

PACKAGE LEAFLET: INFORMATION FOR THE USER

Difene Spray Gel 4%w/w cutaneous spray, solution

Diclofenac sodium

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, please 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

What is in this leaflet:

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

1. What Difene Spray Gel is and what it is used for

Difene Spray Gel contains the active substance diclofenac sodium, which belongs to the group of non-steroidal anti-inflammatory drugs (NSAID). Difene Spray Gel is used for the local symptomatic relief of mild to moderate pain and inflammation following acute blunt trauma of small and medium-sized joints and surrounding structures.

2. What you need to know before you use Difene Spray Gel

Do not use Difene Spray Gel

- If you are allergic to diclofenac sodium, peanut, soya or any of the other ingredients of Difene Spray Gel (listed in section 6).
- If you have ever had an allergic reaction to aspirin (acetylsalicylic acid) or any other NSAID such as ibuprofen with difficulty in breathing, skin rash and runny nose.
- In the last three months of pregnancy – please see section on pregnancy and breast-feeding.
- On open injuries, inflammations or infections of the skin as well as on eczema or mucous membranes.
- In children and adolescents under 14 years of age.

Warnings and precautions

Talk to your doctor or pharmacist before using Difene Spray Gel

- If you have or have had stomach ulcers, liver or kidney problems, a tendency for bleeding or inflammatory bowel disease.
- If you have previously suffered from bronchial asthma or allergies.
- Do not use in eyes, nose or mouth and on open wounds or infected skin areas. If you accidentally get some spray into your eyes rinse thoroughly with clear water and inform your doctor.
- Never swallow Difene Spray Gel
- Do not sunbathe or use sunlamps whilst using this medicine.
- Discontinue use of Difene Spray Gel if any skin rash develops.

- Do not cover the treated area with occlusive (waterproof or non breathable) bandages or plasters.

Do not use near an open flame, lit cigarette or some devices (e.g. hairdryers).

The possibility of systemic side effects from use of Difene Spray Gel cannot be excluded if the medicine is used on large areas of skin and over a prolonged period.

Side effects may be reduced by using the minimum effective dose for the shortest possible duration.

Other medicines and Difene Spray Gel

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

Speak to your doctor before you use Difene Spray Gel:

- If you are taking tablets, capsules or suppositories for pain including any containing diclofenac sodium, acetylsalicylic acid (aspirin) or any other anti-inflammatory agent, as for example ibuprofen. The use of other NSAID (including acetylsalicylic acid or ibuprofen) at the same time as Difene Spray Gel may increase the risk of side effects.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Difene Spray Gel must not be used during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.

Difene Spray Gel should only be used under medical advice during the first 6 months of pregnancy and the dose should be kept as low and duration of treatment as short as possible.

Difene Spray Gel should only be used under medical advice, during breast-feeding as diclofenac sodium passes into breast milk in small amounts. However, Difene Spray Gel should not be applied on the breasts of nursing mothers nor elsewhere on large areas of skin or for a prolonged period of time.

Driving and using machines

Cutaneous application of Difene Spray Gel has no influence on the ability to drive and use machines.

Difene Spray Gel contains

This medicinal product contains:

- propylene glycol (E1520) which may cause mild localised skin irritation in some people. This medicine contains 30 mg propylene glycol in each pump stroke, which is equivalent to 150 mg for each gram of solution.
- peppermint oil which may cause allergic reactions,
- soya, if you are allergic to peanut or soya, do not use this medicinal product.
- 33.3 mg of alcohol (ethanol) per gram, which is equivalent to 3.3% w/w. It may cause a burning sensation on damaged skin.

3. How to use Difene Spray Gel

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

- Remove the protective cap.

- Hold the bottle in an upright position and use as directed onto the painful or swollen site.
- Apply the recommended number of spray strokes

Adults and children aged 14 years and over: The recommended dose is 4 to 5 strokes of Difene Spray Gel applied 3 times daily in regular intervals. The number of strokes depends on the size of the affected area. The maximum number of pump strokes is 15 times daily. The maximum single dose should not exceed 5 pump strokes.

- Difene Spray Gel should be massaged gently into the skin. Wash your hands afterwards unless they are the site being treated.
- Wait until Difene Spray Gel has dried before covering the skin with clothes or bandage. Take care as the spray can stain your clothes if wet.
- Discontinue treatment when your symptoms (pain and swelling) improve. Do not use for more than 7 days without consulting your doctor.
- If there is no improvement in your symptoms after 3 days, or if your symptoms worsen, talk to a doctor.

If you use more Difene Spray Gel than you should

- If you use more of your medicine than you should wipe the surplus Difene Spray Gel off with a tissue.
- If you swallow some of the spray inform your doctor immediately or go to the nearest hospital casualty. Take the bottle and this leaflet with you.

If you forget to use Difene Spray Gel

- Use the spray as soon as you remember, but do not apply more than the recommended dose at once. Then carry on as before.
- Do not use a double dose to make up for a forgotten dose.

If you have any further questions 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.

- Discontinue use of Difene Spray Gel if any skin rash develops. Following the use of topical (applied to the skin) diclofenac preparations reactions at the site of application have been reported commonly. These include rashes, itching, reddening, burning sensations or scaling of the skin.
- If you experience any of the following signs of allergy, **STOP using Difene Spray Gel and tell a doctor or pharmacist immediately:**
 - Skin rash with blisters (*rare: may affect up to 1 in 1,000 people*); hypersensitivity (including hives) (*very rare: may affect up to 1 in 10,000 people*).
 - Wheezing, shortness of breath or feeling of tightness in the chest (asthma) (*very rare: may affect up to 1 in 10,000 people*).
 - Swelling of the face, lips, tongue or throat (*very rare: may affect up to 1 in 10,000 people*).
- **Some side effects are common** (may affect up to 1 in 10 people):
Skin rash, eczema, reddening of the skin, dermatitis (including dermatitis contact), itching (pruritus)*.
- **Some side effects are very rare** (may affect up to 1 in 10,000 people):
The skin may be more sensitive to the sun. Possible signs are sunburn with itching, swelling and blistering.
Rash pustular.

- **Some side effects have unknown frequency** (frequency cannot be estimated from the available data):
Application site reaction, dry skin, burning sensation.

* Pruritus has been reported at a frequency of 0.9% in a clinical trial, 236 patients with ankle distortions were treated with 4-5 pump strokes of Difene Spray Gel t.i.d. (120 patients) or placebo (116 patients) for 14 days.

If the medicine is used for a prolonged period and/or it is used on large areas of the skin, systemic side effects such as stomach pain and disorders, heartburn, liver or kidney problems and hypersensitivity reactions may occur.

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

Website: www.hpra.ie

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

5. How to store Difene Spray Gel

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label, carton and bottle after EXP.

The expiry date refers to the last day of that month.

Store in the original package.

Do not use Difene Spray Gel after 6 months after first opening.

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. Content of the pack and other information

What Difene Spray Gel contains

The active substance is diclofenac sodium 4 % (w/w).

The other ingredients are: isopropyl alcohol, soy bean lecithin, ethanol, disodium phosphate dodecahydrate, sodium dihydrogen phosphate dihydrate, disodium edetate, propylene glycol (E1520), peppermint oil, ascorbyl palmitate, hydrochloric acid 10 % (w/w) or sodium hydroxide 10 % (w/w) (for pH-adjustment) and purified water.

What Difene Spray Gel looks like and contents of the pack

Difene Spray Gel is a golden-yellow, transparent solution, which turns to a gel-like consistency after administration. Each bottle contains 7.5 g, 12.5 g or 25 g cutaneous spray, solution.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Glenwood GmbH

Pharmazeutische Erzeugnisse

Arabellastraße 17

81925 München

Germany

Manufacturer

Pharbil Waltrop GmbH,
Im Wirrigen 25
45731 Waltrop, Germany.

This medicinal product is authorised in the Member States of the EEA and in the United Kingdom (Northern Ireland) under the following names:

United Kingdom (Northern Ireland)	Diclofenac Sodium Spray Gel 4% cutaneous spray, solution
Ireland	Difene 4% Spray Gel
Italy	Fastuadvance 4%, Spray cutaneo soluzione
Estonia	DicloFlex, 40mg/g, nahasprei, lahus
Germany	DicloSpray 40 mg/g Spray zur Anwendung auf der Haut, Lösung
Latvia	DicloFlex 4% uz ādas izsmidzināms aerosols, šķīdums
Hungary	Doloflex 4% külsőleges oldatos spray
Slovenia	DicloFlex 40 mg/g dermalno pršilo, raztopina
Spain	Dolomax 40 mg/ml solución para pulverización cutánea

This leaflet was last revised in June 2023.