

Between text matter to 2D Code the blank space should be min. 5mm.

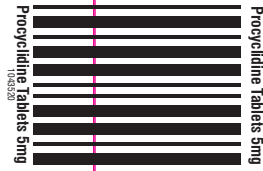
Do not print pink colour line.

- Space for 15 Digit Sequential 2D Data matrix Barcode shall be printed by the vendor.
- 2D data matrix should be minimum 8mm to 10mm height & width.
- 2D data matrix should be printed in the middle of the blank space in the folded Outsert.



Pharma code should be at least 8mm height after folding the Outserts, this is minimum required height to read on line during packing.

Position / Orientation shall be changed depending upon the Printer's Machine suitability.



PACKAGE LEAFLET: INFORMATION FOR THE USER

Procyclidine Tablets 5mg

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 or nurse.
- 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, pharmacist or nurse. This includes any side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Procyclidine Tablets are and what they are used for
2. What you need to know before you take Procyclidine Tablets
3. How to take Procyclidine Tablets
4. Possible side effects
5. How to store Procyclidine Tablets
6. Contents of the pack and other information

1. What Procyclidine Tablets are and what they are used for

Procyclidine Tablets contains the active substance procyclidine hydrochloride.

Procyclidine hydrochloride belongs to a group of medicines called antimuscarinics (anticholinergics). It is most commonly used for Parkinson's disease or symptoms (parkinsonism) due to other causes, including drug induced parkinsonism.

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

Do not take Procyclidine Tablets if you:

- Are allergic to procyclidine hydrochloride or any of the other ingredients of this medicine (listed in section 6)
- Have an obstruction of the intestine and/or stomach
- Have difficulty urinating
- Suffer from glaucoma (eye disease caused by too much pressure within the eye)

Warnings and precautions

Talk to your doctor or pharmacist before taking Procyclidine Tablets if you have had any of the following:

- Pregnant or may become pregnant, or breast-feeding
- Chronic kidney or liver disease
- Difficulty passing water, which in some men may be due to an enlarged prostate
- Suffer from a movement disorder called tardive dyskinesia, in which movements (especially of the limbs) are slow or difficult, or uncontrolled and jerky. This condition may be made worse if you are given procyclidine whilst being treated with neuroleptic drugs
- If you are elderly, your dose may need to be carefully monitored to prevent any side effects
- Suffer from cardiac disorders or from cardiovascular disease (disease of the heart)
- Suffer from stomach cramps, abdominal pains or constipation
- Have ever suffered from or may be predisposed to glaucoma or an obstructive disease of the stomach or intestines (e.g. have been told you are more at risk of these conditions or have a family history of them)
- Suffer from psychotic episodes (experience delusions, hallucinations, speech difficulty or unusual behaviour)
- Have a history of alcohol or drug abuse.

Other medicines and Procyclidine Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

If taken with some other medicines the effects of Procyclidine Tablets or the effects of other medicines may be changed. Please check with your doctor if you are taking any of the following:

- Antihistamines, to relieve allergies such as hay fever (e.g. cetirizine, loratadine)
- Antidepressants (e.g. amitriptyline, paroxetine) or monoamine oxidase inhibitors (MAOIs) (e.g. moclobemide)
- Antipsychotics (neuroleptics) such as the phenothiazine group (e.g. thioridazine - for severe anxiety or schizophrenia)
- Clozapine, to treat schizophrenia
- Amantadine or levodopa (used in Parkinson's disease or some viral infections)
- Ketoconazole (used for fungal infections such as athlete's foot or thrush)
- Quinidine or disopyramide (used for conditions of the heart)
- Tacrine, memantine (for treating symptoms of Alzheimer's disease)
- Cisapride, metoclopramide or domperidone (to treat feeling sick or being sick)
- Sublingual nitrates for angina (e.g. glyceryl trinitrate, isosorbide dinitrate)
- Nefopam, used to treat pain.

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

Procyclidine Tablets may cause blurred vision, dizziness, mental confusion, impaired thinking and memory, disorientation and hallucinations. If you are affected, do not drive or operate machinery.

Procyclidine Tablets contain lactose

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 Procyclidine Tablets

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

Adults:

Initially 2.5 mg three times a day after meals. Your doctor will increase this dose by 2.5 mg to 5 mg a day every 2 to 3 days until they find a dose which works best for you.

The maximum dose is usually 20 mg a day if you are taking your tablets to control symptoms caused by other drugs. The maximum dose may be higher, 30 to 60 mg a day if your Parkinsonism is not caused by drugs.

Children:

Procyclidine Tablets are not recommended for use in children.



Elderly:

A reduced dose may be required.

If you take more Procyclidine Tablets than you should

If you (or someone else) swallow a lot of the tablets all together or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. An overdose is likely to cause mood disturbance, mental confusion, restlessness, agitation, hallucinations and sleeplessness lasting up to twenty-four hours. Please take this leaflet, any remaining tablets, and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take Procyclidine Tablets

If you forget to take a dose at the right time, take it as soon as you remember, then go on as before. Do not take a double dose to make up for a forgotten dose.

If you stop taking Procyclidine Tablets

You should finish all the tablets your doctor has prescribed even if you feel better. You should still take all the tablets you have been given, it may be dangerous to stop taking the medicine without your doctor's advice.

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 the tablets and tell your doctor immediately or go to the nearest hospital casualty department if the following happens:

- An allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

If you are also taking medicines for schizophrenia, mania or mental conditions, you may experience uncontrolled jerky movements of your limbs when you first start to take Procyclidine Tablets. If this happens talk to your doctor immediately - it may be necessary for your doctor to reduce the dose of your other medicine.

Higher doses of procyclidine may cause disorientation, anxiety, agitation, dizziness, confusion or hallucinations and may affect your mental processes or memory. If this happens, talk to your doctor - it may be necessary to reduce the dose of this medicine.

Other unwanted side effects may include the following:

Common (may affect up to 1 in 10 people)

- Dry mouth
- Blurred vision
- Constipation
- Urinary retention.

Uncommon (may affect up to 1 in 100 people)

- Nausea (feeling sick)
- Vomiting (being sick)
- Gingivitis (inflammation of the gums)
- Skin rashes
- Feeling nervous
- Stomach upsets
- Agitation
- Anxiety
- Feeling confused
- Disorientation
- Hallucinations (seeing, hearing or feeling things that aren't there)
- Dizziness
- Impaired thinking or memory.

Rare (may affect up to 1 in 1,000 people)

- Psychotic-like symptoms (e.g. hallucinations or personality changes).

Not known (frequency cannot be estimated from the available data)

- Rapid heart beats (tachycardia).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. 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 Tablets

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

Do not store above 25°C. Store in the original container.

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

Do not throw away any medicines via waste water 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 Procyclidine Tablets contain**

The active substance is procyclidine hydrochloride. Each tablet contains 5mg procyclidine hydrochloride.

The other ingredients are anhydrous lactose (see section 2), maize starch and magnesium stearate.

What Procyclidine Tablets look like and the contents of the pack

The tablets are white, convex tablets which are marked with a "PR5" on one side and a breakline on the reverse side.

Procyclidine Tablets are available in HPDE container bottle with polypropylene cap in packs of 28, 84, 100, 500, 2000 or 5000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder:

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