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Package leaflet: Information for the patient
Numark Allergy Relief for Children 5 mg/5 ml Oral Solution
cetirizine hydrochloride

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 after a few days.

What is in this leaflet

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

1. What Numark Allergy Relief is and what it is used for

Numark Allergy Relief for Children 5 mg/5 ml Oral Solution ("Numark Allergy Relief") treats children aged 6 years and over and adults suffering from hay fever and year-round allergies such as dust or pet allergies. It can also be used to treat the symptoms of urticaria, also known as hives, where the skin looks blotchy, with white raised wheals (bumps) surrounded by redness.

The medicine contains cetirizine hydrochloride which is an antihistamine that helps relieve allergy symptoms associated with the above conditions, such as sneezing, runny nose, watery eyes and skin rashes.

2. What you need to know before you take Numark Allergy Relief

DO NOT TAKE Numark Allergy Relief if:

- you are allergic to cetirizine hydrochloride, hydroxyzine or any of the other ingredients of this medicine, or to any piperazine derivatives (see Section 6 and end of Section 2).
- you have severe kidney failure (creatinine clearance less than 10 ml/min).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Numark Allergy Relief if:

- you have kidney problems as you may need to take a lower dose.
- you are pregnant or are breast-feeding.
- you have problems passing urine.
- you suffer from epilepsy or are at risk of convulsions.
- you have hereditary intolerance to some sugars.
- your symptoms persist.
- you are due to have an allergy test, as this medicine may affect your allergy test result.

Children
 Children younger than 6 years old should not take this medicine.

Other medicines and Numark Allergy Relief
 Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

Numark Allergy Relief with food and drink
 You must avoid excessive alcohol consumption while you are taking this medicine, as with all antihistamine medicines.

Pregnancy and breast-feeding
 Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding. Numark Allergy Relief 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 Numark Allergy Relief 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 Numark Allergy Relief at the recommended dose. You should closely observe your response to the drug after you have taken Numark Allergy Relief if you are intending to drive, engage in potentially hazardous activities or operate machinery. You should not exceed the recommended dose.

Numark Allergy Relief contains:

- sorbitol (E420): this medicine contains 4500 mg sorbitol per 10 ml dose which is equivalent to 450 mg/ml. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.
- methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).
- propylene glycol: this medicine contains 500 mg propylene glycol per 10 ml dose which is equivalent to 50 mg/ml.
- sodium: this medicine contains less than 1 mmol sodium (23 mg) per 10 ml, that is to say essentially 'sodium-free'.
- ethanol: this medicine contains 0.0525 mg of alcohol (ethanol) in each 10 ml which is equivalent to 0.00065625 v/v%. The amount in 10 ml of this medicine is equivalent to less than 1 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

3. How to take Numark Allergy Relief

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. This medicine is to be taken only by mouth, and is not to be taken by children aged under 6 years.

The measuring spoon provided is double-ended. The larger spoon holds 5 ml of your medicine, and the smaller spoon holds 2.5 ml. Each 5 ml spoonful of solution contains 5 mg cetirizine hydrochloride. The usual dose is:

Adults and children aged 12 years and above:	Take two 5 ml spoonfuls once a day.
Children aged 6 – 12 years:	Take one 5 ml spoonful in the morning and one 5 ml spoonful in the evening.

You may need to take a lower dose if you have kidney problems.

If you take more Numark Allergy Relief than you should: 23LF01773PW
 If you take too much of this medicine, talk to a doctor or pharmacist immediately.

If you forget to take Numark Allergy Relief
 If you forget to take a dose, take it as soon as you remember, but wait at least 24 hours before taking the next dose.

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

4. Possible side effects

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

Stop taking the medicine and speak to your doctor immediately if you experience any of the following symptoms:

- A severe allergic reaction including rash, itchiness and fever, swollen throat, face, eyelids or lips. This reaction may start soon after you first take the medicine, or it might start later.
- Swelling of the skin particularly around the face, severe blistering skin rash (may look like round or oval patches of redness and swelling of the skin)
- Suicidal ideation (recurring thoughts of or preoccupation with suicide).

The following side effects have also been reported.

Common side effects (may affect up to 1 in 10 people)

- Tiredness, feeling sleepy
- Headache
- Nausea
- Pain in the abdomen
- Dry mouth
- Diarrhoea
- Dizziness
- Cold-like symptoms of the nose

Uncommon side effects (may affect up to 1 in 100 people)

- Feeling weak or generally unwell
- Feeling agitated
- Tingling in the hands and feet

Rare side effects (may affect up to 1 in 1000 people)

- Fast heart beat
- Oedema (generalised swelling due to water retention)
- Abnormal liver function test results
- Convulsions
- Increased weight
- Urticaria (hives)
- Aggression, confusion, depression, hallucination (hearing or seeing things), sleeplessness

Very rare side effects (may affect up to 1 in 10,000 people)

- Thrombocytopenia (low levels of blood platelets)
- Blurred vision, difficulty focussing
- Rotation of the eyes
- Fainting
- Bad taste in the mouth
- Bed wetting, pain and/or difficulty passing water
- Tremor, tics
- Involuntary movements and/or jerking of the limbs
- Muscle spasms in the neck and shoulders

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

- Increased appetite
- Nightmare
- Loss of memory, memory impairment
- Vertigo (Lack of coordination)
- Urinary retention
- Pruritus (intense itching) and/or urticarial upon discontinuation
- Joint pain
- Rash with blisters containing pus
- Hepatitis (inflammation of the liver)

In very rare cases people have thoughts about committing suicide and if you feel this way then stop taking this medicine and see your doctor.

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 Numark Allergy Relief

Keep this medicine out of the sight and reach of children and do not store above 25°C. Do not use this medicine after the expiry date which is stated on the label. The expiry date refers to the last day of that month. Use within 6 months after opening. 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 Numark Allergy Relief contains

- The active ingredient is cetirizine hydrochloride: 5 mg in each 5 ml of solution.
- The other ingredients are: liquid sorbitol (E420), glycerol, propylene glycol, sodium acetate, acetic acid, saccharin sodium, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), banana flavour and purified water.

What Numark Allergy Relief looks like and contents of the pack
 Numark Allergy Relief is a clear or almost clear colourless solution, with the taste and smell of banana. It is available in pack sizes of 60 ml and 70 ml amber glass bottles, and includes a combined 5 ml / 2.5 ml measuring spoon. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
 Pinewood Laboratories Ltd., Ballymacarbry, Clonmel, Co. Tipperary, Ireland.
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