

Package leaflet : Information for the patient

Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets

Loratadine

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 has told you.

This medicine is available without prescription, for you to treat a mild illness without a doctor's help. You still need to use this medicine carefully to get the best results from them.

- 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 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 5 days.

What is in this leaflet:

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1. What Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets is and what it is used for

What Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets are

Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets contains the active substance Loratadine which belongs to a group of medicines called antihistamines.

How Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets work.

Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets help to reduce your allergy symptoms by stopping the effects of a substance called "histamine", which is produced in the body when you are allergic to something.

When Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets should be taken

Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets relieves symptoms associated with allergic rhinitis (for example, hayfever), such as sneezing, runny or itchy nose, and burning or itchy eyes in adults and children over the age of 2 years who weigh more than 30 kg.

Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets may also be used to help relieve symptoms of urticaria (itching and redness) which is often known as hives or nettle rash.

The effect of Brown & Burk Once-A-Day Hayfever & Allergy 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.

2. What you need to know before you take Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets :

Do not take Brown & Burk Once-A-Day Hayfever & Allergy 10mg tablets if:

- you are hypersensitive (allergic) to Loratadine, or any of the other ingredients of this medicine (listed in section 6).
- you are (or think you may be) pregnant, or are breastfeeding

Warnings and precautions

Talk to your doctor or pharmacist before taking Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets if:

- you have liver disease.
- You are scheduled to have any skin tests for allergies. Do not take Brown & Burk Once-A-Day Hayfever & Allergy 10mg tablets for two days before having these tests. This is because it may affect the test results.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before taking Brown & Burk Once-A-Day Hayfever & Allergy 10mg tablets.

Children

Do not give Brown & Burk Once-A-Day Hayfever & Allergy 10mg tablets to children younger than 2 years old or to children 2 to 12 years old who weigh less than 30 kg. There are other formulations more suitable for children 2 to 12 years old who weigh less than 30 kg.

Other medicines and Brown & Burk Once-A-Day Hayfever & Allergy 10mg tablets:

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, even those not prescribed.

The side effects of Brown & Burk Once-A-Day Hayfever & Allergy 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.

Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets with food, drink and alcohol:

Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets should not be affected by food or drink.

You do not have to avoid alcohol whilst taking this medicine.

Pregnancy

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.

As a precautionary measure, it is preferable to avoid the use of Brown & Burk Once-A-Day Hayfever & Allergy 10mg tablets during pregnancy.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

This medicine should not be taken by women who are breastfeeding because the active ingredient, Loratadine, passes into breast milk.

Driving and using machines:

In clinical trials that assessed driving ability, no impairment was observed in patients receiving loratadine. At the recommended dose, Brown & Burk Once-A-Day Hayfever & Allergy 10mg tablets are not expected to cause you to be drowsy or less alert. However, very rarely some people experience drowsiness, which may affect their ability to drive or use machines.

Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets contains lactose.

Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets contains lactose; thus if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Brown & Burk Once-A-Day Hayfever & Allergy 10mg 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 score line of the tablet is only there to help you break the tablet if you have difficulty swallowing it whole.

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

Do not exceed the dose stated below.

Adults, the elderly, children aged 12 years and over:

One tablet to be swallowed once daily.

Children aged 2 to 12 years:

If the child weighs more than 30 kg, one tablet taken once daily is recommended.

If the child weighs less than 30 kg, the 10mg strength tablet is not recommended.

If you are unsure ask your doctor or pharmacist for advice.

This medicine are not recommended in children under 2 years.

If you take more Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets than you should:

If you (or someone else) have accidentally taken more this medicine than you/they should, contact your doctor or pharmacist immediately, or go to the nearest Accident and Emergency hospital department. No serious problems are expected however, you may get a headache, have a rapid heartbeat or feel sleepy.

If you forget to take Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets:

- Take your recommended dose as soon as you remember; wait at least 24 hours before taking another tablet.
- Do not take a 'double dose' to make up for missed doses.

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 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
- convulsion
- fast or irregular heartbeat
- nausea (feeling sick)
- dry mouth
- upset stomach
- liver problems
- hair loss
- rash
- tiredness

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

- weight increased

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 Brown & Burk Once-A-Day Hayfever & Allergy 10mg Tablets:

- Keep this medicine out of the sight and reach of children. Your medicine may harm them.
- There are no special storage recommendations for this medicine. However, do not store your medicine in a very damp or very hot place, such as the bathroom or kitchen.
- Do not use after the expiry date stated on the outer carton/blister strip after EXP. The expiry date refers to the last day of that month.
- 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.

If there is anything about this medicine you do not understand or are unsure about, your doctor or pharmacist will be able to help or advise you.

6. Contents of the pack and other information

- The active substance in your tablets is loratadine.
Each this medicine contains 10mg of loratadine.
- The other ingredients in your tablets are lactose monohydrate, microcrystalline cellulose, maize starch, magnesium stearate.

This medicine are white or almost white, 8mm round, flat tablets, debossed with letter 'L' on one side and with a score line on other.

This medicine are available in packs of 7, 14 and 30 tablets from your pharmacist.

Marketing Authorisation Holder & Manufacturer

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