

Promazine 25 mg and 50 mg Film-coated Tablets

Promazine 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

1. What Promazine is and what it is used for
2. What you need to know before you take Promazine
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1 What Promazine is and what it is used for

Promazine is one of a group of medicines called phenothiazines, which are used to treat a range of disorders including anxiety, agitation and disturbed behaviour.

Promazine is used to treat:

- agitation and restlessness in the elderly
- short-term additional management of psychomotor agitation (unintentional and purposeless motions brought on by mental tension; symptoms may take the form of restlessness, pacing, tapping fingers or feet, abruptly starting and stopping tasks, meaninglessly moving objects around, and more).

2 What you need to know before you take Promazine

DO NOT take Promazine if you:

- are allergic (hypersensitive) to promazine, any other phenothiazine, or any of the other ingredients of this medicine (listed in section 6)
- have phaeochromocytoma (adrenal gland tumour resulting in high blood pressure, flushing, diarrhoea).

Promazine should not be given to patients in a coma or suffering from central nervous system (CNS) depression, symptoms include decreased rate of breathing, decreased heart rate, and loss of consciousness.

Warnings and precautions

Talk to your doctor or pharmacist before taking Promazine

- have a history of jaundice (yellowing of the skin or whites of the eyes caused by liver or blood problems)
- blood dyscrasias (blood disorders which may be characterised by fever or chills, sore throat, ulcers in your mouth or throat, unusual tiredness or weakness, unusual bleeding or unexplained bruising)
- have liver, kidney or heart disease
- have previously had a stroke, transient ischaemic attack (TIA, stroke that lasts only a few minutes) or heart attack, have a family history of strokes, or have other risk factors which may increase the risk of stroke, such as high cholesterol, uncontrolled high blood pressure, diabetes, you smoke or are a heavy drinker
- have personal or a family history of a certain type of heart disorder known as "QT-prolongation"
- have a history of unexplained fainting or blackouts
- have any disease of the lungs, lower and upper airways, or any condition which causes difficulty in breathing
- have Parkinson's disease (tremor, stiffness and shuffling)
- have epilepsy
- have hypothyroidism (underactive thyroid gland)
- suffer from depression
- have myasthenia gravis (progressive muscular weakness)
- have an enlarged prostate (causing difficulty in passing water)
- have personal or a family history of glaucoma (increased pressure in the eye)

- are taking any other neuroleptic medicines
- are elderly, as it is more likely that you may suffer from certain of the side effects such as drowsiness, low blood pressure, high or low body temperature
- or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots.

Avoid exposure to direct sunlight while you are taking this medicine, as this medicine may cause you to become sensitive to sunlight, particularly if you are taking high doses.

Other medicines and Promazine

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

DO NOT take Promazine with:

- medicines to correct problems with heart rhythm e.g. quinidine, disopyramide, procainamide, amiodarone, dofetilide, sotalol, bretylium
- antimalarials e.g. quinine and mefloquine
- antibiotics such as sparfloxacin, moxifloxacin, intravenous erythromycin
- certain types of (tricyclic or tetracyclic) antidepressants such as amitriptyline, maprotiline
- other antipsychotics e.g. risperidone, amisulpride, sertindole, haloperidol and pimozide
- cisapride, a medicine used in the treatment of certain gastro-intestinal disorders
- certain antihistamines e.g. terfenadine.

Talk to your doctor if you are taking any of the following:

- medicines which can affect the chemicals in your bloodstream known as electrolytes, such as:
 - diuretics e.g. furosemide
 - antibiotics e.g. amphotericin B
 - corticosteroids e.g. hydrocortisone
 - chemotherapy drugs e.g. cisplatin
- sulphonylureas (used to treat diabetes) e.g. gliclazide or glibenclamide
- antiepileptics e.g. phenytoin
- blood pressure tablets
- calcium channel blockers e.g. amlodipine
- sympathomimetics e.g. salbutamol
- antimuscarinics e.g. inhalations used for bronchitis such as ipratropium bromide
- anticholinergics used to treat Parkinson's or restlessness, such as procyclidine, benzhexol, orphenadrine
- tetrabenazine, used to treat essential tremor, chorea, tics, and related disorders
- ritonavir (an antiviral for HIV/AIDS)
- anti-anxiety or sleeping drugs e.g. diazepam, temazepam, zopiclone
- reboxetine (used to treat depression)
- lithium, (used to treat certain types of depression)
- memantine, used to treat dementia
- sibutramine, used to help weight loss
- cimetidine, used to treat stomach ulcer, reflux oesophagitis, Zollinger-Ellison syndrome, or other conditions where gastric acid reduction is beneficial
- antacids, used to treat indigestion and heartburn
- metoclopramide, used to treat feeling or being sick
- kaolin, used to treat diarrhoea
- antispasmodics to treat gut spasm e.g. mebeverine hydrochloride
- medicines used for pain relief called opioid analgesics e.g. tramadol, morphine, codeine
- adrenaline or noradrenaline
- alcohol.

If you are to undergo a surgical procedure that requires a general anaesthetic, make sure you tell your doctor that you are taking Promazine.

Promazine with food, drink and alcohol

DO NOT drink alcohol whilst taking Promazine.

Pregnancy and breast-feeding

DO NOT take Promazine if you are pregnant, planning to become pregnant or breast-feeding. Ask your doctor for advice before taking any medicine.

Driving and using machines

Promazine may cause drowsiness, dizziness, and cloudy or blurred vision. If you are affected by any of these, **DO NOT** drive or operate machinery.

Promazine contains 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.

Promazine 25 mg and 50 mg tablets contain E110 (sunset yellow) and the 25 mg tablets also contains E104 (quinoline yellow) the 50 mg tablets also contain E102 (tartrazine) & E127 (erythrosine) which may cause allergic reactions.

3 How to take Promazine

Always take Promazine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

The tablets should be swallowed preferably with a drink of water. The usual dose is:

Adults:

- For psychomotor agitation
100-200 mg four times daily.

The Elderly:

- For agitation and restlessness
25-50 mg four times daily.

Children:

Promazine is not recommended for use in children.

If you take more Promazine 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 drowsiness, confusion, low blood pressure, low body temperature, fits and coma are possible. Rarely breathing difficulties may occur.

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 Promazine

If you forget to take a tablet, take one as soon as you remember unless it is more than 2 hours after the missed dose; if so, ignore the missed dose and wait until the time of the next dose. DO NOT take a double dose to make up for a forgotten dose.

Stopping treatment with Promazine

DO NOT stop taking your medicine without talking to your doctor first even if you feel better. Your medicine should only be withdrawn gradually under close supervision by 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, Promazine can cause side effects, although not everybody gets them.

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

- an allergic reaction causing swelling of the lips, face or neck leading to severe difficulty in breathing or severe skin rash or hives.

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately if any of the following serious but rare effects happen:

- high body temperature, muscle rigidity, increased involuntary movement or tremor and altered consciousness (neuroleptic malignant syndrome)
- involuntary restless or repetitive limb movements, shaking, inability to sit or stand still
- jaundice (yellowing of the skin or whites of the eyes caused by liver or blood problems)
- Torsades de pointes, a life threatening irregular heart beat (symptoms may include recurrent episodes of palpitations, dizziness, fainting, feeling sick, paleness of the skin, cold sweats, shortness of breath and chest pain)
- cardiac arrest (symptoms include loss of consciousness, breathing stops and no heartbeat or pulse can be felt. Some people may first notice that they have a racing heartbeat or feel dizzy or light-headed just before they faint.)

The following side effects have also been reported:

- nasal congestion
- dry mouth
- agitation, excitement
- apathy (lack of feeling or emotion)
- dizziness, headache
- fast heart rate
- abdominal pain, diarrhoea, constipation
- difficulty in passing water (especially with an enlarged prostate)
- drowsiness, confusion, difficulty sleeping
- epileptic fits
- low blood pressure
- eye problems including blurred vision, clouding or opacity of the front part of the eye (cornea) or lens of the eye, purplish pigmentation of the cornea, the membrane that covers the white part of the eye and lines the inside of the eyelids (conjunctiva), the retina or the skin round the eyes
- high body temperature or low body temperature (especially in the elderly)

- skin rash or itchiness
- sensitivity to light
- contact sensitisation (inflammation of the skin or red, itchy skin rash, due to an immune reaction in response to a substance which has come into contact with the skin)
- suffering from infections more frequently, which may be due to a severe reduction in the number of white blood cells
- lethargy, weakness, dizzy spells and feeling faint, pale skin, which may be due to a reduction in the number of red blood cells (anaemia)
- weight gain
- in women, production of breast milk or menstrual disturbance
- in men, impotence (inability to achieve or maintain an erection), or breast enlargement
- in rare cases, sudden unexplained death has occurred.

The following have been reported at an unknown frequency:

- blood clots in the vein especially in the legs (symptoms include swelling, pain and redness in the leg), which may travel through blood vessels to the lungs causing chest pain and difficulty in breathing. If you notice any of these symptoms seek medical advice immediately.
- In elderly people with dementia, a small increase in the number of deaths has been reported for patients taking antipsychotics compared with those not receiving antipsychotics.

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 Promazine

Keep this medicine out of the sight and reach of children. Store the tablets below 25°C. Keep the container tightly closed.

Do not use Promazine after the expiry date that is stated on the outer packaging. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6 Contents of the pack and other information

What Promazine Tablets contain:

- The active ingredient is promazine hydrochloride 25 mg or 50 mg.
- The other ingredients are lactose monohydrate, maize starch, maize starch (partially pregelatinised), magnesium stearate (E572), hypromellose (E464), hydroxypropyl cellulose (E463), talc (E553b), sunset yellow (E110), titanium dioxide (E171)
- The 25 mg tablets also contain quinoline yellow (E104).
- The 50 mg tablets also contain tartrazine (E102) and erythrosine (E127).

What Promazine Tablets look like and contents of the pack:

- Promazine 25 mg film-coated tablets are round biconvex yellow film-coated tablets embossed with 7Z1 on one side and plain on the reverse.
- Promazine 50 mg film-coated tablets are round biconvex orange film-coated tablets embossed with 7Z2 on one side and plain on the reverse.
- The pack sizes are 50, 100, 250 and 1,000. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation holder
Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom.

Manufacturer

Custom Pharmaceuticals Limited, Conway Street, Hove, East Sussex, BN3 3LW, UK

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