Package Leaflet: Information for the user

Maxstine™ M
SUSPENSION

Bilastine & Montelukast Oral Suspension (10 mg + 4 mg)

Read all of this leaflet carefully before your child starts taking this medicine because it contains important information for you. –

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for your child. Do not pass it on to others. It may harm them, even if their signs of illness are the same as your child's.
- If your child gets any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet?

1. What Maxstine™ M suspension is and what it is used for?

Maxstine™ M suspension contains two active substances: bilastine, an antihistamine, and montelukast, a leukotriene receptor antagonist.

Here's how each works:

When our body has an allergic reaction, inflammatory substances such as leukotrienes and histamine, etc., are released. These substances are produced by the body's immune system in response to allergens.

Bilastine prevents histamine production by inhibiting inflammatory responses mediated by mast cells, basophils, epithelial cells, eosinophils, and lymphocytes. It effectively relieves allergic nasal symptoms such as itching, sneezing, and runny nose (rhinorrhea).

Montelukast targets chemicals called leukotrienes, which cause inflammation in the nasal passages, leading to increased mucus production, swelling of the nasal tissues, and nasal congestion during allergic rhinitis. By blocking these chemicals, Montelukast reduces swelling and symptoms like congestion and inflammation, helping to relieve allergic rhinitis

Maxstine™ M suspension is used to relieve the symptoms of hayfever (sneezing, itchy, runny, blocked-up nose and red and watery eyes) and other forms of allergic rhinitis.

Maxstine™ M is an oral solution is indicated in children aged 6 to 11 years with a body weight of at least 20 kg.

2. What you need to know before you take Maxstine™ M suspension?

Do not use Maxstine™ M suspension:

- if your child is allergic to bilastine, montelukast or any of the other ingredients of this medicine

Warnings and precautions

Talk to your doctor or pharmacist before using Maxstine™ M suspension if your child has moderate or severe renal or hepatic impairment or if your child is taking other medicines (see" Other medicines and Maxstine™ M suspension").

Various neuropsychiatric events (for example behaviour and mood-related changes, depression and suicidality) have been reported in patients of all ages treated with montelukast (see section 4). If you develop such symptoms while taking montelukast, you should contact your doctor.

Children

Do not give this medicine to children under 6 years of age with a body weight below 20 kg since no sufficient data are available.

Other medicines and Maxstine™ M suspension

Tell your doctor or pharmacist if your child is taking, has recently taken or might take any other medicines, including medicines obtained without a prescription. Some medicines should not be taken together and others may need their doses to be altered when taken together.

Always inform your doctor or pharmacist if your child is using or receiving any of the following medicines in addition to Maxstine™ M suspension:

- Ketoconazole (an antifungal medicine)
- Erythromycin (an antibiotic)
- Diltiazem (to treat angina pectoris – pain or tightness in the chest area)
- Cyclosporine (to reduce the activity of your immune system, thus avoiding transplant rejection or reducing disease activity in autoimmune and allergic disorders, such as psoriasis, atopic dermatitis or rheumatoid arthritis)
- Ritonavir (to treat AIDS)
- Rifampicin (an antibiotic)
- phenobarbital (used for treatment of epilepsy)
- phenytoin (used for treatment of epilepsy)

Maxstine™ M suspension with food, drink and alcohol

The oral solution should not be taken with **food or with grapefruit juice or other fruit juices**, as this will decrease the effect of bilastine. To avoid this, you can:

- give your child the oral solution and wait for one hour before your child takes food or fruit juice or
- if your child has taken food or fruit juice, wait for two hours before giving him the oral solution.
- Bilastine, at the dose recommended in adults (20 mg), does not increase the drowsiness produced by alcohol.

Pregnancy, breast-feeding and fertility

This medicine is for use in children from 6 to 11 years of age with a body weight of at least 20 kg. However, the following information should be noted regarding the safe use of this medicine. There are no or limited amount of data from the use of bilastine in pregnant women and during breast-feeding and on the effects on fertility.

In case of pregnancy or breast-feeding, or when planning to have a baby, it is recommended to ask to the doctor for advice before taking this medicine. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

It has been demonstrated that Maxstine™ M suspension does not affect the driving performance in adults. However, the response from each patient to the medicine may be different. Certain side effects (such as dizziness and drowsiness) that have been reported with montelukast may affect some patients' ability to drive or operate machinery Therefore you should check how this medicine affects your child, before you let your child ride bicycles or drive other vehicles or operate machinery.

3. How to take Maxstine™ M suspension?

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Use in children

The recommended dose in children 6 to 11 years of age with a body weight of at least 20 kg is 5 ml of oral solution once daily for the relief of symptoms of allergic rhinitis.

Do not give this medicine to children under 6 years of age with a body weight below 20 kg since no sufficient data are available

The oral solution is for oral use

- The bottle of oral solution is provided with a child-proof cap and must be opened as follows: press the plastic screw-cap downwards and turn anti-clockwise at the same time
- Fill the cup with 5 ml of oral solution
- Administer directly from the cup
- Wash the cup after use

- You should give the oral solution to your child one hour before or two hours after your child has taken any food or fruit juice.

As the duration of treatment depends on your child's underlying disease, your physician will determine for how long your child should take Maxstine™ M.

If you use more Maxstine™ M suspension than you should

If your child, or anyone else, use too much of this medicine, tell your doctor immediately or go to the emergency department of your nearest hospital. Please remember to take this medicine pack or this leaflet with you.

If you forget to use Maxstine™ M suspension

If you forget to give your child the daily dose on time, give it on the same day as soon as you remember. Then, give the next dose on the next day at the usual time as prescribed by the doctor. In any case, do not give a double dose to make up for a forgotten one.

If you stop using Maxstine™ M suspension

Generally, there will be no after-effects when treatment with Maxstine™ M suspension is stopped. 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. If your child experiences symptoms of an allergic reaction the signs of which may include difficulty in breathing, dizziness, collapsing or losing consciousness, swelling of the face, lips, tongue or throat, and/or swelling and redness of the skin, stop giving the medicine and seek urgent medical advice straight away.

Other side effects that may be experienced in children are:

Very common: the following may affect more than 1 in 10 people

- upper respiratory infection

Common: may affect up to 1 in 10 people

- rhinitis (nasal irritation)
- allergic conjunctivitis (eye irritation)
- headache
- stomach pain (abdominal - /upper abdominal pain)
- elevated liver enzymes
- fever

Uncommon: may affect up to 1 in 100 people

- eye irritation
- dizziness
- loss of consciousness

- diarrhoea
- nausea (the feeling of being sick)
- eczema
- urticaria (hives)
- dry mouth, indigestion
- joint or muscle pain, muscle cramps
- bedwetting in children
- weakness/tiredness, feeling unwell, swelling

Rare: the following may affect up to 1 in 1,000 people

- behaviour and mood related changes: disturbance in attention, memory impairment, uncontrolled muscle movements

Very rare: the following may affect up to 1 in 10,000 people

- tender red lumps under the skin, most commonly on your shins (erythema nodosum)
- behaviour and mood related changes: obsessive-compulsive symptoms, stuttering

Reporting of side effects

- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: **www.zuventus.co.in** and click the tab "Safety Reporting" located on the top of the home page.
- By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Maxstine™ M suspension

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

Do not use this medicine after the expiry date which is stated on the carton and the bottle after EXP. The expiry date refers to the last day of that month

Store at a temperature not exceeding 30°C, protected from light & moisture.

Keep bottle well closed after every use.

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

6. Contents of the pack and other information

a) What Maxstine™ M suspension contains

Each 5 ml suspension contains:

Bilastine IP 10 mg

Montelukast Sodium IP equivalent to Montelukast 4 mg

Flavoured syrupy base q.s.

b) What Maxstine™ M suspension looks like and contents of the pack

Maxstine™ M is Sunset Yellow colour oral solution
Each bottle contains 60 ml of oral solution

c) **Marketing Authorisation Holder and Manufacturer**

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