

- constipation
- inflamed gums
- skin rashes.

If you are taking tranquillisers

If you are taking tranquillisers, you may notice you have unusual body movements, particularly your hands, arms and legs. If you are taking procyclidine to control these side effects, you may notice that these side effects become worse. If this happens, see your doctor, who may then change the dose of your tranquilliser.

If any of the side effects get 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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

5. How to store Procyclidine Rosemont

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not use after the expiry date which is stated on the label and carton (exp: month, year).
- The expiry date refers to the last day of that month.
- Do not use Procyclidine Rosemont if you notice that the appearance or smell of your medicine has changed. Talk to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicine no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Procyclidine Rosemont contains

- The active ingredient is procyclidine hydrochloride
- The other ingredients are citric acid (E330), sodium citrate (E331), methyl hydroxybenzoate (E218), propyl hydroxybenzoate (E216), propylene glycol (E1520), liquid maltitol (E965), grape flavour (containing propylene glycol), blackcurrant flavour (containing pulegone, benzyl alcohol, propylene glycol and ethanol) and purified water.

What Procyclidine Rosemont looks like and contents of the pack

A colourless solution with an odour of blackcurrant and grape. It comes in a brown glass bottle holding 150ml of solution.

Marketing Authorisation Holder and Manufacturer

Rosemont Pharmaceuticals Ltd, Yorkdale Industrial Park, Braithwaite Street, Leeds, LS11 9XE, UK.

This leaflet was last revised in 04/2023.

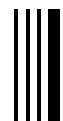
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Package leaflet: Information for the patient

Procyclidine Rosemont 2.5mg/5ml Oral Solution

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 further questions, ask your doctor or pharmacist.
- This medicine has been prescribed only for you. 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 Rosemont is and what it is used for
2. What you need to know before you take Procyclidine Rosemont
3. How to take Procyclidine Rosemont
4. Possible side effects
5. How to store Procyclidine Rosemont
6. Contents of the pack and other information

1. What Procyclidine Rosemont is and what it is used for

The name of your medicine is Procyclidine Rosemont 2.5mg/5ml Oral Solution (called Procyclidine in this leaflet). It contains procyclidine hydrochloride. This belongs to a group of medicines called anticholinergics.

Procyclidine can be used for the symptoms of Parkinsonism (usually slow movement, muscle stiffness and shaking fingers). These symptoms can be caused by Parkinson's Disease, but there are other causes as well.

2. What you need to know before you take Procyclidine Rosemont

Do not take Procyclidine and tell your doctor if:

- you are allergic (hypersensitive) to procyclidine hydrochloride or any other ingredients in this liquid (see section 6). An allergic reaction can include a rash, itching or shortness of breath
- you have difficulty passing water (urine)
- you have a blockage in the stomach or bowel
- you have glaucoma (increased pressure in the eye).

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

Warnings and Precautions

Before you take procyclidine, tell your doctor if:

- you have an enlarged prostate gland
- you have problems with face and tongue movements
- you have liver or kidney problems.

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

Continued overleaf

Other medicines and Procyclidine:

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because procyclidine can affect the way some other medicines work. Also some medicines can affect the way procyclidine works.

Tell your doctor if you are taking any of these medicines

- medicines used to treat schizophrenia such as clozapine
- medicines used for depression such as amitriptyline and paroxetine
- medicines used for Parkinson's Disease such as levodopa or amantadine (also used to treat some viral infections)
- ketoconazole - used to treat some fungal infections
- medicines used to treat Alzheimer's disease such as tacrine and memantine
- medicines used to treat an irregular heart beat such as quinidine, disopyramide
- nefopam used as a painkiller
- antihistamines - used for allergies
- nitrate tablets that dissolve in the mouth - used to treat angina pain
- medicines used to treat nausea and vomiting such as domperidone, metoclopramide.

If you are taking a mixture of procyclidine and medicines for psychoses (e.g. chlorpromazine, trifluoperazine), you should be aware that going to a hot, humid climate may cause fever.

Pregnancy and breast-feeding

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

Driving and using machines

While taking this medicine you may feel light-headed, your eye-sight can become blurry or you could get an unusual feeling of excitement (elation). If this happens, you should not drive a car or use any tools or machines.

Important information about what is in this medicine

- Benzyl Alcohol – This medicine contains 0.26mg of benzyl alcohol in each 5ml. Benzyl alcohol may cause allergic reactions. Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding or if you have liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called “metabolic acidosis”).
- Ethanol – This medicine contains 0.05mg of alcohol (ethanol) in each 5ml. The amount in 5ml of this medicine is equivalent to less than 1ml beer and 1ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.
- Liquid Maltitol (E965) - If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
- Methyl and Propyl parahydroxybenzoates (E218 and E216) – May cause allergic reactions (possibly delayed).
- Propylene Glycol (E1520) - This medicine contains 113mg of propylene glycol in each 5ml.
- Sodium – This medicine contains less than 1 mmol sodium (23mg) per 5ml, that is to say essentially ‘sodium-free’.

3. How to take Procyclidine Rosemont

Take this medicine as your doctor or pharmacist has told you.

Look on the label and ask the doctor or pharmacist if you are not sure.

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Taking this medicine

- this medicine contains 2.5mg of procyclidine hydrochloride in each 5ml
- take this medicine by mouth.

Adults

The usual doses for adults are given below:

Parkinsonism

- a total daily dose of 30mg each day
- this dose may be increased up to 60mg by your doctor
- this dose can be split into two or three smaller doses to be taken through the day
- at the start of treatment you may be asked to take 2.5mg three times each day
- this may be increased further by 2.5mg – 5mg daily every 2-3 days until your symptoms are under control.

Parkinsonism that is caused by other medicines

- usually not more than 20mg each day
- your doctor may stop treatment after 3-4 months to check if you still need the treatment.

Children

This medicine is not usually given to children.

Elderly

If you are an older person you may be more sensitive to the medicine. The chances of you getting side effects are increased.

If you take more Procyclidine than you should

Talk to a doctor or go to a hospital straight away. Take the medicine pack with you so the doctor knows what you have taken. The following effects may happen: feeling restless or agitated, feeling confused, unable to sleep, pupils becoming larger and unusually fast heart beats. These can last up to 4 days. Hearing or seeing things that are not there may also happen. If you have taken much larger amounts than you should, the following effects may happen: feeling drowsy, change in consciousness and coma.

If you forget to take Procyclidine

Do not take a double dose (two doses at the same time) to make up for forgotten doses. Skip the missed dose then go on as before.

If you stop taking Procyclidine

Keep taking procyclidine until your doctor tells you to stop. Do not stop taking your medicine suddenly.

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

4. Possible side effects

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

If you get any of the following side effects, see your doctor as soon as possible:

- hallucinations
- difficulty in passing water (urine)
- blurred vision and dizziness
- feeling confused, worried, nervous or irritable
- reduced concentration or memory.

Tell your doctor if you get any of these side effects:

- dry mouth
- feeling sick (nausea) or being sick (vomiting)

Continued overleaf