Package leaflet: Information for the patient

Difflam-P 3% Cream or Difflam 3% Cream

Benzydamine hydrochloride

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

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

- This medicine is available without prescription. However, you still need to use it carefully to get the best results.
- Keep this leaflet. You may need to read it again.
- Ask your doctor or pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Difflam-P 3% Cream or Difflam 3% Cream is and what it is used for

Difflam-P 3 % Cream or Difflam 3 % Cream contains the active substance benzydamine hydrochloride and belongs to a group of medicines called nonsteroidal anti-inflammatory drugs or NSAIDS.

Difflam-P 3 % Cream or Difflam

3% 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.

2. What you need to know before you use Difflam-P 3% Cream or Difflam 3% Cream

Do not use Difflam-P 3% Cream or Difflam 3% Cream if

you are allergic to benzydamine hydrochloride

 you are allergic to any of the other ingredients of Difflam-P 3 % Cream or Difflam 3 % Cream (see section 6).

Warnings and precautions:

Talk to your doctor, pharmacist or nurse before using Difflam-P 3% Cream or Difflam 3% Cream:

- If you have a history of asthma
- If you are allergic to acetylsalicylic acid or other non-steroidal anti-inflammatory (NSAID) drugs

If any of these apply to you, talk to your doctor, dentist or pharmacist.

Other medicines and Difflam-P 3 % Cream or Difflam 3 % Cream

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

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.

Difflam Cream contains

- Cetyl alcohol which may cause local skin reactions (e.g. contact dermatitis)
- Propylene glycol which may cause skin irritation

3. How to use Difflam-P 3% Cream or Difflam 3% Cream

Important:

Always use Difflam-P 3% Cream or Difflam 3% Cream exactly as your pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

If you get Difflam-P 3% Cream or Difflam 3% Cream in your eyes, mouth, nose or around your genitals or anus.

Do not use Difflam-P 3 % Cream or Difflam 3 % 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.

How much Difflam-P 3% Cream or Difflam 3% Cream to use

The amount of cream used will depend on the size of the area to be treated.

The normal length of cream to be squeezed out of the tube is between a half and a full finger length (35-85 mm).

How to use the cream

Rub the cream gently into the affected area until it seems to disappear.

The cream should be used three times each day for no more than 10 days. Your doctor may tell you to use it more often.

Please wash your hands after applying the cream (unless your hands are being treated).

Contact your doctor if your symptoms worsen or they do not improve.

If you use more Difflam-P 3% Cream or Difflam 3% Cream than you should

It should not cause you any problems if if you use more of your medicine than you should. If you have any concerns, contact your doctor or pharmacist.

If you forget to use Difflam-P 3% Cream or Difflam 3% Cream

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

If you accidentally swallow Difflam-P 3% Cream or Difflam 3% Cream

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

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

4. Possible side effects

Like all medicines Difflam-P 3% Cream or Difflam 3% Cream can cause side effects, although not everybody gets them.

Some side effects could be serious. If you have any of the side effects listed below, seek immediate medical help:

 severe allergic reaction (anaphylaxis) seen as swelling of throat and mouth, difficulty in swallowing or speaking, alterations in heart rate, severe asthma, collapse and unconsciousness

Other side effects include the following, if they get serious, please tell your doctor:

The frequency of these side effects cannot be estimated from the available data:

- Increased sensitivity to sunlight
- Itching
- Skin rash
- Skin redness or swelling
- Difficulty breathing and wheezing

Some people may react after using the product with a severe allergic reaction experiencing symptoms as described above (a so called anaphylactic reaction) which may be potentially life-threatening. In this case you should seek immediate medical assistance.

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. The increased sensitivity to sunlight should disappear if you stop using the cream.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Difflam-P 3% Cream or Difflam 3% Cream

Keep out of the sight and reach of children. Do not use Difflam-P 3 % Cream or Difflam 3 % Cream after the expiry date on the tube. The expiry date refers to the last day of that month. Do not store above 30 °C. Do not store in the refrigerator or freezer.

Medicines should not be disposed of via wastewater or household waste.

Return any medicine you no longer need to

your pharmacist. 6. Contents of the pack and

other information

What Difflam-P 3% Cream or Difflam 3% Cream contains

The active substance is 3 % w/w benzydamine hydrochloride.

The other ingredients are glycerol monostearate 40–55, cetyl alcohol, decyl oleate, eumulgin B1, propylene glycol, perfume, methyl hydroxybenzoate, propyl hydroxybenzoate and purified water.

For advice on what to do if you are allergic to any of these ingredients see section 2.

What Difflam-P 3% Cream or Difflam 3% Cream looks like

Difflam-P 3% Cream or Difflam 3% Cream is a white cream. It comes in a 35 g, 50 g or 100 g tube. Not all pack sizes may be marketed.

Marketing Authorisation Holder

Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

Manufacturer

Mahuacuter
3M Health Care Limited
3M House
Morley Street
Loughborough
Leicestershire
LE11 1EP

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If this leaflet is difficult to see or read or you would like it in a different format, please contact Mylan Products Ltd, Station Close, Potters Bar, Hertfordshire, EN6 1TL, United Kingdom.

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