lack of emotion

■ fit

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-exited

■ 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 (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

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

6. Contents of the pack and other information

What Promazine Hydrochloride 50mg/5ml Oral Syrup contains

The active ingredient is promazine hydrochloride.

The other ingredients are methyl hydroxybenzoate (E218), ethyl hydroxybenzoate (E214), propyl hydroxybenzoate (E216), propylene glycol (E1520), sucrose, liquid glucose, ascorbic acid (E330), lime flavour (containing propylene glycol and glycerol) and purified water.

What Promazine Hydrochloride 50mg/5ml Oral Syrup looks like and contents of the pack

A colourless to orange-brown coloured syrup with an odour of lime.

This syrup is also used as anti-emetic and sedative.

How to store Promazine Syrup

Keep this medicine out of the sight and reach of children

Store below 20°C. Protect from light

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.

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

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

This leaflet was last revised in 10/2020
**Important information about what is in this medicine:**

- Methyl hydroxybenzoate (E218), Ethyl hydroxybenzoate (E214) and Propyl hydroxybenzoate (E216). May cause allergic reactions (possibly delayed).
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Liquid glucose. This medicine contains 1.3g glucose in each 5ml. 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.

**3. How to take Promazine Syrup**

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 50mg of promazine hydrochloride in each 5ml.
- Take this medicine by mouth.
- The dose prescribed and how often you should take the doses will depend upon the condition being treated and on you. You will start treatment on a low dose which will be increased as necessary by your doctor.
- Older people will be given a lower dose. Your doctor will gradually increase this dose.

**If you take more Promazine Syrup 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 agitation, feeling excited, fits and coma.

**If you forget to take Promazine Syrup**

- 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 Syrup**

Keep taking Promazine Syrup. If your doctor tells you to stop. The doctor will lower your dose gradually.

**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 syrup. An allergic reaction may include any kind of skin rash, itching skin, boils or some lips and mouth, sudden wheezing, flushing or tightness of the chest or collapse.
- you have any of the following symptoms:
  - unusually fast heart rate, take blood pressure and risk of stroke and collapse.
  - 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.

**Continued overleaf**
Important information about what is in this medicine:
- Methyl hydroxybenzoate (E218), Ethyl hydroxybenzoate (E214) and Propyl hydroxybenzoate (E216). May cause allergic reactions (possibly delayed).
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Liquid glucose. This medicine contains 1.3g glucose in each 5ml. 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 1.8g sucrose in each 5ml. 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.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
- Propylene glycol (E1520). This medicine contains 78.2mg propylene glycol in each 5ml.
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 using the yellow card at the back of this leaflet. 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

Yellow Card Scheme

Information on the safety of this medicine.

Reporting of side effects

1. What Promazine Syrup is and what it is used for

The name of your medicine is Promazine Hydrochloride 50mg/5ml Oral Syrup (referred to as Promazine Syrup 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, particularly if you are an older person, have dementia, have a learning disability or have had a stroke.

What is in this leaflet:

1. What Promazine Syrup is and what it is used for
2. What you need to know before you take Promazine Syrup
3. How to take Promazine Syrup
4. Possible side effects
5. How to store Promazine Syrup
6. Contents of the pack and other information

What Promazine Hydrochloride 50mg/5ml Oral Syrup contains

The active ingredient is promazine hydrochloride.

The other ingredients are methyl hydroxybenzoate (E218), ethyl hydroxybenzoate (E214), propyl hydroxybenzoate (E216), propylene glycol (E1520), sucrose, liquid glucose, ascorbic acid (E330), lime flavour (containing propylene glycol and glycerol) and purified water.

What Promazine Hydrochloride 50mg/5ml Oral Syrup looks like and contents of the pack

A colourless to orange-brown coloured syrup with an odour of lime.

It comes in a brown glass bottle holding 150ml of syrup.

Marketing Authorisation Holder and Manufacturer

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

This leaflet was last revised in 10/2020

B7TD1RBJ1