

PATIENT INFORMATION LEAFLET

MAXSTINE M Tablet

Bilastine (20 mg) and Montelukast (10 mg)

Read all of this leaflet carefully before you start 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. See section 4.

What is in this leaflet

1. What MAXSTINE M is and what it is used for
2. What you need to know before you take MAXSTINE M
3. How to take MAXSTINE M
4. Possible side effects
5. How to store MAXSTINE M
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1. What MAXSTINE M is and what it is used for

MAXSTINE M contains the active substance bilastine which is an antihistamine and Montelukast, a leukotriene receptor antagonist that blocks the substance called leukotrienes. Leukotrienes can cause the narrowing and swelling of airways in your lungs and also cause allergy symptoms. By blocking leukotrienes, this medicine improves asthma symptoms, helps control asthma and improves seasonal allergy symptoms (also known as hay fever or seasonal allergic rhinitis).

MAXSTINE M 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 -20 mg tablet is indicated in adults and adolescents (15 years and over)

2. What you need to know before you take MAXSTINE M 20 mg tablets

Do not take MAXSTINE M

if you are 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 if you have moderate or severe renal impairment and in addition you are taking other medicines (see “Other medicines and MAXSTINE M”).
- If your asthma or breathing gets worse, tell your doctor immediately.
- Oral MAXSTINE M Tablets is not meant to treat acute asthma attacks. If an attack occurs, follow the instructions your doctor has given you. Always have with you, your inhaled rescue medicine for asthma attack.
- Any patient on anti-asthma medicines should be aware that if you develop a combination of symptoms such as a flu-like illness, pins and needles or numbness of arms or legs, worsening of pulmonary symptoms, and/or rash, you should consult your doctor.
- You should not take acetyl-salicylic acid (aspirin) or anti-inflammatory medicines (also known as non-steroidal anti-inflammatory drugs or NSAIDS) if they make your asthma worse.
- It is important that you or your child takes all asthma medicines as prescribed by your doctor.

MAXSTINE M should not be used in place of other asthma medications your doctor has prescribed for you.

Patients should be aware that various neuropsychiatric events (for example behaviour and mood related changes) have been reported in adults, adolescents and children with Montelukast (see section 4). If you develop(s) such symptoms while taking MAXSTINE M tablets, you should consult your doctor.

Children

Do not give this medicine to children under 15 years of age.

Do not exceed the recommended dose. If symptoms persist, consult your doctor.

Other medicines and MAXSTINE M

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

In particular, please discuss with your doctor if you are taking any of the following medicines:

- Ketoconazole (an antifungal medicine)
- Erythromycin (an antibiotic)
- Diltiazem (to treat angina)
- 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)
- Rifampicin (used to treat tuberculosis and some other infections)
- Gemfibrozil (used for treatment of high lipid levels in plasma).

MAXSTINE M with food, drink

These tablets 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:

- take the tablet and wait for one hour before taking food or fruit juice or

- if you have taken food or fruit juice, wait for two hours before taking the tablet.

Pregnancy, breast-feeding and fertility

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.

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

Driving and using machines

It has been demonstrated that bilastine 20 mg 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 patient's ability to drive or operate machinery, therefore caution is advised.

3. How to take MAXSTINE M

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

The recommended dose in adults and adolescents aged 15 years and over, is 1 tablet (20/10 mg) a day.

- The tablet is for oral use.
- The tablet must be taken one hour before or two hours after intake of food or fruit juice (see section 2, MAXSTINE M with food, drink”).
- Swallow your tablet with a glass of water.

Regarding the duration of treatment, your physician will determine the type of disease you are suffering from and will determine for how long you should take MAXSTINE M.

If you take more MAXSTINE M than you should

If you, or anyone else, have taken too many MAXSTINE M tablets, contact your doctor or pharmacist 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 take MAXSTINE M

Do not take a double dose to make up for a forgotten dose.

If you forget to take your dose on time, take it as soon as possible, and then go back to your regular dosing schedule.

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 you experience symptoms of an allergic reaction the signs of which may include difficulty in breathing, dizziness, collapsing or losing consciousness, swelling of your face, lips, tongue or throat, and/or

swelling and redness of the skin, stop taking the medicine and seek urgent medical advice straight away.

Bilastine

Other side effects that may be experienced in adults and adolescents are:

Common: may affect up to 1 in 10 people

- Headache
- Drowsiness
- Uncommon: may affect up to 1 in 100 people
- abnormal ECG heart tracing
- blood tests which show changes in the way the liver is working
- dizziness
- stomach pain
- tiredness
- increased appetite
- irregular heartbeat
- increased weight
- nausea (the feeling of being sick)
- anxiety
- dry or uncomfortable nose
- belly pain
- diarrhoea
- gastritis (inflammation of the stomach wall)
- vertigo (a feeling of dizziness or spinning)
- feeling of weakness
- thirst
- dyspnoea (difficulty in breathing)
- dry mouth
- indigestion
- itching
- cold sores (oral herpes)
- fever
- tinnitus (ringing in the ears)
- difficulty in sleeping
- blood tests which show changes in the way kidney is working
- blood fats increased

Frequency not known: cannot be estimated from the available data

- palpitations (feeling your heart beat)
- tachycardia (fast heart beat)
- vomiting

Side effects that may be experienced in children are:

Common: may affect up to 1 in 10 people

- rhinitis (nasal irritation)

- allergic conjunctivitis (eye irritation)
- headache
- stomach pain (abdominal /upper abdominal pain)

Uncommon: may affect up to 1 in 100 people

- eye irritation
- dizziness
- loss of consciousness
- diarrhoea
- nausea (the feeling of being sick)
- lip swelling
- eczema
- urticaria (hives)
- fatigue

Montelukast

Tell your doctor right away if you get one or more of these symptoms:

In asthmatic patients treated with montelukast, very rare cases of a combination of symptoms such as flu like illness, pins and needles or numbness of arms and legs, worsening of pulmonary symptoms and/or rash (Churg - Strauss syndrome) have been reported.

Stop taking this medicine and seek medical attention immediately if you get one or more of these symptoms:

- serious allergic reactions (Hypersensitivity) including potentially life-threatening reactions including, swelling of the face, lips, tongue and/or throat which may cause difficulty in breathing or swallowing.
- swelling (inflammation with eosinophilia) of the lungs
- suicidal thoughts and actions
- hepatitis (swelling of your liver) which can cause abdominal pain, nausea, vomiting, producing dark urine, jaundice (yellowing of the skin and whites of the eyes).
- severe skin reactions (erythema multiforme) and tender red lumps under the skin commonly on your shins (erythema nodosum) that may occur without warning.

In clinical studies with Montelukast 10 mg tablets, the most commonly reported side effects (occurring in more than 1 in 100, or less than 1 in 10 treated patients) thought to be related to this medicine were:

- Abdominal pain
- Headache

In clinical studies with montelukast 5 mg chewable tablets, the most commonly reported side effects (occurring in at least 1 of 100 patients and less than 1 of 10 paediatric patients treated) thought to be related to this medicine was:

- Headache

These were usually mild and occurred at a greater frequency in patients treated with montelukast than placebo (a pill containing no medication).

Additionally, while the medicine has been on the market, the following have been reported:

Very common side effects (may affect more than 1 in 10 people):

- Infection of the throat or the airways going into the lungs.

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

- Diarrhoea
- Nausea
- Vomiting
- Rash
- abnormal liver function
- fever

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

- nose bleed
- dry mouth
- indigestion
- bruising
- itching
- hives
- joint and / or muscle pain, muscle cramps
- pins and needles/ numbness
- weakness/ tiredness
- feeling unwell
- swelling
- feeling dizzy
- feeling drowsy
- seizure (having a fit)
- Behaviour and mood related changes, such as:
 - dream abnormalities
 - nightmares
 - trouble sleeping
 - sleep walking
 - irritability
 - feeling anxious
 - restlessness
 - agitation including aggressive behaviour or hostility
 - depression

Rare side effects (may affect up to than 1 in 1,000 people):

- increased bleeding tendency
- tremor
- palpitations
- disturbance in attention
- memory impairment
- Serious allergic reaction which causes swelling of the face, lips, mouth, tongue or throat (angioedema)

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

- hallucinations (seeing things which are not there)
- disorientation
- stuttering

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: Website: www.zuventus.co.in and click the tab "Safety Reporting" located on the top right end of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine.

You can also report the side effect with the help of your treating physician.

5. How to store MAXSTINE M

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 blisters after EXP.

Store below 30°C. Protected from light & moisture.

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 to protect the environment.

6. Contents of the pack and other information

What MAXSTINE M contains

Each film coated bilayered tablet contains:

Bilastine.....20 mg

Montelukast.....10 mg

Excipients.....q.s.