

Akineton® 2 mg Tablets

(biperiden hydrochloride)

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

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1 What Akineton tablets are and what they are used for

The name of your tablets is Akineton Tablets 2mg - called Akineton tablets in this leaflet. 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 tablets 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 tablets

Do not take Akineton tablets:

- * If you are allergic (hypersensitive) to biperiden hydrochloride or any of the other ingredients in Akineton tablets (please see section 6 overleaf).
- * 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 tablets:

- * If you suffer from thyroid problems.
- * Some people may be more sensitive 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

Other medicines and Akineton tablets

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 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 tablets 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 lactation if considered essential by the doctor

Driving and using Machines

Akineton tablets can make you feel drowsy, particularly if you are taking some other medicines (see the list above). Do not drive, operate machinery or do anything that requires you to be alert until you know how the tablets affect you.

Akineton tablets 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 tablets

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

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: A lower dose may be prescribed, with careful dose increases, as necessary.

Children aged 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.

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Package leaflet: Information for the user (continued)

If you take more Akineton tablets 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 tablets

If you forget to take a dose, take the next dose at the usual time. Never double-up on a dose to make up for the one you have missed.

If you stop taking Akineton tablets

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 medicine, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, Akineton can cause side effects, although not everybody gets them. Side effects with Akineton may include:

- * Hypersensitivity (allergic reactions) (which may include difficulty in breathing, swelling of the lips or face, rash or itching. If you experience these, stop taking your medicine and go to your doctor immediately).

- * Dizziness
- * Delirium (decreased awareness, confusion, loss of reality)

- * Difficulty in focusing
- * Poor co-ordination of muscular movement (ataxia)

Rare side effects include also a slowing of the heart rate, low blood pressure (following administration by injection), hallucinations, seizures, convulsions and trouble urinating (particularly in patients with prostate adenoma).

If you experience any of these, stop taking your medicine and inform your doctor immediately.

Other possible side effects are:

- * Altered sleep pattern
- * Tiredness
- * Drowsiness
- * Agitation
- * Memory disturbance
- * Fear, nervousness
- * Excitement
- * Euphoric mood
- * Dilation of the pupil
- * Dry mouth
- * Reduced sweating
- * Constipation
- * Gastric problems, feeling sick (nausea)
- * Fast heart beat (tachycardia)
- * Headache
- * Difficulty with speaking
- * Sensitivity to light (photosensitivity)
- * Increased pressure in the eye (glaucoma)

Occasionally, allergic skin rashes or twitching of the arms, legs or face (dyskinesia) have been reported.

Not Known (cannot be estimated from the available data)

- * Inflammation of the salivary glands located in front of each ear (parotitis).

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, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Akineton tablets

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

Do not take your tablets after the 'use by' (expiry) date shown on the pack. The expiry date refers to the last day of that month.

Do not store them above 25°C, keep the blister in the outer carton.

If your doctor decides to stop the treatment, return any left over to your pharmacist. Only keep the tablets if your doctor tells you to.

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

This leaflet does not contain the complete information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist who have access to additional information.

What this medicine contains:

The active substance is 2 mg biperiden hydrochloride.

The other ingredients are:

Calcium hydrogen phosphate, copovidone, potato starch, lactose monohydrate (see section 2), magnesium stearate, corn starch, microcrystalline cellulose,talc.

What this medicine looks like and contents of the pack

Akineton tablets are circular, biplanar, white tablet with a bisecting score on one surface. The scoreline allows the tablet to be divided into equal doses. Akineton is available in packs of 100 tablets.

Parallel distributed by:

Lexon Pharmaceuticals (Ireland) Limited, Block 3, Harcourt Centre, Harcourt Road, Dublin 2, Ireland.

Repackaged by:

Lexon Pharmaceuticals (Ireland) Limited, Units 22 & 25, Block 4, Port Tunnel Business Park, Clonshaugh, Dublin 17, Ireland.

The manufacturer is:

Laboratorio Farmaceutico S.I.T. Srl - Via Cavour, 70 - 27035 Mede, Italy.

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Tel: +35318710550 for help.