

**MEDICA THROAT SPRAY MENTHOL, 20 mg/10 ml; 5 mg/10 ml,
oromucosal spray
Chlorhexidine gluconate - Lidocaine hydrochloride**

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

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



- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 to 4 days.

What is in this leaflet:

1. What Medica throat spray menthol is and what it is used for.
2. What you need to know before you use Medica throat spray menthol.
3. How to use Medica throat spray menthol.
4. Possible side effects.
5. How to store Medica throat spray menthol.
6. Contents of the pack and other information.

1. WHAT MEDICA THROAT SPRAY MENTHOL IS AND WHAT IT IS USED FOR.

Medica throat spray menthol is a spray for local action in the mouth and the pharynx.

It is an antiseptic and local pain-killer.

Medica throat spray menthol is recommended for:

- The treatment of the symptoms of a sore throat, red throat, disorders of the pharynx accompanied by irritation.
- In case of a bacterial infection accompanied by fever, an additional treatment is necessary.
- Medica throat spray menthol is sugar-free and is therefore also suited for diabetics.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MEDICA THROAT SPRAY MENTHOL.

Do not use Medica throat spray menthol

- If you are allergic to chlorhexidine gluconate or lidocaine hydrochloride or any of the other ingredients of Medica throat spray menthol (listed in section 6).
- On children younger than 6 years old.

Warnings and precautions

Talk to your doctor or pharmacist before using Medica throat spray menthol.

- Medica throat spray should not be used for long periods, uninterruptedly or repeatedly. Limit the use to the strictly necessary relief of pain and irritation.
- Eye and ear contact has to be avoided. If the spray enters the eyes, promptly wash these with plenty of water.
- In case of an excessive dose (more than 1 bottle per day) there is a small risk of decrease of the control over the swallowing reflex.
- For young children who have a history of convulsions. This medicine actually contains menthol.
- Medica throat spray menthol contains alcohol. Please also read the section headed: "Medica throat spray menthol contains menthol and alcohol".
- If you are using other medication. Please also read the section headed: "Other medicines and Medica throat spray menthol".

Consult your doctor if one of the above warnings applies to you, or if this has been the case in the past.

Children

Do not use this medicine on children younger than 6 years old.

Other medicines and Medica throat spray menthol

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

- Do not use simultaneously with medication for mild cases of Alzheimer's (cholinesterase inhibitors).
- Do not use simultaneously with other disinfectants.

Medica throat spray menthol with food and drink

No special precautions needed.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Medica throat spray menthol contains alcohol. Please also read the section headed: "Medica throat spray menthol contains menthol and alcohol".

If the precautions aforementioned are respected, Medica throat spray menthol may be used during pregnancy and breast-feeding. You are advised to inform your doctor that you are using this medicine.

Driving and using machines

No special precautions needed.

Medica throat spray menthol contains menthol and alcohol

Medica throat spray menthol contains menthol: be careful with young children who have a history of convulsions.

Medica throat spray menthol contains alcohol (44,4% (v/v) ethanol), i.e. up to 180 mg per 5 sprays, equivalent to 4,5 ml beer or 2 ml wine per 5 sprays. This is harmful for those suffering from alcoholism. This must be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

3. HOW TO USE MEDICA THROAT SPRAY MENTHOL.

Always use Medica throat spray menthol exactly as your doctor or pharmacist has told you.

Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

Adults and children from 12 years old: 3 to 5 sprays per time, 6 to 10 times per day.

Children from 6 years old: 2 to 3 sprays per time, 3 to 5 times per day.

Aim the atomizer towards the pharynx and press the sprinkler nozzle.

This medicine must not be used for long periods. Consult a doctor, if your symptoms worsen or do not improve after 3 to 4 days.

When the product after a number of applications is no longer used, the risk of a clogged atomizer exists, causing the pump to stop working. To avoid this problem, it is necessary to remove the atomizer from the pump and to put in a cup of hot water for several minutes. Allow the atomizer to dry before attaching it back to the pump.

If you use more Medica throat spray menthol than you should

If you have used too much Medica throat spray menthol, contact your doctor, your pharmacist or the Anti-Poison center (070/245.245) immediately.

This medicine contains only a fraction of the toxic dose. If used appropriately the risks of an overdose are very small.

Symptoms of an overdose are: restlessness, tinnitus, breathing difficulties, disruption of the cardiac rhythm, decrease of the control over the swallowing reflex.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS.

Like all medicines, Medica throat spray menthol can cause side effects, although not everybody gets them.

- Very seldom: allergic reactions of the skin and of mucous membranes.
- Taste disorders, an irritating feeling on the tongue, and severe allergic reactions (anaphylactic reactions) may occur.
- In case of protracted and uninterrupted use a brown colouring of the teeth can occur. This brown colour is easy to remove, however.

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

5. HOW TO STORE MEDICA THROAT SPRAY MENTHOL.

Keep this medicine out of the sight and reach of children. Store below 25°C. Do not use Medica throat spray menthol after the expiry date which is stated on the label/the carton after “EXP”.

The first two figures indicate the month, the following two or four figures the year. The expiry date refers to the last day of that month.

6. CONTENTS OF THE PACK AND OTHER INFORMATION.

What Medica throat spray menthol contains

- The active substances are: chlorhexidine gluconate 20 mg/10 ml – lidocaine hydrochloride 5 mg/10 ml.
- The other ingredients are: ethanol – glycerol – menthol – eucalyptol – saccharin sodium – citric acid monohydrate – purified water.

What Medica throat spray menthol looks like and contents of the pack

Medica throat spray menthol is available in a bottle with spray pump with 30 ml oromucosal spray (absorption through the mucous membrane of the mouth).

Marketing Authorisation Holder and Manufacturer

Laboratoria QUALIPHAR N.V./S.A. - Rijksweg 9 - 2880 Bornem - Belgium

Marketing authorisation number: BE167894

Freely available.

Also available in the same range:

MEDICA THROAT SPRAY LEMON, 20 mg/10 ml; 5 mg/10 ml, oromucosal spray: Antiseptic and local pain-killer for the mouth and the pharynx

MEDICA THROAT TABLETS MENTHOL, 5 mg/1 mg, compressed lozenges: Antiseptic and local pain-killer for the mouth and the pharynx

MEDICA THROAT TABLETS LEMON, 5 mg/1 mg, compressed lozenges: Antiseptic and local pain-killer for the mouth and the pharynx

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