

Patient Information Leaflet

Read all of this leaflet carefully before you start taking this medicine because it contains important information top 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. Do not pass it 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.

Your medicine is called Procyclidine hydrochloride 5mg Tablets, but will be referred to as Procyclidine hydrochloride throughout this leaflet.

What is in this leaflet:

- 1 What Procyclidine hydrochloride is and what it is used for
- 2 What you need to know before you take Procyclidine hydrochloride
- 3 How to take Procyclidine hydrochloride
- 4 Possible side effects
- 5 How to store Procyclidine hydrochloride
- 6 Contents of the pack and other information

1 What Procyclidine hydrochloride is and what it is used for

Procyclidine hydrochloride contains a medicine called procyclidine. This belongs to a group of medicines called anticholinergics. They stop a substance called acetylcholine working in your body.

Procyclidine hydrochloride is used to:

- * treat and relieve the signs of Parkinson's disease such as:
 - stiff muscles, paralysis and tremor
 - problems talking, writing and walking
 - producing too much saliva and dribbling
 - sweating and uncontrolled eye movements
 - depression
- * stop side effects called 'extrapyramidal effects', which are caused by some medicines. These may include signs similar to the Parkinson's disease or restlessness and unusual head and body movements.

2 What you need to know before you take Procyclidine hydrochloride

Do not take Procyclidine hydrochloride if:

- * you are allergic (hypersensitive) to procyclidine or any of the other ingredients of Procyclidine hydrochloride (see section 6)
- * you have problems passing water (urinary retention)
- * you suffer from a problem caused by too much pressure in your eye called 'closed angle glaucoma'
- * you have stomach cramps and pains or constipation.

Do not take if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist before taking Procyclidine hydrochloride.

Warnings and precautions

Talk to your doctor or pharmacist before taking your medicine if:

- * you are elderly. Your dose may need to be carefully monitored to prevent any side effects
- * you suffer from a problem caused by too much pressure in your eye called 'narrow angle glaucoma' or if you have a higher chance to get glaucoma
- * you have an obstructive disease of your bowel
- * you have an enlarged prostate gland
- * you have a mental illness and are taking Procyclidine hydrochloride to control the side effects of your medicines. Occasionally people who take this medicine may have a psychotic episode
- * you have kidney or liver problems

- * In some patients who use Procyclidine hydrochloride to control side effects of other medicines, involuntary repetitive body movements may occur. If this happens to you, your doctor may decide to give you lower doses. If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Procyclidine hydrochloride.

Children

Do not give this medicine to children.

Other medicines and Procyclidine hydrochloride

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription. This includes herbal medicines. This is because Procyclidine hydrochloride can affect the way some other medicines work. Also some other medicines can affect the way Procyclidine hydrochloride works. In particular tell your doctor or pharmacist if you are taking any of the following:

- * medicines used to treat mental health problems (including Alzheimer's disease and dementia)
- * levodopa and amantadine, used in Parkinson's disease
- * disopyramide, quinidine and nitrate tablets (including tablets that dissolve under the tongue), used to treat heart problems
- * cisapride, domperidone and metoclopramide, used to treat sickness, indigestion and feeling sick (nausea)
- * antihistamines, used to treat hayfever and allergies
- * nefopam, used to treat pain
- * ketoconazole, used to treat fungal infections
- * paroxetine.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Procyclidine hydrochloride.

Pregnancy and breast-feeding

Talk to your doctor before taking this medicine if you are pregnant, might become pregnant or are breast-feeding.

Driving and using machines

You may have blurred vision, dizziness, confusion or disorientation while taking Procyclidine hydrochloride. If this happens do not drive or use any tools or machines.

Procyclidine hydrochloride contains lactose (a type of sugar).

If you have been told by your doctor that you cannot tolerate or digest some sugars, talk to your doctor before taking this medicine.

3 How to take Procyclidine hydrochloride

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

- * Swallow the tablets with a drink of water.
- * You can take Procyclidine hydrochloride at any time of day, with or without food. Some people find they feel less sick if they take it at meal times.
- * The tablet may be cut or broken in half along the break-line to divide the dose in two equal halves.

To treat Parkinson's disease:

- * The recommended starting dose is half a tablet three times a day.
- * This can be increased by half or one tablet each day, every two or three days until an effect is seen. This is known as the 'maintenance dose'. The daily maintenance dose is usually three to six tablets.
- * The maximum your doctor may decide to prescribe is 12 tablets.
- * Although the dose is usually taken three times a day, your doctor may ask you to take a fourth dose before bedtime.

To treat uncontrolled body movements (extrapyramidal symptoms) caused by taking other medicines:

Procyclidine hydrochloride can be used to control side effects caused by other medicines.

- * The recommended starting dose is half a tablet three times a day.
- * This can be increased by half a tablet each day until an effect is seen.
- * The daily maintenance dose is usually two to six tablets.
- * Your doctor may decide to stop your Procyclidine hydrochloride after three or four months to see if your side effects return.

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* If you need Procyclidine hydrochloride for a longer period of time, your doctor may decide to stop every now and then.

Elderly

If you are elderly, your dose may need to be carefully monitored to prevent any side effects.

Use in children

Procyclidine hydrochloride tablets are not usually recommended for use in children.

If you take more Procyclidine hydrochloride than you should

If you take more Procyclidine hydrochloride than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you forget to take Procyclidine hydrochloride

Take a dose as soon as you remember it and then go on as before.

If you stop taking Procyclidine hydrochloride

Do not stop taking Procyclidine hydrochloride without talking to your doctor.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4 Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

If you are taking a medicine for mental illness (called a neuroleptic) at the same time as Procyclidine hydrochloride:

- * you can develop uncontrolled movements of your face and tongue (tardive dyskinesia). The dose of either of your medicines may need to be adjusted.
- * unusual body movements, particularly of your hands, arms and legs which may have previously been occurring with the medicine for your mental illness can be made worse by the addition of Procyclidine hydrochloride.

If either of these happens, tell your doctor straight away.

Common (affects less than 1 in 10 people)

- * problems passing water (urinary retention)
- * blurred vision
- * dry mouth
- * constipation.

Uncommon (affects less than 1 in 100 people)

- * feeling sick (nausea) or being sick (vomiting)
- * inflamed gums (gingivitis)
- * dizziness, nervousness, feeling confused, not knowing where you are (feeling disoriented), reduced concentration or memory, hearing unexpected noises or seeing unexpected sights (hallucinations), anxiety, agitation (feeling irritable)
- * skin rash.

Rare (affects less than 1 in 1,000 people)

- * 'psychotic disorder', which includes symptoms occurring together such as dizziness, confusion, reduced concentration or memory, disorientation, hearing unexpected noises or seeing unexpected sights (hallucinations), anxiety, agitation (feeling irritable).

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store Procyclidine hydrochloride

- * Keep this medicine out of the sight and reach of children.
- * Do not store above 25°C.
- * Do not use this medicine after the expiry date which is stated on the foil and carton. The expiry date refers to the last day of that month.
- * 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.
- * If your medicine becomes discoloured or shows any signs of deterioration, consult your pharmacist who will tell you what to do.

6 Contents of the pack and other information

What Procyclidine hydrochloride contains

- * The active substance is procyclidine hydrochloride 5 mg. Each tablet contains 5 mg of procyclidine hydrochloride
- * The other ingredients are magnesium stearate, povidone, sodium carboxymethyl starch type A and lactose monohydrate.

What Procyclidine hydrochloride looks like

Procyclidine hydrochloride 5mg Tablets are white, round, biconvex tablets, one face with a break-line and coded KT above the break-line and 05 below the break-line with a score-line on the other face. Procyclidine hydrochloride comes in bottles of 100 tablets.

Product Licence Holder and Manufacturer

This medicine is manufactured by Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, D-23843 Bad Oldesloe, Germany and is procured from within the EU and repackaged by the Product Licence Holder: Lexon (UK) Limited, Unit 18, Oxleasow Road, East Moons Moat, Redditch, Worcestershire, B98 0RE.

If you have any questions or are not sure about anything, ask your doctor or pharmacist. They will have additional information about this medicine and will be able to advise you.

POM

15184/1600 Procyclidine hydrochloride 5mg Tablets

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