

PATIENT INFORMATION LEAFLET

Maxtra-P Oral Drops

Paracetamol, Phenylephrine Hydrochloride, Chlorpheniramine Maleate

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, 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.

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1. What Maxtra-P Oral Drops is and what it is used for

Maxtra-P Oral Drops contains a combination of ingredients which are effective in relieving the symptoms associated with colds and flu, including relief of aches and pains, sore throats, headache, nasal congestion and lowering of temperature.

Paracetamol is a painkiller and reduces your temperature when you have a fever.

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

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

2. What you need to know before you take Maxtra-P Oral Drops

Do not take Maxtra-P Oral Drops:

- If you have ever had an allergic reaction to any of the ingredients

- 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) or if you are taking or have taken within the last two weeks monoamine oxidase inhibitors (MAOIs) (e.g. moclobemide) prescribed for depression
- If you are taking beta blockers
- If your child is under 2 years of age

Take special care with Maxtra-P Oral Drops

- **Contains paracetamol.** Taking too much paracetamol can cause serious harm to your liver.
- **Do not drive or operate machinery.** This product may cause dizziness. If affected do not drive or operate machinery.
- **Do not drink alcohol** (beer, wine, spirits etc) while taking this product.

Ask your doctor before you take this medicine

- If you have a blood vessel disease such as Raynaud's Phenomenon
- If you have an enlarged prostate
- If you have epilepsy, heart or circulation disease, liver 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
- If you have high blood pressure or glaucoma
- If you have asthma, bronchitis or bronchiectasis
- If you have an overactive thyroid
- If you have difficulty passing urine
- If you have an obstruction in their intestine
- If you have a rare blood disease called porphyria

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

If you are taking other medicines

Talk to your doctor or pharmacist before taking Maxtra-P Oral Drops 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) tranquillisers or other medicines for mental problems
- Drugs to treat heart disease (e.g. Digoxin)

- If you take blood thinning drugs (anticoagulants e.g. Warfarin)
- Other antihistamines
- Strong painkillers
- Sleeping tablets
- Phenytoin (for epilepsy)
- Atropine

Driving and using machines: This medicine may cause drowsiness. If affected do not drive or operate machinery. Avoid alcoholic drink

Pregnancy and breast feeding

Do not use if you are pregnant or breast feeding unless advised by a doctor.

3. How to take Maxtra-P Oral Drops

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

2 to 5 years of age	1 ml every 4 to 6 hours or as directed by physician
6 to 11 years of age	2 ml every 4 to 6 hours

Do not give to children under 2 years.

Do not give more than the amount recommended above.

If symptoms do not go away within 5 days talk to your pharmacist or doctor.

If you take too much: Talk to your doctor or go to your nearest hospital casualty department straight away. Take the medicine and this leaflet with you.

4. Possible side effects

Like all medicines, Maxtra-P Oral Drops can have side effects, but not everybody gets them. A small number of people have had side effects.

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.
- Very rare cases of serious skin reactions have been reported.
- Skin rash or peeling, or mouth ulcers, sensitivity to sunlight, other allergic reactions
- Breathing problems. These are more likely if you have experienced them before when taking other painkillers such as ibuprofen or aspirin.
- Unexplained bruising or bleeding.
- Reoccurring fevers or infections.
- Nausea, sudden weight loss, loss of appetite
- Visual disturbances. This is rare but is more likely in those with glaucoma.

- Difficulty passing water. This is more likely to occur in men with an enlarged prostate gland.
- Drowsiness (which may make your child fall asleep)
- Dizziness, blurred vision, headaches, fits
- Dry mouth, difficulty in passing urine, sweating
- 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

These reactions are rare.

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.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

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 Maxtra-P Oral Drops

Store at a temperature not exceeding 25°C

Keep out of reach of children.

Protect from light.

6. Contents of the pack and other information

What Maxtra-P Oral Drops contains

Each ml contains:

Paracetamol 125 mg

Phenylephrine Hydrochloride 2.5 mg

Chlorpheniramine Maleate 1 mg

Packing

A bottle of 15 ml

Marketing Authorisation Holder

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Nahur (W), Mumbai, 400078 Maharashtra, India

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