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

The name of this medicine is Numark Allergy & Hayfever 10mg Tablets and will be referred to as Allergy & Hayfever 10mg Tablets throughout this leaflet.

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse

- 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 you feel worse or if your symptoms change. See section 4.

What is in this leaflet:

- 1. What Allergy & Hayfever 10mg Tablets are and what are they used for
- What you need to know before you take Allergy & Hayfever 10mg Tablets
- How to take Allergy & Hayfever 10mg Tablets
- Possible side effects

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- How to store Allergy & Hayfever 10mg Tablets
- Contents of the pack and other information

What Allergy & Hayfever 10mg Tablets are and what are they used for

This medicine contains Loratadine which belongs to a group of medicines called antihistamines, which act to relieve the symptoms of allergies in adults and children over the age of 2 years who weigh more than 30kg.

It can be used to relieve the symptoms of sneezing, runny and itchy nose and eye irritation and other allergies such as pet and dust allergies. It can also be used to treat raised symptoms of urticaria which is often known as hives and nettle rash.

The effect of Allergy & Hayfever 10mg Tablets will last a whole day and should help you to continue your normal daily activities and sleep.

You must talk to a doctor if you do not feel better or if you feel worse

What you need to know before you take Allergy & Hayfever 10mg Tablets

Do not take Allergy & Hayfever 10mg Tablets:

- If you are allergic (hypersensitive) to Loratadine or any of the other ingredients in these tablets (listed in section 6)
- You are pregnant or breast-feeding.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before you take Allergy & Hayfever 10mg Tablets if you:

- have severe liver problems (you may need to take the medicine less often, see "How to take Allergy & Hayfever 10mg Tablets")
- are scheduled to have any skin tests for allergies. Do not take Allergy & Hayfever 10mg Tablets for two days before having these tests. This is because it may affect the test results.

If any of the above applies to you (or you are not sure), talk to your doctor, pharmacist or nurse before taking Allergy & Hayfever 10mg Tablets.

Children

Do not give Allergy & Hayfever 10mg Tablets to children younger than 2 years or to children 2 to 12 years old who weigh less than 30kg. There are other formulations more suitable for children 2 to 12 years old who weigh less than 30kg.

Other medicines and Allergy & Hayfever 10mg **Tablets**

The side effects of Allergy & Hayfever 10mg Tablets may increase when used together with medicines that alter the performance of some enzymes responsible for drug-metabolism in the liver. However, in clinical studies, no increase in side effects of Loratadine was seen with products that altered the performance of these enzymes.

Talk to your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines taken without a prescription.

Allergy & Hayfever 10mg Tablets with alcohol Allergy & Hayfever 10mg Tablets have not been shown to add to the effects of an alcoholic drink.

Pregnancy and breast-feeding

Do not take Allergy & Hayfever 10mg Tablets if you are pregnant, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not take Allergy & Hayfever 10mg Tablets if you are breast-feeding. Allergy & Hayfever 10mg Tablets is excreted in breast milk.

Driving and using machines

These tablets can cause some people to feel drowsy. If you are affected do not drive or operate machinery.

In clinical trials that assessed driving ability, no impairment was observed in patients receiving Loratadine. At the recommended dose, Allergy & Hayfever 10mg Tablets are not expected to cause you to be drowsy or less alert.

Allergy & Hayfever 10mg Tablets contain Lactose If you have been told by your doctor that you have an intolerance to some sugars talk to your doctor before taking this medicine.

3. How to take Allergy & Hayfever 10mg Tablets

The following section contains instructions on how many tablets to take and when.

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

The break line of the tablet is only there to help you break the tablet if you have difficulty swallowing it whole.

Giving this medicine to children

A syrup may be preferable for children. It is important to know how much your child weighs to make sure that you give the correct amount of medicine. For example a 9 year old child weighs about 30kg (4st 7lb). If in doubt weigh your child and then follow the instructions in the table.

NUMARK

Allergy & Hayfever 10mg Tablets

Loratadine

Do not give to children under 2 years or who weigh 30kg (4st 7lb) or less.

How much to take

| Age and Weight | How much to take | How often to take |
|---|------------------|-------------------|
| Children of 2 to 12 years who weigh more than 30kg (4st 7lb) | 1 x tablet | Once daily |
| Adults and children over 12 years | 1 x tablet | Once daily |

If you have severe liver problems your doctor or pharmacist may advise you to take the recommended amount every other day. If this applies to you follow their instructions.

- Swallow the tablet with a drink of water
- Do not take more than the amount recommended
- · If symptoms do not go away talk to your pharmacist

If you forget to take Allergy & Hayfever 10mg

- If you forget to take your dose, take it as soon as you remember, then continue to take it as usual.
- Do not take a double dose to make up for a forgotten dose. If you have any further questions on the use of this product, ask your doctor, pharmacist or nurse.

If you take more Allergy & Hayfever 10mg Tablets than you should

If you take too many tablets by mistake contact your nearest hospital casualty department or tell your doctor immediately. Také your tablet pack with you.

Symptoms of an overdose may include sleepiness, rapid heartbeat and headache.

4. Possible side effects

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

If you get any of these serious side effects, stop taking the tablets. See a doctor at once:

· Difficulty in breathing, swelling of the face, neck, tongue or throat (these are severe allergic reactions)

The most commonly reported side effects in adults and children over 12 years of age are:

- drowsiness
- headache
- increased appetite
- difficulty sleeping

The most commonly reported side effects in children aged 2 to 12 years are:

- headache
- nervousness
- tiredness

The following very rare side effects (may affect up to 1 in 10,000 people) have also been seen during the marketing of Loratadine:

- severe allergic reaction (including swelling)
- dizziness
- · fast or irregular heartbeat
- nausea (feeling sick)
- dry mouth
- upset stomach

- liver problems
- hair loss
- rash
- tiredness convulsion

The frequency of the following side effects is not known:

· Weight gain.

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 Allergy & Hayfever 10mg Tablets

Check the expiry date printed on the label or the side of the box. Do not use after the expiry date stated on the box. The expiry date refers to the last day of the month.

There are no special storage recommendations for Loratadine, however do not store your medicine in a very damp or very hot place, such as the bathroom or kitchen.

In case of any visible signs of deterioration, you should discard the package.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures help to protect the environment.

Keep out of the sight and reach of children.

6. Contents of the pack and other information

What Allergy & Hayfever 10mg Tablets contain: Each Allergy & Hayfever 10mg Tablet contains 10mg of Loratadine.

The other ingredients are: Lactose Monohydrate, Microcrystalline Cellulose, Maize Starch, Magnesium Stearate.

What Allergy & Hayfever 10mg Tablets looks like and contents of the pack:

Each tablet is white round and flat with a break line. Packs are 30 and 60 tablets in blister packs in cartons. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer: Relonchem Limited, Cheshire House, Gorsey Lane, Widnes, Cheshire, WA8 0RP, UK.

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