

Package leaflet: Information for the patient

Chlorphenamine 4 mg Tablets

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 or 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.
- You must talk to your doctor if you do not feel better or if you feel worse.

What is in this leaflet:

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

1. What chlorphenamine tablets are and what they are used for

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 is used to relieve the symptoms of allergic conditions such as hay fever (seasonal allergic rhinitis), runny nose (rhinitis), urticaria (also known as "hives"), pruritus (itch), insect bite or sting reactions, allergies to foods or medicines.

It helps to relieve the symptoms associated with the above conditions such as itchy skin rashes; sneezing; itchy, runny or blocked nose; red, itchy and watering eyes.

2. What you need to know before you take chlorphenamine tablets

If the answer to any of the following questions is YES, DO NOT take this medicine without consulting your doctor:

- Have you previously suffered an allergic reaction to a medicine containing chlorphenamine or to any of the other ingredients in this medicine (listed in section 6).
- Have you taken a medicine called a Monoamine Oxidase Inhibitor (MAOI) to treat depression in the last 14 days?

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking chlorphenamine tablets if any of the following apply to you:

- Very high blood pressure.
- Epilepsy.
- · Heart disease, liver disease or kidney disease.
- · Glaucoma.
- · Enlarged prostate.
- · Bronchitis, asthma or bronchiectasis.

Talk to your doctor before taking this medicine if you are taking other medicines containing other antihistamines, including products for the relief of colds and coughs.

Other patient groups

Children and the elderly are more susceptible to the neurological anticholinergic effects of chlorphenamine.

This medicine is **NOT SUITABLE** for any children under 6 years.

Other medicines and chlorphenamine tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, any of the following:

- Medicines which have a sedative effect (e.g. drugs to help sleeping problems or anxiety) as they are likely to increase the sedative effects of chlorphenamine such as Mono Amine Oxidase Inhibitors (MAOIs).
- The effects of phenytoin (a medicine used to treat epilepsy) may be increased when taken with chlorphenamine.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Warning:

Do not drive or operate machinery if the tablets make you feel drowsy, dizzy or if you experience blurred vision

Avoid drinking alcohol while taking this medicine.

Chlorphenamine tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars contact to your doctor before taking this medicine.

Chlorphenamine tablets contain Sunset Yellow (E110)

This can cause allergic reactions.

Dimension: 150 x 230mm Front Side

ARTWORK DETAIL LABEL

THE WORK DETAIL LABEL									
Product	CHLORPHENAMINE 4mg Tablets								
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert						
Dimension	150 x 230 mm			Pack					
New Item Code	1049328	Old Item Code	1037637						
Colour Shades	Black			No. of Colours	1				
Change Control No.	PC-0DF/2023/502 - Record Number: 394743	Artwork Version	6.0						
Design/Style	Front & Back Printing. To be supplied in UNFOLDED size.								
Substrate	60 GSM Paper.								
Special Instructions	Printing clarity to be clear & sharp.								
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.								
					_				

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.



3. How to take chlorphenamine tablets

For oral use. The tablets should be swallowed with a drink of water. You should take your medicine as directed by your doctor. The pharmacist's label should tell you how much to take and how often.

If it does not or if you are not sure ask your doctor or pharmacist.

The usual doses are as follows:

Adults and the elderly: One tablet (4 mg) every four to six hours (maximum of 6 tablets daily).

Children and adolescents

Children 6-12 years of age: Half a tablet (2 mg) every four to six hours (maximum of 3 tablets daily).

Not recommended for children under 6 years of age. The dose prescribed by your doctor may be different to the usual dose given above; always follow your doctor's or pharmacist's instructions for taking medicines.

The tablet can be divided into equal doses.

If you have taken more than you should:

If you or anyone else has taken too many tablets you should contact your doctor or nearest hospital casualty department immediately. Do not attempt to drive. Symptoms in children include hallucinations, excitement and convulsions. In adults symptoms include drowsiness, coma and convulsions.

If you forget to take a dose of chlorphenamine tablets

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Children and older people are more prone to side effects.

The most common side effect is drowsiness.
This can be helpful if symptoms are particularly troublesome at night.

Stop taking this product and consult your doctor if you:

- Experience allergic reaction which can be severe. Signs include raised and itchy skin, swelling of the face or mouth causing difficulty breathing.
- Experience liver problems.
- Experience anaemia or unexplained bleeding or bruising.
- Experience difficulty passing water.
- Collapse.

Dimension: 150 x 230mm

The following side effects may occur:

- Difficulty concentrating, feeling tired, dizziness, headache or blurred vision.
- Loss of appetite, indigestion, feeling or being sick, diarrhoea, tummy pain or dry mouth.
- Low blood pressure (you may feel faint) or changes in heart rhythm.

- · Chest tightness or thickening of the phlegm.
- Skin peeling, itchy rash and sensitivity to the sun.
- Ringing in the ears.
- Twitching, muscular weakness and abnormal co-ordination.
- Confusion, excitability, irritability, low mood or nightmares.
- · 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

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store chlorphenamine tablets

Do not use the medicine after the expiry date and if the "expiry date" on the label has passed, take the medicine back to the pharmacist.

Always keep your medicine in a safe place out of the sight and reach of children.

Store below 25°C. Protect from light.

6. Contents of the pack and other information

What chlorphenamine tablets contain

The active ingredient is 4mg of chlorphenamine maleate.

The other ingredients are lactose, maize starch, magnesium stearate, colloidal silicon dioxide and the colours quinolone yellow (E104) and sunset yellow (E110).

What chlorphenamine tablets looks like and contents of the pack

Yellow uncoated convex tablets with break-line on one side.

The tablets are supplied in containers of 28, 30, 100, 250, 500 or 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation holder and Manufacturer: Strides Pharma UK Limited

Unit 4, The Metro Centre Dwight Road Watford WD18 9SS United Kingdom.

This leaflet was last revised in December 2023.

PL 13606/0043

19328



Back Side

ARTWORK DETAIL LABEL

Product	CHLORPHENAMINE 4mg Tablets							
Buyer/Country	Strides Pharma UK Ltd.	Component	Pack Insert					
Dimension	150 x 230 mm			Pack				
New Item Code	1049328	Old Item Code	1037637					
Colour Shades	Black			No. of Colours	1			
Change Control No.	PC-ODF/2023/502 - Record Number: 394743	Artwork Version	6.0					
Design/Style	Front & Back Printing. To be supplied in UNFOLDED size.							
Substrate	60 GSM Paper.							
Special Instructions	Printing clarity to be clear & sharp.							
Autocartonator Requirements	Pack insert supply should be as per auto-cartonator. Refer auto-cartonator drawing for instructions.							

Caution to the printer: Before processing, please ensure that the ARTWORK received for printing is exactly in line with APPROVED ARTWORK provided to you. In case of any FONTS/DESIGN are Mis-matching with the APPROVED ARTWORK, please inform PDC for further action. DO NOT MAKE ANY CHANGE TO THE ARTWORK WITHOUT WRITTEN INSTRUCTIONS FROM PDC.