#### **Consumer Medicine Information**

#### What is in this leaflet

This leaflet answers some of the common questions people ask about Mucosoothe. It does not contain all the information that is known about Mucosoothe.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

#### Keep this leaflet with the medicine.

You may need to read it again.

#### What Mucosoothe is for

Mucosoothe is indicated for the topical anaesthesia and relief of pain and discomfort of mucous membranes of the mouth, throat and upper gastrointestinal tract.

The active ingredient, lignocaine belongs to a group of medicines called local anaesthetics. It works by making the nerves unable to pass messages to the brain.

Your doctor will have explained why you are being treated with Mucosoothe and told you what dose you should use.

### Follow all directions given to you carefully.

They may differ from the information contained in this leaflet.

Your doctor or pharmacist may recommend this medicine for another use. Ask them if you want more information.

Mucosoothe is not addictive.

#### Before you use Mucosoothe

#### When you must not use it

Do not use Mucosoothe if you are pregnant or breastfeeding unless your doctor says it is safe. Ask your doctor about the risks and benefits involved.

Lignocaine has been widely used during pregnancy and there have been no reports of any ill effects on the baby.

When used correctly, it is unlikely that any Mucosoothe will get into your breast milk if you are breastfeeding.

Do not use Mucosoothe for teething pain.

### Do not use Mucosoothe after the use by (expiry) date printed on the pack.

It may have no effect at all, or worse, an entirely unexpected effect if you take it after the expiry date.

Do not use Mucosoothe if the packaging is torn or shows signs of tampering.

Do not use it to treat any other complaints unless your doctor or pharmacist tells you to.

Do not give this medicine to anyone else. Before you start to use it

You must tell your doctor if:

- 1. you have any allergies to
- other local anaesthetics
- ingredients listed at the end of this leaflet
- any other substances
  If you have an allergic reaction, you may get a skin rash, hayfever, breathing difficulties or feel faint.

### 2. you have any of these medical conditions

- · epilepsy
- · heart problems
- · liver problems
- · kidney problems
- open wounds or infection where the solution will be used

It may not be safe for you to take Mucosoothe if you have any of these conditions.

#### Taking other medicines

### Tell your doctor if you are taking any other medicines, including

- · ones to control your heartbeat
- ones for blood pressure (antihypertensives)
- · ones for epilepsy or fits
- cimetidine
- any medicines that you buy at the chemist, supermarket or health food shop.

These medicines may affect the way Mucosoothe works.

Your doctor or pharmacist can tell you what to do if you are taking any of these medicines.

If you have not told your doctor or pharmacist about any of these things, tell them before you use any Mucosoothe.

#### Using Mucosoothe

#### How to use it

Shake the bottle well before use.

#### Adults

The dose is 15mL, not more often than every three hours as required. For anaesthesia (numbing) of the mouth swish the gel for 30 seconds and then spit out.

For anaesthesia (numbing) of the upper gastrointestinal tract and throat, the gel should be gargled and may be swallowed.

#### Children 3-12 years

No more than 4mg/kg (0.2mL/kg) of bodyweight or 5mL (100mg lignocaine HCl), whichever is lower, should be used as above, not more often than every three hours, as required. No more than 4 doses should be given in a 24 hour period.

#### Children under 3 years

No more than 4mg/kg (0.2mL/kg) of bodyweight or 1.25mL (25mg lignocaine HCl), whichever is lower, should be accurately measured and applied with a cotton swab to the area, not more often than every three hours, as required. No more than 4 doses should be given in a 24 hour period.

#### Overdose

Telephone your doctor or the Poisons Information Centre (13 11 26) or go to casualty at your nearest hospital immediately if you think that you or anybody else may have taken too much Mucosoothe even if there are no signs of discomfort or poisoning.

The lignocaine in Mucosoothe can be absorbed into the blood, therefore it is important to use the correct amount of this medicine to avoid an overdose.

The first signs of overdose are dizziness, blurred vision, tremor or nervousness. In the rare case of problems occurring, you will be watched closely by medical staff.

#### While you are using it

#### Things to be careful of

Be careful driving or operating machinery after you have been given Mucosoothe. You may be drowsy and your reflexes may be slow.

### You should not exceed the recommended dose unless your doctor tells you to.

This may cause serious side effects if too much Mucosoothe is taken.

## You must not eat or drink anything within 60 minutes of using Mucosoothe in the mouth or throat area.

You may swallow your food the wrong way, or burn or bite your mouth.

Please talk to your doctor or pharmacist about these possibilities if you think they may bother you.

If you show signs of systemic toxicity (eg. lethargy, shallow breathing, seizure activity), emergency medical attention should be sought immediately and no additional product should be administered.

#### Side effects

## Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Mucosoothe.

Mucosoothe will help to relieve pain and discomfort in most people, but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

### Tell your doctor if you notice any of the following and they worry you:

- skin rash or irritation
- drowsiness

These are all mild side effects of Mucosoothe.

# Tell your doctor immediately or go to casualty at your nearest hospital if you notice any of the following:

- wheezing or difficulty breathing
- · chest pain
- · severe rash or itching
- · increased sweating
- numbness

These are all serious side effects. You may need urgent medical attention.

Serious side effects are rare.

Lignocaine can pass into the bloodstream, and in high doses can rarely cause more serious side effects. These may include:

- fits
- unconsciousness
- breathing problems
- low blood pressure
- slow heartbeat
- collapse

These are very serious side effects. You will need urgent medical attention or hospitalisation.

All of these side effects are very rare.

## Tell your doctor if you notice anything else that is making you feel unwell.

Some people may get other side effects while taking Mucosoothe.

#### Storage

Keep your Mucosoothe in the bottle until it is time to use it. Keep tightly closed after use

Keep it in a cool place where the temperature stays below 30°C.

Do not store it or any other medicine in the bathroom or near a sink.

Heat and dampness can destroy some medicines.

### Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Do not leave it in the car on hot days.

#### Disposal

Ask your pharmacist what to do with any solution you have left over if your doctor tells you to stop using it, or you find that the expiry date has passed. Unused product should be discarded in a manner that prevents possible exposure to children and pets.

#### **Product Description**

Mucosoothe is a pink viscous solution, with a blackcurrant odour, packaged in a 200mL bottle.

Each mL contains:

- 21.3 mg lidocaine (lignocaine) hydrochloride monohydrate [equivalent to 20 mg of lidocaine (lignocaine) hydrochloride]
- Sodium methyl hydroxybenzoate
- Sodium propyl hydroxybenzoate
- Amaranth
- Blackcurrant flavour (PI number: 367)
- · Carmellose sodium
- Purified water

#### Sponsor

Orion Laboratories Pty Ltd T/A Perrigo Australia 25-29 Delawney Street Balcatta WA 6021

This leaflet was prepared in September 2015

Date of last amendment March 2020

Australian Registration Number:

Mucosoothe AUST R 239126

®Mucosoothe is a registered trademark of Orion Laboratories Pty Ltd