SAME SIZE ARTWORK
LEAFLET SIZE: 170 mm x 540 mm

Patient leaflet: Information for the user

Promazine hydrochloride 25 mg/5 mL Syrup
Promazine hydrochloride 50 mg/5 mL Syrup

Promazine 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 your 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
3. How to take Promazine
4. Possible side effects
5. How to store Promazine
6. Contents of the pack and other information

1. What Promazine is and what it is used for

The name of your medicine is Promazine hydrochloride 25 mg/5 mL or 50 mg/5 mL Syrup (referred to as Promazine in this leaflet). It contains promazine hydrochloride. This belongs to a group of medicines called phenothiazines. Promazine can be used to calm your emotions particularly if you feel restless and agitated.

2. What you need to know before you take Promazine

Do not take Promazine and tell your doctor if:
- if you are allergic (hypersensitive) to promazine or medicines like promazine or any other ingredients in this liquid (listed in section 6). The signs of allergic reaction can include a rash, itching or shortness of breath;
- if you are pregnant or breast-feeding;
- if you have bone marrow depression. This means that your immune system is not working as well as usual. Your body will find it harder to fight infection;
- if you have a tumour of your adrenal gland that causes high blood pressure (phaeochromocytoma);
- if you have dulled senses such as feeling sleepy or uncoordinated, having blurred vision, slurred speech or being less aware of your surroundings (CNS depression).

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 Promazine.

Warnings and precautions

Talk to your doctor or pharmacist before taking Promazine if:
- you have liver problems or a history of jaundice (yellowing of the skin and whites of the eyes)
- you have a history of blood problems including low levels of potassium or magnesium
- you or someone else in your family has a history of blood clots, as medicines like these have been associated with formation of blood clots
- you have heart problems including unusual heart beats, heart disease or heart failure
- you have lung and breathing problems
- you have kidney problems
- you have Parkinson's Disease
- you have had a stroke or you have any of the following that can increase your risk of having a stroke:
  - a heart attack
  - a TIA (transient ischaemic attack). This is a type of stroke where symptoms last less than 24 hours
  - an artificial heart valve
  - uncontrolled high blood pressure
  - diabetes
  - high cholesterol
  - a family history of strokes
  - you smoke
  - you drink excess alcohol (this tends to weaken blood vessels and can raise blood pressure)
- you have epilepsy
- you have or have had in the past narrow angle glaucoma (this is abnormal pressure in the eye accompanied by pain and blurred vision)
- you have an underactive thyroid
- you have a condition that causes muscle weakness with tiredness, called myasthenia gravis
- you have an enlarged prostate gland
- older people should take promazine with caution in very hot or cold weather. This is because there is a risk of having a higher body temperature than usual in hot weather (hyperthermia) and a lower body temperature in cold weather (hypothermia) if you take this medicine
- if you are going to have an anaesthetic, tell your doctor or dentist that you are taking promazine.

Other important information to take into account before you take this medicine
- if you or members of your family have heart problems (including heart failure, heart attack or uneven heart beats) or you have low potassium or magnesium in your blood, your doctor may do some tests on your heart and blood before giving you this medicine
- your doctor may also want to give you regular blood and eye tests during your treatment,
- do not go into direct sunlight if you are taking high doses of this medicine. This is because you may become more sensitive to strong sunlight while taking this medicine

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

Other medicines and Promazine

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines you buy without a prescription, including herbal medicines. This is because promazine can affect the way some other medicines work. Also some medicines can affect the way promazine works.
Tell your doctor if you are taking any of these medicines:
- heart medicines such as quinidine, disopyramide, procainamide, amiodarone, sotalol, dofetilide, bretylium
- medicines to treat high blood pressure
- medicines that control your emotions such as chlorpromazine, trifluoperazine, antidepressants such as amitriptyline and maprolitine, pimozide, sertindole, haloperidol, lithium, MAOIs (Monoamine Oxidase Inhibitors), reboxetine
- medicines that dull the senses such as sleeping tablets
- medicines to treat epilepsy
- medicines used to treat malaria such as quinine and mefloquine
- antibiotics such as sparfloxacin, moxifloxacin and intravenous erythromycin
- medicines used to treat Parkinson's Disease such as levodopa
- medicines to treat allergies such as hayfever (antihistamines) for example terfenadine
- medicines used to treat stomach problems such as cimetidine and cisapride
- medicines to treat diabetes, for example, chlorpropamide, glibenclamide, gliclazide or tolbutamide
- strong painkillers such as codeine
- medicines used to stop the body producing red blood cells such as carbamazepine, co-trimoxazole, chloramphenicol, sulphonamides, pyralizone, azapropazone, penicillamine and cytotoxics (used in cancer treatment)
- medicines that help the body get rid of water and affect electrolyte balance (diuretics) such as furosemide or indapamide
- metoclopramide, used to treat nausea (feeling sick) and vomiting
- tetrabenazine, used to treat disorders that cause unnatural movements
- ritonavir, used to treat HIV and AIDS
- tramadol, used to treat pain
- sympathomimetics, medicines that copy the effects of substances such as adrenaline that naturally occur in the body, for example, salbutamol or pseudoephedrine
- memantine, used to treat Alzheimer's disease
- kaolin, used to treat diarrhoea.

Promazine with food, drink and alcohol

You must not drink alcohol whilst taking this medicine. This is because this medicine may make you feel drowsy and drinking alcohol will make you even more drowsy. Drinking alcohol may also affect the condition you are suffering from.

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 for advice before taking this medicine. You should not use this medicine if you are pregnant or breast-feeding unless your doctor feels it is absolutely necessary.
The following symptoms may occur in newborn babies, of mothers that have used promazine in the last trimester (last three months of their pregnancy): shaking, muscle stiffness and/or weakness, sleepiness, agitation, breathing problems, and difficulty in feeding. If your baby develops any of these symptoms you may need to contact your doctor.

Driving and using machines

Do not drive or use tools or machines if this medicine makes you drowsy or gives you blurred vision. When using this medicine, alcohol and some other medicines may make you feel more drowsy than usual.

Important information about what is in this medicine

Promazine contains:
- Sodium metabisulfite. May rarely cause severe hypersensitivity reactions and bronchospasm.Methyl parahydroxybenzoate, Ethyl parahydroxybenzoate and Propyl parahydroxybenzoate. May cause allergic reactions (possibly delayed).
- Propylene glycol. This medicine contains 88.6 mg or 78.2 mg propylene glycol in each 5 mL, for 25 mg/5 mL or 50 mg/5 mL, respectively.
- Liquid glucose. This medicine contains 1.3 g glucose in each 5 mL. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.
- Sucrose. This medicine contains 1.8 g sucrose in each 5 mL. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May be harmful to the teeth.
- This medicine contains less than 1 mmol sodium (23 mg) per 5 mL, i.e. is essentially "sodium-free".

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3. How to take Promazine

Always take this medicine exactly as your doctor or pharmacist has told you. Look on the label and check with your doctor or pharmacist if you are not sure.

Taking this medicine
- This medicine contains 25 mg or 50 mg of promazine hydrochloride in each 5 mL.
- Take this medicine by mouth
- If you feel that the effect of your medicine is too strong or too weak, do not change the dose yourself, but talk to your doctor or pharmacist.

The recommended dose is

Adults
- 100 mg to 200 mg four times a day.
- In ederly patients the recommended dose is 25 mg to 50 mg up to four times a day
- The dose prescribed and how often you should take the doses will depend upon the condition being treated and on your response. You will start treatment on a low dose which will be increased as necessary by your doctor.
- The lowest effective dose for the shortest period possible should be used.

Children
This product should not be given to children.

If you take more Promazine 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. Signs of an overdose may include deep sleep, feeling agitated, feeling excited, fits and coma.

If you forget to take Promazine
- 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 Promazine
Keep taking Promazine until your doctor tells you to stop. The doctor will lower your dose gradually. If you stop taking the medicine suddenly you may get withdrawal symptoms. Signs include:
- feeling or being sick, sweating and difficulty sleeping (insomnia)
- your original symptoms becoming worse
- movements that you can't control.

If you have any further questions on the use of this medicine, 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 medicine straight away and see your doctor if:
- **you have an allergic reaction to Promazine:**

An allergic reaction may include any kind of skin rash, flaking skin, boils or sore lips and mouth, sudden wheezing, fluttering or tightness of the chest or collapse;
- **you have any of the following symptoms:**
  - unusually fast heartbeat, unstable blood pressure (feeling dizzy, light-headed or faint) and sweating. These are early warning signs of a disorder caused by the type of medicine you are taking;
  - very high body temperature, muscle stiffness or a change in consciousness leading to coma;
  - yellowing of the skin and whites of your eyes (jaundice) with fever and possible liver damage.

If you get any of the following side effects, see your doctor as soon as possible:
- blood clots in the veins 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**
- lack of emotion
- fits
- blood problems. You may notice signs such as high temperature or chills, sore throat, ulcers in your mouth or throat and unusual tiredness, yellowing of the skin, weakness or breathlessness;
- heart changes including fast heart beats, unusual heart beats, heart attack. Symptoms of a heart attack are chest pain which may spread to the shoulders, neck or arms and shortness of breath. If you get these see a doctor straight away. Unexplained deaths have been reported but it is not proven that they were caused by promazine
- fever
- low body temperature
- low blood pressure. You may feel dizzy when standing up
- unusual movements, often of the mouth, lips, eyes and tongue. These movements can also include trembling and shaking of the hands and feet, twisting of the body, shuffling walk and stiffness of the arms and legs and unable to sit still
- eye changes such as blurred vision, clouding of the lens or purple colouring of the eye
- feeling confused, agitated or over-excited
- eye changes such as pain in the eye, blurred vision or loss of vision, seeing halos around lights, clouding of the lens or purple colouring of the eye.

Tell your doctor if you get any of these side effects:
- unable to sleep, feeling sleepy, drowsy or dizzy
- dry mouth, blocked nose
- constipation, difficulty in passing water particularly if you have an enlarged prostate
- skin rash caused by medicine spilt on your skin, skin rashes, skin reaction to direct sunlight;
- swelling of the breasts (particularly in men) and breast milk production
- sexual impotence
- headache, upset stomach
- light periods or absence of periods
- weight gain.

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 below 30°C. Store in the original package in order to protect from light.

25 mg/5 mL:
After first opening, keep the bottle tightly closed and discard any unused syrup after 10 days.

50 mg/5 mL:
After first opening, keep the bottle tightly closed and discard any unused syrup after 20 days.

Do not use this medicine 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 this medicine if you notice that the appearance or smell of your medicine has changed. Talk to your pharmacist.

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.

6. Contents of the pack and other information

What Promazine contains
- The active ingredient is Promazine hydrochloride.
- The other ingredients are propylene glycol (E1520), methyl parahydroxybenzoate (E218), ethyl parahydroxybenzoate (E214), propyl parahydroxybenzoate (E216), sucrose, liquid glucose, ascorbic acid, sodium metabisulfite (E223), lemon lime flavor (containing propylene glycol) and purified water.

What Promazine looks like and contents of the pack
A colourless to light yellowish orange brown coloured syrup.

It comes in a amber coloured PET bottle holding 150 ml of syrup, with child resistant, tamper evident with foam liner and 20 ml graduated polypropylene measuring cup (graduation 2.5 ml, 5 ml and 10 ml).

It comes in a amber coloured glass bottle (Type-III) holding 150 ml of syrup, with child resistant, tamper evident with foam liner and 20 ml graduated polypropylene measuring cup (graduation 2.5 ml, 5 ml and 10 ml).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Glenmark Pharmaceuticals Europe Limited
Building 2, Croxley Green Business Park
Croxley Green, Watford
Hertfordshire
WD18 8YA
United Kingdom

Manufacturer
Glenmark Pharmaceuticals Europe Limited
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Other sources of information:
To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000

Please be ready to give the following information:

Product name	Reference number
Promazine hydrochloride 25 mg/5 mL Syrup	**PL 25258/0435**
Promazine hydrochloride 50 mg/5 mL Syrup	**PL 25258/0436**

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Job No: GM2936			**Artwork Sign-off(digitally):**	
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