

**PACKAGE LEAFLET**

Package leaflet: Information for the user  
**Difflam Cream 3% w/w Cream**  
Benzydamine hydrochloride

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

The name of your medicine is Difflam 3% w/w Cream, which will be called Difflam Cream throughout this leaflet

**What is in this leaflet:**

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

**1. WHAT DIFFLAM CREAM IS AND WHAT IT IS USED FOR**

Difflam Cream belongs to a group of medicines called non-steroidal anti-inflammatory drugs or NSAIDS.

Difflam Cream works by stopping pain and swelling (inflammation). When rubbed into the skin of the affected area it is used to treat aches and pains including:

- Sprains
- Strains
- Bruises
- Sore muscles
- Stiff joints
- Rheumatism

**2. WHAT YOU NEED TO KNOW BEFORE YOU USE DIFFLAM CREAM**

**Do not use Difflam Cream:**

- If you are allergic to benzydamine or any of the other ingredients of this medicine (listed in section 6).

### **Warnings and precautions**

Talk to your doctor or pharmacist before using Difflam Cream.

- The cream should be kept away from your eyes and mucosal surfaces (such as mouth, nose, genitals or anus).
- Avoid sun exposure during treatment.

Take special care with Difflam:

- If you have a history of Asthma.
- If you are allergic to acetylsalicylic acid or to other anti-inflammatory painkillers called NSAIDs

### **Other medicines and Difflam Cream**

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

### **Pregnancy and breastfeeding**

You should not use Difflam Cream while pregnant or breast-feeding unless your doctor tells you to.

### **Driving and using machines**

There is no known effect on driving or using machinery.

### **Difflam Cream contains methylhydroxybenzoate, propylhydroxybenzoate, cetyl alcohol, stearyl alcohol and propylene glycol**

Difflam Cream contains some ingredients that may cause side effects. These are:

- Stearyl alcohol, cetyl alcohol and propylene glycol, which may cause local skin reactions (e.g. contact dermatitis, which is an inflammation of the skin).
- Methylhydroxybenzoate and propylhydroxybenzoate, which may cause allergic reactions (possibly delayed).

## **3. HOW TO USE DIFFLAM CREAM**

Always use this medicine exactly described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Do not use Difflam Cream in or near your eyes, mouth, nose or around your genitals or anus. If any cream does get in or onto these parts of your body, wash them immediately with cold water.

Difflam Cream may be applied and massaged lightly into the skin up to three times a day, and in more severe conditions up to six times daily.

### **If you use more Difflam Cream than you should**

It should not cause any problems if you accidentally swallow some of your medicine. If you have any concerns, contact your doctor or pharmacist.

### **If you forget to use Difflam Cream**

Do not apply a double dose to make up for a missed dose. Simply apply the next dose as planned.

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

#### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, this medicine can cause side effects, although not everybody gets them. You may experience the following:

- Itching
- Skin rash
- Skin redness or swelling
- Difficulty breathing and wheezing
- Severe allergic reactions (anaphylactic reaction) which can be potentially life-threatening

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 via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

Some people become more sensitive to the effects of sunlight after using this cream. This means that the skin may become red and painful after only a few minutes in the sun. These side effects should disappear if you stop using the cream.

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

#### **5. HOW TO STORE DIFFLAM CREAM**

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the original container after “EXP”. The expiry date refers to the last day of that month.

Do not store above 25°C. Do not freeze. Keep the lid tightly closed.

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 Diffiam Cream contains**

The active substance is 3% w/w benzydamine hydrochloride. The other ingredients are glycerol monostearate 40-55 cetyl alcohol, decyl oleate, methyl hydroxybenzoate (E218), propylhydroxybenzoate (E216), propylene glycol, perfume eumulgin B1 (eumulgin B1 may contain cetyl and stearyl alcohol) and purified water.

**What Difflam Cream looks like and contents of the pack.**

Difflam Cream is a white to ivory-white homogeneous, perfumed cream. It comes in a 50g tube.

**Marketing Authorisation Holder and Manufacturer****Marketing Authorisation Holder**

Mylan IRE Healthcare Limited,  
Unit 35/36, Grange Parade,  
Baldoye Industrial Estate,  
Dublin 13,  
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**Manufacturer**

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