of the sight and reach of children.

Do not take your tablets after the expiry date, which is stated on the label and carton after "EXP". The expiry date refers to the last day of that month.
Do not store above 25°C. Keep the blister in the outer carton.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Akineton contains

- The active substance is biperiden hydrochloride. Each tablet contains 2 mg of biperiden hydrochloride.
- The other ingredients are maize starch, lactose monohydrate (see section 2), microcrystalline cellulose, calcium hydrogen phosphate, copovidone, talc, magensium stearate and potato starch.

What Akineton looks like and contents of the pack

Appearance of tablet: Circular, biplanar (flat faced), white tablet with a bisecting score on one surface. The tablet can be divided into equal doses.

Each pack contains 100 tablets.

Marketing Authorisation Holder and Manufacturer:

Laboratorio Farmaceutico S.I.T. Srl – Via Cavour, 70 – 27035 Mede (PV) - Italy

This leaflet was last revised in December 2020.