

Title:	Chlorphenamine PIL	<div>Colours (Printed)</div> <div><div>Black</div><div>Process</div></div> <div>Colours (Non printed)</div> <div><div>Cutter</div><div>SPECIAL</div></div>
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Package leaflet: Information for the patient

Chlorphenamine

2mg/5ml Oral Solution

This medicine will be called Chlorphenamine Solution in this leaflet.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse.

What is in this leaflet:

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

1. What Chlorphenamine Solution is and what it is used for

Chlorphenamine 2mg/5ml Oral Solution contains the active ingredient Chlorphenamine Maleate. Chlorphenamine belongs to a group of medicines called antihistamines. Histamine is one of the chemicals released in the body when there is an allergic reaction and chlorphenamine works by blocking the action of histamine.

Chlorphenamine Solution is used to relieve the symptoms caused by allergies such as hayfever, pet or house mite allergies, skin allergies, allergies caused by foods or medicines or insect bite reactions. It will help relieve symptoms such as itchy, watery eyes; an itchy, runny or blocked nose; itchy skin, redness or swelling. It may also be used to relieve the itchy rash caused by chickenpox.

2. What you need to know before you take Chlorphenamine Solution

Do not take Chlorphenamine Solution if:

- You know you are allergic to chlorphenamine, any other antihistamines or to any of the other ingredients (these are listed in Section 6)
- You have taken a monoamine oxidase inhibitor (also known as MAOIs), a medicine to treat depression in the last 14 days.

Warnings and precautions

Talk to your doctor or pharmacist before taking if:

- You have epilepsy
- You have an enlarged prostate gland
- You have raised eye pressure (conditions such as glaucoma)
- You have very high blood pressure, heart, liver or kidney disease
- You have any breathing problems such as bronchitis, bronchiectasis or asthma.

Other medicines and Chlorphenamine Solution

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Chlorphenamine Solution can affect some other medicines you may be taking. This is especially important if you have taken a monoamine oxidase inhibitor (also known as MAOIs) in the last 14 days, as listed above under “Do not take”. Make sure your doctor or pharmacist also knows if you are taking any of the following:

- Medicines to treat sleeping problems or anxiety (e.g. diazepam, nitrazepam)
- Phenytoin (to treat epilepsy)
- Any other medicines containing antihistamines, including products for the relief of coughs and colds.

Chlorphenamine Solution with alcohol

Avoid alcohol whilst taking this medicine as its effect may be increased.

Pregnancy, breast-feeding and fertility

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

This medicine may cause drowsiness, blurred vision, dizziness or impair movement. If affected do not drive or operate machinery.

Chlorphenamine Solution contains maltitol liquid, E217, E219 and propylene glycol

- If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor or pharmacist before taking this medicine as it contains maltitol liquid (E965). It may also have a mild laxative effect. Each 5ml dose contains 1.25g maltitol liquid (approx 3 kcal).
- This medicine contains sodium methyl parahydroxybenzoate (E219) and sodium propyl parahydroxybenzoate (E217) which may cause allergic reactions (possibly delayed).
- This medicine contains 4.8 mg of propylene glycol (E1520) in each 5 ml, which is equivalent to 0.96 mg/ml.
- This medicine contains less than 1 mmol sodium (23 mg) per 5 ml, that is to say essentially "sodium free".

3. How to take Chlorphenamine Solution

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

The usual doses are as follows:

Children 1 to 2 years: One 2.5 ml dose twice a day. Leave at least 4 hours between the two doses. No more than 2 doses (5 ml) should be given in any 24 hours.

Children 2 to 6 years: One 2.5 ml dose every 4-6 hours. No more than 6 doses (15 ml) should be given in any 24 hours.

Children 6 to 12 years: One 5 ml dose every 4-6 hours. No more than 6 doses (30 ml) should be given in any 24 hours.

Adults and children over 12 years: Two 5 ml doses (10 ml) every 4-6 hours. No more than 6 doses (60 ml) should be taken in any 24 hours.

Elderly: Check with your doctor or pharmacist before you take this medicine as you may be more likely to get side effects including confusion and you may need to take a lower daily dose.

Not recommended for children under 1 year.

Do not take more than the recommended dose. If symptoms persist consult your doctor.

Continued, please turn over.

For oral use. Use the syringe provided. A plastic adaptor is also provided with this pack. This needs to be inserted into the neck of the bottle before using the syringe for the first time (for instructions, see “How to use the oral syringe” below).

How to use the oral syringe:

1. Remove the cap from the bottle by turning it anti-clockwise.
2. Push the plastic adaptor into the neck of the bottle.
Note: The adaptor must always stay in the bottle.
3. Take the syringe and check the plunger is fully down.
4. Keep the bottle upright and insert the oral syringe firmly into the plastic adaptor.
5. Turn the whole bottle with the syringe upside down.
6. Then pull the plunger slowly out to the mark showing the number of millilitres (ml) you need for your dose.
7. Turn the whole bottle with the syringe the right way up and take the syringe out of the bottle.
8. Place the syringe inside the mouth and press the plunger slowly to gently release the medicine.
9. After use, the bottle cap should be replaced leaving the adaptor in place. The syringe should be washed and dried.

If you take more Chlorphenamine Solution than you should:

If you take more medicine than you should, speak to your doctor or pharmacist straightaway. Take your medicine or the pack with you so that they know what you have taken.

If you forget to take a dose of Chlorphenamine Solution:

If you miss a dose don’t worry. Miss this dose and carry on with the normal routine. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Side effects may be more likely in the elderly and children.

Chlorphenamine may make you feel drowsy; this can range from just feeling slightly drowsy to a deep sleep. If you are at all concerned at how drowsy you feel or your child appears contact your doctor as soon as possible.

Stop taking this medicine and seek immediate medical help if you or your child experience:

- An allergic skin reaction such as rash, itching, scaling or peeling; increased sensitivity to sunlight or an itchy raised skin rash (also known as “hives”).

The following side effects have also been reported:

- Inflammation of the liver (symptoms include yellowing of the skin or whites of the eyes, loss of appetite, pale stools and dark urine)
- Blood disorders including anaemia (a reduction in red blood cells which can make the skin pale and cause weakness or breathlessness)
- Palpitations (feeling your heartbeat) or a faster or irregular heartbeat
- Low blood pressure (symptoms include feeling light-headed or faint).

If you notice any of the above tell your doctor or pharmacist as soon as possible.

Other effects which have been reported are:

- Blurred vision, ringing in the ears
- Problems passing urine, abdominal pain, indigestion, diarrhoea, feeling or being sick, loss of appetite, dry mouth

- Muscle weakness or lack of co-ordination, twitching
- Depression, nightmares, confusion, excitability, feeling irritated
- Tightening of the chest, thickening of phlegm (mucus)
- Headache, dizziness, inability to concentrate, weariness/tiredness
- Children may become excited.

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 Chlorphenamine Solution

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

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

Do not store above 25°C. Keep the bottle in the outer carton to protect from light.

Discard 28 days after opening.

Do not use if the seal on the bottle is broken.

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 Chlorphenamine Solution contains

Each 5 ml of medicine contains 2 mg of the active ingredient, chlorphenamine maleate. The other ingredients are xanthan gum, sodium methyl parahydroxybenzoate (E219), sodium propyl parahydroxybenzoate (E217), maltitol liquid (E965), sodium saccharin, citric acid monohydrate, strawberry flavour (containing propylene glycol (E1520) and flavouring substances) and purified water. (See also end of section 2 “Chlorphenamine Solution contains”).

What Chlorphenamine Solution looks like and contents of the pack

The medicine is a clear, colourless liquid, with a strawberry flavour. It is supplied to your pharmacist in bottles containing 150 ml.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Kent Pharma UK Limited, 2nd Floor, Connect 38, 1 Dover Place, Ashford, Kent, England, TN23 1FB.

Manufactured by Thorpe Laboratories Ltd., Golf Road Industrial Estate, Mablethorpe, Lincolnshire, LN12 1NB, UK.

Marketing Authorisation Number: PL 51463/0142

This leaflet was last revised in November 2022.

If you would like the leaflet in a different format, please contact the Marketing Authorisation holder at the above address.