Package leaflet: Information for the Patient

MAXTRA® Oral Drops

(Phenylephrine Hydrochloride 5mg/Chlorpheniramine Maleate 2mg Oral Drops 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® is and what it is used for

MAXTRA® is an Oral Drops 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® drops 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® Oral Drops:

- 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 you have kidney or liver problems, overactive thyroid, diabetes, high blood pressure or heart or circulation disease
- 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

Pregnancy and breastfeeding: Not applicable.

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
- 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)
- Drugs to lower blood pressure
- Appetite suppressants or stimulants
- 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
Not applicable.

3. How to take MAXTRA® Oral Drops
Check the seal is not broken before first use. If it is, do not give the medicine. Give this medicine to your child to swallow Do not give more than the amount recommended.

A 1 ml dropper with markings is provided with the solution to administer medication accurately to children. The markings on the dropper allow caregivers to measure precise doses, ensuring the child receives the correct amount of medication. This helps in preventing underdosing or

overdosing, which is particularly important for maintaining the efficacy and safety of the treatment in pediatric patients.

The recommended dosage of MAXTRA® in
In children 4 to 6 years: 0.5 ml every 4 to 6 hours or as directed by physician.
In children > 6 to 12 years: 1 ml every 4 to 6 hours
Adults and children > 12 years: 2 ml every 4 to 6 hours

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

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.

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 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® Oral Drops
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

A Bottle of 15 ml.

What MAXTRA® Oral Drops contains
Each ml contains:
Phenylephrine Hydrochloride IP 5 mg
Chlorpheniramine Maleate IP 2 mg
Excipients q.s.
In a flavoured syrup base

Manufacturer

Zuventus healthcare Ltd.

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Station, Nahur (West), Mumbai - 400 078, India.
At: A-22, M.I.D.C., Additional Ambernath,
District Thane - 421 506.
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