

# DIFFLAM MOUTH GEL

Benzydamine hydrochloride / Cetylpyridinium chloride (1% w/w / 0.1% w/w)

## What is in this leaflet

1. What Difflam Mouth Gel is used for
2. How Difflam Mouth Gel works
3. Before you use Difflam Mouth Gel
4. How to use Difflam Mouth Gel
5. While you are using it
6. Side effects
7. Storage and disposal of Difflam Mouth Gel
8. Product description
9. Manufacturer and Product Registration Holder
10. Date of revision

## What Difflam Mouth Gel is used for

Difflam Mouth Gel is used to relieve inflammation and pain in the mouth, denture ulcers and sore gums.

Cetylpyridinium chloride has antiseptic activities.

## How Difflam Mouth Gel works

Difflam Mouth Gel works by reducing the pain, redness and swelling.

## Before you use Difflam Mouth Gel

### -When you must not use it

Do not use this medicine if you have an allergy to:

- any medicine containing Benzydamine hydrochloride or Cetylpyridinium chloride
- any of the ingredients listed at the end of this leaflet.

Do not use this medicine if you are pregnant or plan to become pregnant. It may affect your developing baby if you use it during pregnancy. Your pharmacist or doctor will discuss the benefits and possible risks of taking the medicine during pregnancy.

Do not use this medicine after the expiry date printed on the pack or if the

packaging is torn or shows signs of tampering.

If you are not sure whether you should start using this medicine, talk to your pharmacist or doctor.

### -Before you start to use it

Tell your pharmacist if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your pharmacist if you have or have had any of the following medical conditions:

- impaired kidney or liver function

It is not known if Benzydamine hydrochloride or Cetylpyridinium chloride passes into the breast milk. Your pharmacist or doctor will discuss the potential benefits and risks of using the medicine if you are breastfeeding.

If you have not told your pharmacist or doctor about any of the above, tell him/her before you start using Difflam Mouth Gel.

### -Taking other medicines

Tell your pharmacist or doctor if you are taking any other medicines, including any that you get without a prescription or that are herbal from your pharmacy, supermarket or health food shop.

Your pharmacist or doctor will have more information on medicines to be careful with or avoid while using this medicine.

## How to use Difflam Mouth Gel

Follow all directions on the pack or those given to you by your pharmacist or doctor carefully.

If you do not understand the instructions on the box, ask your pharmacist or doctor for help.

### -How much to use

Apply approximately 1 cm of gel with finger and gently massage into the sore area. Do not eat or drink for 15 minutes.

Children under 6 years: Not recommended to use.

### -When to use it

Apply every 2-3 hours up to maximum 12 times per day.

### -How long to use it

Use Difflam Mouth Gel as long as necessary or as directed by your doctor or pharmacist.

### -If you forgot to use it

If you forget to use Difflam Mouth Gel, use the next dose as soon as you remember.

Do not take a double dose to make up for a dose you have missed.

### -If you use too much (overdose)

Immediately telephone your doctor for advice, or go to the Accident and Emergency at the nearest hospital. If you think that you or anyone else may have use or accidental swallow too much Difflam Mouth Gel, do this even if there are no signs of discomfort or poisoning.

## While you are using Difflam Mouth Gel

### -Things you must do

Your pharmacist or doctor will assess your condition and decide if you should continue to use the medicine.

### -Things you must not do

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

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not use more than the recommended dose unless your pharmacist or doctor tells you to.

-Things to be careful of

If your condition does not improve, please see your doctor or pharmacist for further advice.

**Side effects**

Tell your pharmacist or doctor as soon as possible if you do not feel well while you are using Difflam Mouth Gel.

This medicine helps most people, yet 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 attention if you get some of the side effects.

Do not be alarmed by the following list of possible side effects. You may not experience any of them.

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

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

- oral numbness
- burning and stinging sensation
- mouth dryness and thirst

The above list includes the side effects of your medicine. They are usually mild.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

These side effects are very rare. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Center for Adverse Drug Reaction Monitoring by calling Tel:03-78835549, or visiting the website [npra.moh.gov.my](http://npra.moh.gov.my) (Public→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))

**Storage and disposal of Difflam Mouth Gel**

-Storage

Keep your medicine in the original pack until it is time to use it.

Keep your medicine in a cool dry place where the temperature stays below 30° C.

Do not store Difflam Mouth Gel or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

-Disposal

Ask your pharmacist what to do with any medicine that is left over, or if the expiry date has passed.

**Product description**

-What it looks like

Difflam Mouth Gel is a clear, colourless, peppermint flavoured gel.

It is packed in a 10gm tube.

-Ingredients

-Active ingredient(s)

Each gm of Difflam Mouth Gel contains:

- Benzylamine hydrochloride 10mg
- Cetylpyridinium chloride 1mg

-Inactive ingredients

- saccharin sodium
- polysorbate 20
- glycerol
- hydroxyethylcellulose
- peppermint oil
- purified water

-MAL Number

MAL13015051ACZ

**Manufacturer**

Ensign Laboratories Pty Ltd  
490-500 Wellington Road,  
Mulgrave Victoria,  
Australia 3170.

**Product Registration Holder**

iNova Pharmaceuticals (Singapore) Pte Ltd (Incorporated in Singapore)  
Malaysia Branch  
6F-2A, 6<sup>th</sup> Floor,  
Tower 4, The PFCC,  
Jalan Puteri 1/2 , Bandar Puteri,  
47100 Puchong,  
Selangor, Malaysia

**Date of revision**

15/08/2018

**Serial Number**

NPRA(R4/1)140818/00240