

PACKAGE LEAFLET: INFORMATION FOR THE USER

Diclac 1% w/w Gel

Diclofenac Sodium

ROWEX[®]

Read all of this leaflet carefully before you start taking 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Diclac Gel is and what it is used for
2. What you need to know before you use Diclac Gel
3. How to use Diclac Gel
4. Possible side effects
5. How to store Diclac Gel
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1 What Diclac Gel is and what it is used for

Diclac belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to treat pain and inflammation. Diclac Gel can be used topically to treat pain and inflammation in:

- Osteoarthritis of superficial joints such as the knee
- Localised forms of soft tissue rheumatism
- Trauma of tendons, ligaments, muscle and joints e.g. due to sprains, strains and bruises.

2 What you need to know before you use Diclac Gel

Do not use Diclac Gel if:

- you are allergic to diclofenac sodium or any of the other ingredients of this medicine (Listed in section 6)
- you are an asthmatic
- you have ever had an allergic reaction after taking medicines to treat inflammation or pain (e.g. acetylsalicylic acid/aspirin, diclofenac or ibuprofen). Reactions may include asthma, runny nose, skin rash, face swelling. If you think you may be allergic, ask your doctor for advice.
- you have broken or denuded skin
- you are pregnant or breast-feeding

If any of these apply to you, tell your doctor and do not use Diclac Gel. Your doctor will decide whether this medicine is suitable for you.

Warnings and precautions

Talk to your doctor or pharmacist before using Diclac if:

- you suffer from asthma, hayfever (seasonal allergic rhinitis) or any other long standing problem of the respiratory system such as nasal polyps or chronic obstructive airways disease
- you have a tendency to develop allergic skin rashes, skin itching or hives
- you have an inflammatory disease called systemic lupus erythematosus or any connective tissue disease
- you have a bleeding disorder, or any other blood problems, including the rare liver condition called porphyria
- you have a peptic ulcer, gastrointestinal bleeding or intestinal inflammation, of which may include blood in your stools or black stools
- you have liver or kidney problems

If any of these apply to you, tell your doctor before using Diclac Gel. Diclac Gel, like other anti-inflammatory medicines, may cause severe allergic skin reactions (e.g.rash). Therefore, inform your doctor immediately if you experience such reactions.

Elderly

Elderly patients may be more sensitive to the effects of Diclac Gel than other adults. Therefore,

they should follow doctor's instructions particularly carefully and use the lowest dose that provides relief of symptoms. It is especially important for elderly patients to report undesirable effects promptly to their doctor.

Children and adolescents below 14 years

Contraindicated

Other medicines and Diclac

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This is important because some medicines should not be taken together with diclofenac. No drug interactions during treatment with Diclac Gel have been reported, but the following interactions occur with oral forms of diclofenac.

It is particularly important to tell your doctor if you are taking any of the following medicines:

- lithium or selective serotonin-reuptake inhibitors (SSRIs, medicines used to treat some types of depression)
- digoxin (a medicine used for heart problems)
- diuretics (medicines used to increase the amount of urine)
- ACE inhibitors or beta-blockers (classes of medicines used to treat high blood pressure or heart failure)
- other anti-inflammatory medicines such as acetylsalicylic acid/aspirin or ibuprofen
- corticosteroids (medicines used to provide relief for inflamed areas of the body)
- anti-coagulants (medicines used to prevent blood-clotting)
- medicines used to treat diabetes, except insulin
- methotrexate (a medicine used to treat some kinds of cancer or arthritis)
- ciclosporin (a medicine primarily used in patients who have received organ transplants)
- some medicines used against infection (aminoglycosides, quinolone antibacterials)

Pregnancy and 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.

- During the first and second trimester of pregnancy, diclofenac should not be used unless clearly necessary.
- As with other NSAIDs it is advisable not to take diclofenac during the last three months of pregnancy as it could harm the unborn child or cause problems during delivery: The use of diclofenac is contraindicated in the third trimester of pregnancy.
- Do not use Diclac Relief Gel if you are breast-feeding, because small amounts can pass into breast milk and may harm your baby, although the systemic effect should be low.

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

Driving and using machines

Usually diclofenac does not affect your ability to drive and use machines. However, it may cause side effects such as blurred vision, dizziness or drowsiness (see section 4). If any of these affect you, do not drive or use machines and contact your doctor immediately.

3 How to use Diclac Gel

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

- Your doctor will tell you how to use Diclac Gel and how long to use it. It is important to use the lowest dose which adequately controls your inflammation/pain and for the shortest possible period of time. Review treatment after 14 days.
- Depending on how you first respond to the

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treatment your doctor might suggest changing to a higher or lower dose.

- Never exceed your doctor's recommended dose.
- Do not take by mouth.
- Be careful not to get the gel into your eyes. If this happens rinse your eyes with clean water and tell your doctor.
- Diclac Gel must be applied to intact skin and not be rubbed into open wounds, cuts or any other area where the skin is abnormal.
- After rubbing the gel into the skin, do not cover with bandages or sticking plaster.

Adults and children 14 years and over

Diclac should be rubbed gently into the skin around the painful or swollen area. Depending on the size of the site to be treated, 2-4 g (a circular shaped mass approximately 2.0-2.5cm in diameter) should be applied 3-4 times daily. After application the hands should be washed unless they are the site being treated. You may notice a slight cooling effect when you rub the gel into the skin.

Children aged 14 years and over

If the symptoms worsen the patient/parents of the adolescent is/are advised to consult the doctor.

Elderly

Older people tend to be more at risk of the side effects of NSAIDs, so it is particularly important that older people use the lowest possible dose of Diclac Gel which is effective.

If you use more Diclac Gel than you should

The low systemic absorption of topical diclofenac renders overdosage unlikely. If you have accidentally ingested Diclac Gel tell your doctor or pharmacist or go straight to the nearest hospital. If possible take your gel with you, so that the doctor can see what you have been taking.

If you forget to use Diclac Gel

If you forget to use Diclac Gel, apply it as soon as you remember, then go on as before. If it is nearly time for your next dose, you should simply apply the gel at the usual time. Do not apply more than the total daily dose in 24 hours.

Do not apply 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. Generally Diclac Gel is well tolerated, but there are a few side effects associated with this product.

Some rare or very rare side effects can be serious. Stop using Diclac Gel and tell your doctor straight away or go to the emergency department at your nearest hospital if any of the following happens:

- allergic reaction with swelling of the face, lips, mouth, tongue or throat often associated with rash and itching, which may cause difficulty to swallow, hypotension (low blood pressure), fainting, wheezing and feelings of tightness in the chest (signs of asthma).
- red or purple skin (possible signs of blood vessel inflammation), skin rash with blisters, blistering of the lips, eyes and mouth, skin inflammation with flaking or peeling.

If the product is used for a long time or applied to a relatively large area of skin, the possibility that diclofenac sodium may be absorbed cannot be ruled out. If absorbed the following effects could occur, but they would be very rare:

- stomach discomfort
- nausea
- vomiting
- diarrhoea

If you experience any of these, tell your doctor straight away.

Other side effects

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.

If you use Diclac Gel for more than a few weeks, you should make sure to visit your doctor for regular check ups to ensure that you are not suffering from unnoticed undesirable effects.

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 IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517.

Website: www.imb.ie;

e-mail: imbpharmacovigilance@imb.ie

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

5 How to store Diclac Gel

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 tube and carton after EXP.

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

Do not store above 25°C

Keep the tube 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 Diclac Gel contains

- The active substance is diclofenac sodium.
Each 50 g of gel contains 0.5 g diclofenac sodium
- The other ingredients are alpha-tocopherol (copherol F1300), carbomer (carbopol 980NF), decyl oleate, 2-octyldodecanol, lecithin (phospholipon 80), ammonia solution 10%, disodium edetate, perfume oil "verte de crème", isopropyl alcohol and purified water.

What Diclac Gel looks like and contents of the pack

Diclac Gel is a slightly yellow emulsion, cutaneous gel with an alcoholic smell. It is available in a 50 g tube.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Rowex Ltd, Bantry, Co Cork, Ireland

Manufacturers:

Salutas Pharma GmbH, Otto-von-Guericke Allee 1, 39179 Barleben, Germany

Salutas Pharma GmbH, Lange Göhren 3, 39171 Osterweddingen, Germany

Rowa Pharmaceuticals Ltd, Bantry, Co Cork, Ireland

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