

PACKAGE LEAFLET

Package leaflet: Information for the patient

Procyclidine Hydrochloride 5 mg Tablets (procyclidine 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 Procyclidine is and what it is used for
2. What you need to know before you take Procyclidine
3. How to take Procyclidine
4. Possible side effects
5. How to store Procyclidine
6. Contents of the pack and other information

1. What Procyclidine is and what it is used for

Procyclidine belongs to a group of medicines called anticholinergics, which stop a substance called acetylcholine working in your body. Procyclidine is used to:

- reduce the symptoms of Parkinson's disease by helping muscle control and reducing stiffness
- control Parkinson-like side effects caused by certain medicines used to treat mental health conditions.

2. What you need to know before you take Procyclidine

Do not take Procyclidine:

- if you are allergic to procyclidine or any of the other ingredients of this medicine (listed in section 6)
- if you have glaucoma (increased pressure in the eye)
- if you have been told you have a blockage in your intestine (gut)
- if you are unable to, or have difficulty, passing urine and are not currently receiving any form of treatment for this from your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking Procyclidine:

- if you have liver or kidney disease
- if you have high blood pressure or a heart condition
- if you have difficulty passing urine due to an enlarged prostate gland
- if you have a history of blockages in your intestine (gut)
- if you have a family history of glaucoma (increased pressure in the eye), or you have been told that you may be at risk of developing glaucoma
- if you suffer from repetitive movements of the hands, mouth, tongue, lips and eyes, which you are unable to control and may be caused by certain medicines. Procyclidine can make these symptoms worse. If this occurs, talk to your doctor who may advise that you change the amount of medicine that you take
- if you have a mental health condition

- if you are taking a phenothiazine medicine and are in, or travelling to, an area with high temperatures and/or high humidity (this medicine may make it more likely that your body is unable to regulate body temperature normally and your body temperature may become higher than normal).

Other medicines and Procyclidine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription, including the following:

- medicines for mental health conditions (such as Alzheimer's disease, dementia, depression, schizophrenia), e.g. tacrine, memantine, monoamine oxidase inhibitors, paroxetine, tricyclic and related antidepressants (such as amitriptyline), clozapine and phenothiazines
- medicines which may be known as parasympathomimetics e.g. nicotine (used to help stop smoking), pilocarpine (used to treat dry mouth or certain types of glaucoma), bethanechol (used to help pass urine)
- medicines used to treat nausea, sickness and indigestion such as cisapride, domperidone and metoclopramide
- medicines often used to treat Parkinson's disease such as amantadine and levodopa
- medicines for heart complaints e.g. disopyramide, quinidine and buccal (dissolved on the gum in the mouth) or sublingual (placed under the tongue to dissolve) nitrate tablets (usually used to help treat chest pain (angina))
- medicines for treating pain, in particular, nefopam
- ketoconazole used to treat a fungal infection
- antihistamines.

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.

Driving and using machines

Do not drive or operate machines if you feel dizzy, confused, disorientated or suffer blurred vision whilst taking Procyclidine.

Procyclidine contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Procyclidine

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

- Take your dose with a glass of water
- Taking your dose after a meal may mean that you notice less side effects as a result of taking this medicine

Your doctor may start you on a low dose of procyclidine and gradually increase it until you have reached the correct dose to control your symptoms. If you feel your symptoms are getting worse, tell your doctor.

Adults:

Treatment of Parkinson's disease – The recommended starting dose is half a tablet (2.5 mg of procyclidine) three times a day. If symptoms are not controlled, every two or three days your doctor may recommend that you increase the amount you are taking by 2.5 mg or 5 mg (additional half tablet or one tablet per day) until symptoms are controlled.

The recommended maximum dose is 30 mg (6 tablets) of procyclidine, but if necessary your doctor may recommend that you take up to 60 mg (12 tablets) of procyclidine a day.

Although the dose is usually taken three times a day, your doctor may also recommend that you take a fourth dose before bedtime if needed.

Treatment of Parkinson-like symptoms caused by medicine - The recommended starting dose is half a tablet (2.5 mg of procyclidine) three times a day. If symptoms are not controlled, your doctor may recommend that you increase the amount you are taking by 2.5 mg (additional half tablet) each day until symptoms are controlled.

The recommended maximum dose is 30 mg (6 tablets) of procyclidine a day.

It is recommended that your doctor withdraws treatment with procyclidine every 3 or 4 months to see if the symptoms have gone away. If the symptoms return, your doctor will normally recommend that you continue with treatment with procyclidine.

Older people: Smaller doses than those stated above may be given. This is because older people may be more sensitive to the effects of procyclidine.

Use in children and adolescents: Procyclidine is **not** suitable for children and adolescents.

If you take more Procyclidine than you should

If you take more Procyclidine than you should, contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you. Symptoms of overdose include: fast heartbeat, agitation, restlessness, confusion, severe inability to sleep, excitement (although occasionally people may feel anxious and aggressive) and disorientation. The pupils in the eye may not open or close when light is shined on them and hallucinations (seeing or hearing things that are not real) may also occur. In severe cases, you may feel very sleepy, fall into unconsciousness or into a coma.

If you forget to take Procyclidine

If you forget to take your dose of Procyclidine, take it as soon as you remember unless it is almost time for your next dose. **Do not** take a double dose to make up for the dose you missed.

If you stop taking Procyclidine

Do not suddenly stop taking Procyclidine unless your doctor advises you to do so. If you stop taking the tablets too quickly, your original symptoms may return.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop taking this medicine and tell your doctor immediately if you:

- suffer symptoms of an allergic reaction such as skin rash, swelling of the face, lips, tongue or throat or difficulty breathing. These are signs of a serious allergic reaction (frequency not known: cannot be estimated from the available data).
- experience a mental health condition, which can cause unusual thoughts and perceptions such as hallucinations (seeing or hearing things that are not real) or delusions (a belief or strong feeling which is not based on real information or experiences). This side effect is rare (may affect up to 1 in 1,000 people).

Tell your doctor straight away if you suffer from any of the following side effects:

- nervousness

- fast heart beat
- dizziness
- confusion, or reduced ability to understand what is going on
- reduced memory, disorientation
- feeling anxious or agitated
- hallucinations.

These effects are uncommon (may affect up to 1 in 100 people) but you may need medical attention or your doctor may need to reduce your dose.

Common side effects (may affect up to 1 in 10 people) are:

- dry mouth
- blurred vision
- constipation
- difficulty urinating (passing water).

Uncommon side effects (may affect up to 1 in 100 people) are:

- inflammation of the gums in the mouth
- feeling sick, being sick
- rash.

If you are taking Procyclidine to help control side effects of medicines being used to treat mental health conditions, you may notice an apparent worsening of symptoms.

Reporting side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any 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

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Procyclidine

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

Do not use this medicine after the expiry date which is stated on the carton or bottle label after 'EXP'. The expiry date refers to the last day of that month.

Store below 25°C.

For blister packs, store in the original package in order to protect from light and moisture.

For bottles, keep the bottle tightly closed in order to protect from light and moisture.

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 to protect the environment.

6. Contents of the pack and other information

What Procyclidine contains

The active substance is procyclidine. Each tablet contains 5 mg of procyclidine hydrochloride. The other ingredients are lactose anhydrous, microcrystalline cellulose and magnesium stearate.

What Procyclidine looks like and contents of the pack

The tablets are white, marked 'PE' above the breakline and '5' below the breakline on one side and 'G' on the reverse. Procyclidine is available in containers (which may contain a plastic spacer at the top of the container) and blister packs of 5, 7, 10, 14, 15, 20, 21, 25, 28, 30, 50, 56, 60, 84, 90, 100, 112, 120, 168, 180, 250 and 500 tablets. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan, Potters Bar, Hertfordshire, EN6 1TL, U.K.

Manufacturer

Gerard Laboratories, 35-36 Baldoyle Industrial Estate, Grange Road, Dublin 13.
Generics [UK] Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL.

This leaflet was last revised in July 2015