

Package leaflet: Information for the user

Medispray oromucosal spray, solution Chlorhexidine digluconate 2 mg/ml Lidocaine hydrochloride monohydrate 0.5 mg/ml

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 2 days.

What is in this leaflet:

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

1. WHAT MEDISPRAY IS AND WHAT IT IS USED FOR.

Medispray is a spray for local action in the throat.

It is an antiseptic and local pain-killer.

Medispray is recommended for:

- The treatment of the symptoms of painful, irritated sore throats.

Medispray is for use in adults, adolescents and children over 12 years.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE MEDISPRAY.

Do not use Medispray

- If you are allergic to chlorhexidine digluconate or lidocaine hydrochloride monohydrate or any of the other ingredients of Medispray (listed in section 6).
- If you have an allergy to any other local anaesthetics.
- In children younger than 12 years old.
- If you suffer from a blood disorder called methaemoglobinaemia (change in the haemoglobin in the blood).
- Do not use and see your doctor if you have difficulty in swallowing.
- You must see a doctor if your sore throat worsens during use, does not improve after 2 days or is accompanied by high fever, headache, nausea or vomiting.

Medispray may very rarely cause generalised allergic reactions and anaphylactic shock.

If you experience any of the following reactions stop using Medispray and get immediate medical help:

Swelling of the face, lips, tongue or throat; a red itchy skin rash; wheezing or difficulty breathing; feeling faint and dizzy; a strange metallic taste in the mouth; collapse.

You may be having an allergic reaction.

Warnings and precautions

Talk to your doctor or pharmacist before using Medispray.

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.
- If you have asthma.

- If you have severe shock.
- If you have heart block.
- Do not exceed the stated dose.
- Medispray is not intended for prolonged use. It should only be used when clearly necessary for the relief of pain and irritation.
- Medispray should be used with caution if the lining (mucous membrane) of the throat is damaged. Avoid eye and ear contact. 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 difficulty swallowing and food inhalation.
- Medispray contains alcohol. Please also read the section headed: "Medispray contains alcohol".
- If you are using other medication. Please also read the section headed: "Other medicines and Medispray".

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 in children younger than 12 years old.

Other medicines and Medispray

Interactions with other medicines is unlikely following short term treatment with low dose topical lidocaine (Medispray) when used at the recommended doses, however please tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Medispray with food and drink

No special precautions needed.

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 or pharmacist for advice before taking this medicine.

Medispray contains alcohol. Please also read the section headed: "Medispray contains alcohol".

Driving and using machines

No special precautions needed.

Medispray contains alcohol

This medicine contains 139 mg of alcohol (ethanol) in each dose (5 sprays of 0.425 ml) which is equivalent to 41.6 % (v/v). The amount in each dose (5 sprays) of this medicine is equivalent to 3.5 ml of beer or 1.5 ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects.

Medispray contains sodium

Medispray contains less than 1 mmol sodium (23 mg) per dose unit, that means that it is essentially 'sodium-free'.

Medispray is a sugar free preparation and can be used by patients with diabetes.

3. HOW TO USE MEDISPRAY.

Always use Medispray exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

This medicine must not be used for long periods. Consult your doctor if your symptoms worsen or do not improve after 2 days.

It is advisable to clean the nozzle preventively on a daily basis with the following procedure:

1. Turn the spray upside down and press the spray head until no more liquid comes out.
2. Remove the nozzle from the spray pump and place it in a hot water bath for a few minutes.
3. Take the nozzle out of the water and let it dry.
4. Place the dry nozzle on the spray pump by turning it downwards so that it blocks the spray pump.

Please note that prior to first use or re-use 8 actuations must be fired to waste.
Aim nozzle at back of throat and spray on to the affected area.
Do not inhale whilst using the spray.

Do not exceed the stated dose.

The recommended dose is:

Adults, adolescents and children over 12 years

The dose is 3 to 5 sprays (0.3 - 0.5 ml). This can be repeated 6 to 10 times per day.
The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.
Repeat the dose every hour as needed up to a maximum of ten times in 24 hours.

Children under 12 years

Should not be used in children under 12 years of age.

If you use more Medispray than you should

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

If you accidentally swallow some liquid straight from the bottle, see a doctor straight away. Take the pack with you to show which medicine you have swallowed.

If you forget to use Medispray

Do not take a double dose to make up for a forgotten dose.

If you stop using Medispray

No special precautions needed.

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

4. POSSIBLE SIDE EFFECTS.

Like all medicines, Medispray can cause side effects, although not everybody gets them.

The following severe side effects may occur:

Rare (may affect up to 1 in 1,000 people):

Allergic reactions, hypersensitivity, anaphylactic shock

In any of these cases you should stop the treatment and immediately contact your doctor or pharmacist.

The following side effects may occur as well:

Not known (frequency cannot be estimated from the available data):

Skin inflammation, itching, redness of the skin, eczema, rash that can be accompanied by itchy skin bumps, skin irritation and blisters.

Taste disorders, a burning feeling on the tongue and occasionally swollen glands.

Brown-discoloration of the teeth and tongue that is removable.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

HPRA Pharmacovigilance

Website: www.hpra.ie

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE MEDISPRAY.

Keep this medicine out of the sight and reach of children. Store below 25°C. Do not refrigerate or freeze. Do not use this medicine after the expiry date which is stated on the label/the carton after "EXP". The expiry date refers to the last day of that month. Discard 3 months after first use. Do not

throw away any 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.

What Medispray contains

- The active substances are: chlorhexidine digluconate 2 mg/ml and lidocaine hydrochloride monohydrate 0.5 mg/ml. 1 spray contains 177 micrograms chlorhexidine digluconate and 42 micrograms lidocaine hydrochloride monohydrate.
- The other ingredients are: ethanol, glycerol, levomenthol, cineole, saccharin sodium, citric acid monohydrate, purified water.

What Medispray looks like and contents of the pack

Medispray is a clear, colourless solution. Medispray is available in a bottle with spray pump with 30 ml oromucosal spray, solution (absorption through the mucous membrane of the mouth).

Bottle: Glass bottle, amber

Closure: Synthetic pump dip tube, tamper proof cap and cannula (polypropylene, polyethylene, stainless steel, butyl and acetalic resin).

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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

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