

Package leaflet: Information for the user
Numark Hayfever Relief 10 mg Tablets

Read all of this leaflet carefully because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist 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 or pharmacist. This includes 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 after 3 days.

The name of your medicine is Numark Hayfever Relief 10mg Tablets. In the rest of this leaflet, it is called Hayfever Relief Tablets

What is in this leaflet:

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

1. What Hayfever Relief Tablets are and what they are used for

Cetirizine dihydrochloride, the active ingredient of the tablets is an antihistamine. It blocks the effects of a substance called histamine which occurs naturally in the body. Histamine is involved in allergic reactions.

In adults and children aged 6 years and above, cetirizine is used to treat people who have hay fever (seasonal allergic rhinitis), year round allergies such as dust or pet allergies (perennial allergic rhinitis) and urticaria (swelling, redness and itchiness of the skin).

Antihistamines like cetirizine relieve the unpleasant symptoms and discomfort associated with these conditions, such as sneezing, irritated, runny and blocked up nose, itchy, red and watering eyes and skin rashes.



2. What you need to know before you take Hayfever Relief Tablets

Do not take Hayfever Relief Tablets if:

- you have severe kidney problems (severe renal failure with creatinine clearance below 10 ml/min).
- you are allergic to cetirizine dihydrochloride, any of the other ingredients of this medicine (listed in section 6), to hydroxyzine or piperazine derivatives (closely related active ingredients of other medicines).

Warnings and precautions

Talk to your doctor or pharmacist before taking Hayfever Relief Tablets:

- If you are a patient with renal insufficiency, please ask your doctor for advice; if necessary, you will take a lower dose. The new dose will be determined by your doctor.
- If you have problems passing urine (like spinal cord problems or prostate or bladder problems), please ask your doctor for advice.
- If you are an epileptic patient or a patient at risk of convulsions, you should ask your doctor for advice.
- If you are scheduled for allergy testing, ask your doctor if you should stop taking Hayfever Relief Tablets for several days before testing. This medicine may affect your allergy test results.

Children

Do not give this medicine to children below the age of 6 years because the tablet formulation does not allow the necessary dose adjustments.

Other medicines and Hayfever Relief Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Hayfever Relief Tablets with food and alcohol

Food does not affect absorption of cetirizine.

No clinically significant interactions have been observed between alcohol (at the blood level of 0.5 per mille (g/l) corresponding to one glass of wine) and cetirizine used at the recommended doses. However, there are no data available on the safety when higher doses of cetirizine and alcohol are taken together. Therefore, as it is the case with all antihistamines, it is recommended to avoid taking Hayfever Relief Tablets with alcohol.

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.

Hayfever Relief tablets should be avoided in pregnant women. Accidental use of the drug by a pregnant woman should not produce any harmful effects on the foetus.

Nevertheless, the medicine should only be administered if necessary and after medical advice.

Cetirizine passes into breast milk. Therefore, you should not take Hayfever Relief Tablets during breast-feeding unless you have contacted a doctor.

Driving and using machines

Clinical studies have produced no evidence of impaired attention, alertness and driving capabilities after taking Hayfever Relief Tablets at the recommended dose.

You should closely observe your response to the drug after you have taken Hayfever Relief Tablets if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

Hayfever Relief Tablets contain lactose

If you have been told by your doctor that you have an intolerance to some sugars, please contact your doctor before taking these tablets.

3. How to take Hayfever Relief Tablets

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 tablets need to be swallowed with a glass of liquid. The tablet can be divided into equal doses. Do not take more than one tablet each day.

Use in children aged 6-12 years:

- The recommended dose is 5mg twice daily as a half tablet twice daily.

Adults and adolescents aged 12 years and over:

- The recommended dose is 10 mg once daily as one tablet. If the tablets make you feel drowsy or dizzy, taking half a tablet twice a day may be better than taking one tablet once a day.

Other form(s) of this medicine may be more suitable for children; ask your doctor or pharmacist.

Patients with renal impairment

Patients with moderate renal impairment are recommended to take 5 mg once daily.

If you suffer from severe kidney disease, please contact your doctor or pharmacist who may adjust the dose accordingly.

If your child suffers from kidney disease, please contact your doctor or pharmacist who may adjust the dose according to your child's needs.

If you feel that the effect of Hayfever Relief Tablets is too weak or too strong, please consult your doctor.

Duration of treatment

The duration of treatment depends on the type, duration and course of your complaints. Please ask your doctor or pharmacist for advice.

If you take more Hayfever Relief Tablets than you should

If you think you have taken an overdose of Hayfever Relief Tablets please inform your doctor. Your doctor will then decide what measures, if any, should be taken.

After an overdose, the side effects described below may occur with increased intensity. Adverse effects such as confusion, diarrhoea, dizziness, tiredness, headache, ailing, dilating of pupil, itching, restlessness, sedation, somnolence, stupor, abnormal rapid heart rate, tremors and urinary retention have been reported.

If you forget to take Hayfever Relief Tablets

Do not take a double dose to make up for a forgotten dose. If you forget to take a tablet, you should take one as soon as you remember, but wait at least 24 hours before taking your next tablet.

If you stop taking Hayfever Relief Tablets

Rarely, pruritus (intense itching) and/or urticaria may return if you stop taking Hayfever Relief Tablets.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

The following side effects are rare or very rare, but you must stop taking the tablets and speak to your doctor straight away if you notice them:

- Allergic reactions, including severe reactions and angioedema (serious allergic reaction which causes swelling of the face or throat). These reactions may start soon after you first take the medicine, or it might start later.

Common (may affect up to 1 in 10 patients)

- Somnolence (sleepiness)
- Dizziness, headache
- Pharyngitis, rhinitis (in children)
- Diarrhoea, nausea, dry mouth
- Fatigue

Uncommon (may affect up to 1 in 100 patients)

- Agitation
- Paraesthesia (abnormal feelings of the skin)
- Abdominal pain
- Pruritus (itchy skin), rash
- Asthenia (extreme fatigue), malaise

Rare (may affect up to 1 in 1,000 patients)

- Allergic reactions, some severe (very rare)
- Depression, hallucination, aggression, confusion, insomnia
- Convulsions
- Tachycardia (heart beating too fast)
- Liver function abnormal
- Urticaria (hives)
- Oedema (swelling)
- Weight increased

Very rare (may affect up to 1 in 10,000 patients)

- Thrombocytopenia (low levels of blood platelets)
- Tics (habit spasm)
- Syncope, dyskinesia (involuntary movements), dystonia (abnormal prolonged muscular contractions), tremor, dysgeusia (altered taste)
- Blurred vision, accommodation disorder (difficulty focusing), oculogyration (eyes having uncontrolled circular movements)
- Abnormal elimination of urine (bed wetting, pain and/or difficulty passing water)

Not known (frequency cannot be estimated from the available data)

- Joint pain
- Increased appetite
- Suicidal ideation (recurring thoughts of or preoccupation with suicide), nightmare
- Amnesia, memory impairment
- Vertigo (sensation of rotation or movement)
- Urinary retention (inability to completely empty the urinary bladder)
- Pruritus (intense itching) and/or urticaria upon discontinuation
- Rash with blisters containing pus
- Hepatitis (inflammation of the liver)

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: <http://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 Hayfever Relief Tablets

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

This medicinal product does not require any special storage conditions. Do not use after the expiry date which is stated on the blister strip and carton.

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 protect the environment.

6. Contents of the pack and other information

What Hayfever Relief Tablets contain

The active substance is cetirizine; each film-coated tablet contains 10 mg of cetirizine dihydrochloride. The other ingredients are microcrystalline cellulose, lactose monohydrate, crospovidone, anhydrous colloidal silica, magnesium stearate, hypromellose (E464), titanium dioxide (E171) and polyethylene glycol (macrogol 400).

What Hayfever Relief Tablets look like and contents of the pack

Hayfever Relief Tablets are white, or almost white, oval-shaped tablets with a score line on one side. Hayfever Relief Tablets are available from your pharmacist in packs of 7, 10, 14, 20, 30, 50, 60 or 90 Tablets. Not all pack sizes may be marketed.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only).

Please be ready to give the following information:

Product name	Reference number
Numark Hayfever Relief 10 mg Tablets	PL 29831/0035

This is a service provided by the Royal National Institute of Blind People.

Marketing Authorisation Holder:

Wockhardt UK Limited,
Ash Road North, Wrexham, LL13 9UF. United Kingdom

Manufacturer:

CP Pharmaceuticals Limited,
Ash Road North, Wrexham, LL13 9UF. United Kingdom

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