

Package leaflet: Information for the Patient

Maxtra[®] Syrup

Phenylephrine Hydrochloride (**5mg**) /Chlorpheniramine Maleate (**2mg**) IP

Read all of this leaflet carefully before you are given 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, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

What is in this leaflet

1. What **Maxtra[®]** syrup is and what it is used for
2. What you need to know before you are given **Maxtra[®]** syrups
3. How **Maxtra[®]** syrups is given
4. Possible side effects
5. How to store **Maxtra[®]** syrups
6. Contents of the pack and other information

1. What Maxtra[®] is and what it is used for

Maxtra[®] is a syrup that contains:

Chlorphenamine Maleate, which belongs to a group of medicines called antihistamines, which act to relieve the symptoms of allergic reactions.

Phenylephrine hydrochloride is a decongestant which unblocks your nose and sinuses helping you breathe more easily.

Maxtra[®] is used to treat cough and cold with nasal congestion.

Maxtra syrup should not be used in children below 4 years of age.

2. What you need to know before you take Maxtra[®]

Do not take Maxtra[®] syrup:

- If your child is under 4 years.
- If your child is having an asthma attack
- If your child is allergic to any of the ingredients, or any other antihistamines (your child may have had a rash, difficulty breathing, swollen lips or face after taking them)
- If your child is taking monoamine oxidase inhibitors (for depression) or has taken them in the last 14 days
- If you have kidney or liver problems, overactive thyroid, diabetes, high blood pressure or heart or circulation disease
- If you have an enlarged prostate
- If you have phaeochromocytoma or glaucoma
- If you are taking tricyclic antidepressants (e.g. Imipramine or amitriptyline)
- If you are taking beta blockers.

Do not take with any other flu, cold or decongestant product.

Other important information

Do not drink alcohol (e.g. wine, beer, spirits) whilst taking this medicine.

Talk to your pharmacist or doctor if you are a man with prostate problems.

Pregnancy and breastfeeding: Do not take this medicine.

Other medicines and Maxtra[®]

Chlorpheniramine Maleate

Before you give this medicine, make sure that you tell your pharmacist about ANY other medicines you might be giving your child at the same time, particularly the following:

- Other antihistamines
- Strong painkillers
- Sleeping tablets

- Tranquillisers, antidepressants or other medicines for mental problems
- Phenytoin (for epilepsy)
- Atropine

Phenylephrine Hydrochloride

Talk to your doctor or pharmacist before taking this medicine if you are taking any prescribed medicines; particularly

- Metoclopramide or domperidone (for nausea [feeling sick] or vomiting [being sick])
- Ergotamine or methylsergide (for migraine)
- Colestyramine (to lower blood cholesterol)
- Drugs to lower blood pressure
- Appetite suppressants or stimulants
- Drugs to treat depression such as tricyclic antidepressants (e.g. Amitriptyline)
- Heart disease (e.g. Digoxin)
- Blood thinning drugs (anticoagulants e.g. Warfarin).

If you are unsure about interactions with any other medicines, talk to your pharmacist or doctor. This includes medicines prescribed by your doctor and medicine you have bought for your child, including herbal and homeopathic remedies.

Warnings and precautions

Talk to your doctor or pharmacist before taking Maxtra®:

- If your child has epilepsy, heart or circulatory disease, liver problems
- If your child has high blood pressure or glaucoma
- If your child has asthma, bronchitis or bronchiectasis
- If your child has an overactive thyroid
- If your child has difficulty passing urine
- If your child has an obstruction in their intestine
- If your child has a rare blood disease called porphyria
- If you have a blood vessel disease such as Raynaud's Phenomenon
- If you have liver or kidney problems.
- If you have a severe infection as this may increase the risk of metabolic acidosis.

Signs of metabolic acidosis include:

- Deep, rapid, difficult breathing
- Feeling sick (nausea), being sick (vomiting)
- Loss of appetite

Contact a doctor immediately if you get a combination of these symptoms

Driving and using machines

This product may cause dizziness. If affected, do not drive or operate machinery.

3. How to take Maxtra®

Check the seal is not broken before first use. If it is, do not give the medicine.

Always use the plastic cap supplied with the pack. The plastic cap can be used to measure 2.5 ml or 5 ml by drawing the liquid to the correct mark on it.

Give this medicine to your child to swallow.

Do not give to children under 4 years.

Do not give more than the amount recommended.

The recommended dosage of MAXTRA® in

In children 4 to 6 years: 2.5 ml every 4 to 6 hours or as directed by the Physician.

In children > 6 to 12 years: 5 ml every 4 to 6 hours.

Adults and children > 12 years: 10 ml every 4 to 6 hours.

Do not give continuously for more than 5 days without medical advice. If symptoms do not go away within 5 days talk to your pharmacist or doctor.

If you take more Maxtra® than you should

If you have too much of this medicine, talk to your doctor straight away. Take your medicine and this leaflet with you.

4. Possible side effects

Chlorpheniramine Maleate

Most people will not have problems, but some may get some of these.

- Drowsiness (which may make your child fall asleep)
- Dizziness, blurred vision, headaches, fits
- Dry mouth, difficulty in passing urine, sweating
- Skin rash, sensitivity to sunlight, other allergic reactions
- Indigestion, stomach pain, loss of appetite

- Tremors, muscle pain or weakness, impaired movement or co-ordination, pins and needles
- Change in heart rate, palpitations, low blood pressure, ringing in the ears, hair loss
- Blood problems such as anaemia, weariness
- Sleep disturbance
- Liver problems (which may cause yellowing of the skin or eyes)
- Chest pain
- Cough, phlegm on the chest – these may be caused by thickened bronchial secretions (mucous) in your lungs
- Difficulty concentrating, irritability, depression
- Hyperactivity in children
- Confusion in the elderly

Phenylephrine Hydrochloride

Stop taking this medicine and tell your doctor immediately if you experience:

- Allergic reactions which may be severe such as skin rash and itching sometimes with swelling of the mouth or face or shortness of breath.
- Skin rash or peeling, or mouth ulcers. Very rare cases of serious skin reactions have been reported.
- Unexplained bruising or bleeding.
- Re-occurring fevers or infections.
- Nausea, sudden weight loss, loss of appetite and yellowing of the eyes and skin.
- Visual disturbances. This is rare but is more likely in those with glaucoma.
- Unusually fast pulse rate or a sensation of an unusually fast or irregular heartbeat.
- Difficulty passing water. This is more likely to occur in men with an enlarged prostate gland.

The following side effects may occur. Tell your doctor if you get them:

- Raised blood pressure, headache, dizziness, difficulty sleeping, nervousness, anxiety, diarrhoea or sickness.

Very young children and elderly adults may be more likely to get some of these side effects.

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 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 Maxtra®

Do not store above 25°C.

Store in the original package.

Keep this medicine in a safe place out of the sight and reach of children, preferably in a locked cupboard.

Use by the date on the end flap of the carton or on the foil edge.

Do not throw away 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

1 x 60 ml

What Maxtra® contains

Each 5 ml syrup contains: Phenylephrine Hydrochloride IP (5 mg), Chlorpheniramine Maleate, IP (2 mg), and Mentholated flavoured syrup base (q.s.).

Details Manufacturer

Zuventus Healthcare Ltd.
Survey No. 6/2, Aladahalli Village,
Sompura Hobli, Nelamangala Taluk,
Bengaluru Rural - 562 111, India.
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