Package leaflet: Information for the patient

Maxtra Gargle Oral Rinse

(Benzydamine Mouthwash BP 0.15% w/v)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you.

• This medicine is available without prescription. However, you still need to use it carefully to get the best results.

• Keep this leaflet. You may need to read it again.

• Ask your doctor, dentist or pharmacist if you need more information or advice.

• You must contact a doctor if your symptoms worsen or do not improve.

• 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 Gargle Oral Rinse is and what it is used for

2. What you need to know before you use Maxtra Gargle Oral Rinse

3. How to use Maxtra Gargle Oral Rinse

4. Possible side effects

5. How to store Maxtra Gargle Oral Rinse

6. Contents of the pack and other information.

1. What Maxtra Gargle Oral Rinse is and what it is used for

Maxtra Gargle Oral Rinse contains the active substance Benzydamine hydrochloride which is a locally acting analgesic and anti-inflammatory. Maxtra Gargle Oral Rinse used for the relief of painful inflammatory conditions of the mouth and throat including:

- Sore throat following removal of the tonsils
- Mouth ulcers, Sore throat, Mouth ulcers due to radiation therapy
- For use after dental operations, discomfort associated with Dentures or dental work

2. What you need to know before you use Maxtra Gargle Oral Rinse

Do not use Maxtra Gargle Oral Rinse if:

• you are allergic to benzydamine hydrochloride

• you are allergic to any of the other ingredients of Maxtra Gargle Oral Rinse (see section 6).

Warnings and Precautions

Talk to your doctor, pharmacist or nurse before using Maxtra Gargle Oral Rinse**:**

• If you have a history of asthma

• If you are allergic to acetylsalicylic acid or other non-steroidal anti-inflammatory (NSAID) drugs

If any of these apply to you, talk to your doctor, dentist or pharmacist.

Other medicines and Maxtra Gargle Oral Rinse

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and 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.

3. How to use Maxtra Gargle Oral Rinse

Important:

Always use Maxtra Gargle Oral Rinse exactly as your Doctor/Pharmacist has told you. You should check with your doctor, dentist or pharmacist if you are not sure.

If you get Maxtra Gargle Oral Rinse in your eyes

Do not use Maxtra Gargle Oral Rinse in or near your eyes.

If any Oral Rinse gets in your eyes, wash them immediately with cold water.

How much Maxtra Gargle Oral Rinse to use

- Adults, adolescents and elderly: The usual dose is 15 ml of solution to be used every 1½ to 3 hours. Use the measuring cup provided to measure the dose.
- Children: This medicine is not suitable for children aged 12 years or under.

How to use the Oral Rinse

The solution should be rinsed around the mouth or used as a gargle for 20 to 30 seconds and then spat out.

This solution should not be swallowed. This solution should not be used for more than 7 days unless your doctor or dentist tells you to.

If your symptoms worsen or do not improve contact your doctor.

If you use more Maxtra Gargle Oral Rinse than you should

If you take too much or you accidentally swallow large quantities of your medicine, contact immediately your doctor or pharmacist for advice.

If you forget to use Maxtra Gargle Oral Rinse

Do not take a double dose to make up for a missed dose. Simply take the next dose as planned. If you have any further questions about the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Maxtra Gargle Oral Rinse can cause side effects, although not everybody gets them.

Some side effects could be serious. If you have any of the side effects listed below, seek immediate medical help:

- Serious allergic reaction (anaphylactic shock), signs of which may include difficulty breathing, chest pain or chest tightness, and/or feeling dizzy/faint, severe itching of the skin or raised lumps on the skin, swelling of the face, lips, tongue and/or throat, and which may be potentially life threatening.

Other side effects include the following, if they get serious, please tell your doctor:
Uncommon (affects 1 in 1,000 people):

- Numbness and/or stinging in the mouth and/or throat.

Very rare (affects less than 1 in 10,000 people):

- Difficulty breathing and wheezing
- Itching
- Skin rash.

Not known (frequency cannot be estimated from the available data)
• Skin redness or swelling
• Allergic reaction (Hypersensitivity).

If this solution stings your mouth, the next dose can be diluted with some water to reduce this effect.
Some people may react after using the product with a severe allergic reaction experiencing symptoms as described above (a so called anaphylactic reaction) which may be potentially life-threatening. In this case you should seek immediate medical assistance.

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 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 Gargle Oral Rinse

- Keep out of the sight and reach of children.
- Do not use Maxtra Gargle Oral Rinse after the expiry date on the bottle. The expiry date refers to the last day of that month.
- If you store the product without the original carton, make sure it is kept out of the direct sunlight.
- Medicines should not be disposed of via wastewater or household waste.
- Return any medicine you no longer need to your pharmacist.

6. Contents of the pack and other information

What Maxtra Gargle Oral Rinse contains:

The active substance is benzydamine hydrochloride.

Benzydamine Hydrochloride BP ……0.15% w/v
Hydrochloric flavoured vehicle containing Ethanol IP 10%.....q.s.

The other ingredients are tartrazine supra & brilliant blue FCF.

For advice on what to do if you are allergic to any of these ingredients see section 2.

What Maxtra Gargle Oral Rinse looks like
It comes in a PET clear 120 ml bottle with silver cap and 15 ml measuring cup

Marketing Authorisation Holder

Zuventus Healthcare Limited
Zuventus House, Plot Y2, CTS No.: 358/A2,
Near Nahur Railway Station,
Nahur (W), Mumbai 400 078, Maharashtra, India.

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