

Package leaflet: Information for the user

Difene 1% w/w gel (DICLOFENAC SODIUM 1% GEL)

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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1. What DIFENE 1% w/w GEL is and what it is used for
2. What you need to know before you use DIFENE 1% w/w GEL
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1. What DIFENE 1% w/w GEL is and what it is used for

DIFENE 1% w/w GEL contains the active substance diclofenac sodium, which belongs to the group of non-steroidal anti-inflammatory drugs (NSAIDs).

DIFENE 1% w/w GEL is used to relieve the acute pain and swelling affecting small or medium-sized joints and surrounding tissues due to sprains, strains and bruising.

It can also be used for the treatment of soft tissue rheumatism.

2. What you need to know before you use DIFENE 1% w/w GEL

Do not use DIFENE 1% w/w GEL

- If you are allergic (hypersensitive) to diclofenac sodium or any other ingredient of DIFENE 1% w/w GEL. Please refer to section 6 of this leaflet for the ingredients of Difene.
- If you have ever had an allergic reaction (skin rash, difficulty in breathing or runny nose) to aspirin (acetylsalicylic acid) or any other NSAIDs such as ibuprofen.
- If you are in the last three months of pregnancy – please see section on ‘Pregnancy and breastfeeding’.
- If you have a stomach ulcer.
- If you have ever had an allergic reaction to propylene glycol or isopropyl alcohol.
- Use in children and adolescents is not recommended.

If any of these apply to you, tell your doctor or pharmacist. Your doctor will decide whether this medicine is suitable for you.

Warning and precautions

Talk to your doctor:

- If you have liver problems
- If you have kidney problems
- If you have a tendency for bleeding or inflammatory bowel disease

- If you have a history of stomach ulcers
- If you have ever suffered from bronchial asthma or any other allergies
- Do not use in eyes, nose or mouth and on open wounds or infected skin areas. If you accidentally get some gel into your eyes rinse thoroughly with clear water and inform your doctor
- If you have a history of gastrointestinal bleeding
- This medicine should be used with great caution with elderly patients
- Never swallow DIFENE 1% w/w GEL
- Do not sunbathe or use sunlamps whilst using this medicine
- Do not cover the treated area with occlusive (waterproof or non breathable) bandages or plasters
- This medicine is not to be used by children.

If you have been using Difene for a long time you should be under regular supervision by your doctor.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Speak to your doctor before you use DIFENE 1% w/w GEL if you are taking:

- tablets, capsules or suppositories for pain including any containing diclofenac sodium, aspirin or any other anti-inflammatory agent, for example ibuprofen
- water tablets (diuretic)
- steroids which are used as the main treatment for certain inflammatory conditions (corticosteroids)
- medicines used to thin your blood (anticoagulants) such as warfarin
- mood stabilising drugs such as lithium
- immunosuppressive agents are drugs that inhibit or prevent activity of the immune system (ciclosporine)
- medicines which may be used to treat cancer (methotrexate)
- tablets to treat diabetes
- medicines for heart conditions or high blood pressure (beta blockers, ACE inhibitors, digoxin)
- quinolone antibiotics (ciprofloxacin, ofloxacin)
- aminoglycosides antibiotics used in serious infections (streptomycin)
- drugs for the treatment of gout (probenecid)
- treatment of hypertension and congestive heart failure (angiotensin receptor blockers)
- if taking tablets to relieve the symptoms of inflammation and pain (COX inhibitors)
- anticoagulants such as heparin
- The use of acetylsalicylic acid or any other NSAIDs (including aspirin or ibuprofen) at the same time as DIFENE 1% w/w GEL may increase the risk of side effects
- medicine for epilepsy (phenytoin)
- cholesterol medication (colestipol)
- medicine used to reduce bile acid (cholestyramine)
- medicine used for gout (sulfapyrazone)
- antifungal medication (voriconazole)

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 are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Do not use DIFENE 1% w/w GEL if you are in the last 3 months of pregnancy. You should not use DIFENE 1% w/w GEL during the first 6 months of pregnancy unless clearly necessary and advised by your doctor. If you need treatment during this period, the lowest dose for the shortest time possible should be used.

Oral forms (e.g. capsules) of Difene can cause adverse effects in your unborn baby. It is not known if the same risk applies to DIFENE 1% w/w GEL when it is used on the skin.

Diclofenac sodium may be passed into breast milk. Therefore DIFENE 1% w/w GEL is not recommended for use by breast-feeding mothers and must not be applied to the breast area of breast-feeding mothers.

Consult your doctor for further information if you are pregnant or breast-feeding.

Important information about some of the ingredients of DIFENE 1% w/w GEL

- DIFENE 1% w/w GEL contains 250 mg propylene glycol in each gram of gel, which may cause skin irritation.

3. How to use DIFENE 1% w/w GEL

Always use DIFENE 1% w/w GEL exactly as your doctor has told you.

You should check with your doctor or pharmacist if you are not sure.

Adults:

- The usual dose is dependent on the size of the area to be treated and is usually a 3/4 to 1 inch (2–2.5 cm) diameter circle applied 2 to 4 times daily. DIFENE 1% w/w GEL must only be used on unbroken skin. It is important to use DIFENE 1% w/w GEL correctly. Follow the instructions carefully.
- Apply the prescribed amount of gel to the painful or swollen site.
- DIFENE 1% w/w GEL should be massaged gently into the skin. Wash your hands afterwards unless they are the site being treated.
- Do not cover the area where you have applied the gel with bandages or sticking plaster.
- If you experience no improvement after 2 weeks of use or your condition worsens talk to your doctor.
- Treatment with DIFENE 1% GEL should not exceed 6 weeks.
- Elderly patients are more prone to unwanted effects and the smallest amount possible should be used that will provide relief.

If you use more DIFENE 1% w/w GEL than you should

- If you use more of your medicine than you should wipe the surplus DIFENE 1% w/w GEL off with a tissue.
- If you swallow some of the gel inform your doctor immediately or go to the nearest hospital emergency department. Take the tube and this leaflet with you.

Using the gel over large areas of the body or for long periods of time may cause side effects as the medicine enters the blood stream.

Such as:

- Gastrointestinal disturbances
- Irritability
- Fluid retention
- Rash

- Renal dysfunction, in which kidneys don't work properly
- Anaphylaxis may occur, symptoms of which include swelling of the lips, face or neck leading to difficulties breathing.

It can rarely cause:

- Gastrointestinal bleeding
- Hepatitis
- A disease or disorder of the blood (blood dyscrasias)
- Difficulties in breathing and wheezing (bronchospasm)
- Allergic reaction caused by the medicine (erythema multiforme)

If you forget to use DIFENE 1% w/w GEL

- Use the gel as soon as you remember, but do not apply more than the recommended dose. Then carry on as before.
- Do not use a double dose to make up for a forgotten dose.
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If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, DIFENE 1% w/w GEL can cause side effects, although not everybody gets them.

Discontinue use of DIFENE 1% w/w GEL if any skin rash develops. Following the use of other topical (applied to the skin) Diclofenac preparations, reactions at the site of application have been reported. These include rashes, itching, reddening, burning sensations or scaling of the skin.

The frequency of the side effects listed below is defined using the following convention:

Very common ($\geq 1/10$);

Common ($\geq 1/100$ to $< 1/10$)

Uncommon ($\geq 1/1,000$ to $< 1/100$)

Rare ($\geq 1/10,000$ to $< 1/1,000$)

Very Rare ($< 1/10,000$)

Not Known (cannot be estimated from available data).

Common:

- Rash
- Eczema
- Redness of the skin
- Inflammation of the skin
- Itchy skin

Rare:

- Blisters on the skin

Very Rare:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing, skin rash or hives)
- Rapid swelling of the skin
- Rash which occurs with lesions
- Asthma, shortness of breath

- Photosensitivity reactions, abnormal responses to sunlight or artificial light.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 1% w/w GEL

- Keep out of the reach and sight of children.
- Do not store above 25°C.
- Do not use DIFENE 1% w/w GEL after the expiry date stated on the carton and bottle after EXP. The expiry date refers to the last day of that month.
- Once opened discard after 6 months.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What DIFENE 1% w/w GEL contains

- The active substance is diclofenac sodium 1% w/w.
- The other ingredients are hypromellose, propylene glycol, PEG-7-glycerylcocoate, isopropyl alcohol and purified water.

What DIFENE 1% w/w GEL looks like and contents of the pack

DIFENE GEL is a slight turbid, colourless gel which contains the active ingredient diclofenac sodium 1% w/w.

DIFENE-GEL is available in tubes of 50 g.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Glenwood GmbH

Arabellastraße 17

81925 München

Germany

Manufacturer:

C.P.M. Contract Pharma GmbH

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D-83620 Feldkirchen-Westerham

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