

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

DICOREN GEL, 10 mg/g

Diclofenac sodium

Read all of this leaflet carefully because it contains important information for you

DICOREN GEL is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use DICOREN GEL carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share DICOREN GEL with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 7 days.

What is in this leaflet

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

1. What DICOREN GEL is and what it is used for

DICOREN GEL contains diclofenac sodium. Diclofenac sodium is a phenylacetic acid derivative which acts as an anti-inflammatory and analgesic medicine.

DICOREN GEL is used for the symptomatic relief of localised traumatic inflammation and pain.

2. What you need to know before you use DICOREN GEL

Do not use DICOREN GEL

- If you are hypersensitive (allergic) to diclofenac sodium, acetylsalicylic acid (aspirin) and other nonsteroidal anti-inflammatory medicines, or any of the other ingredients of DICOREN GEL (listed in section 6).
- If asthma, urticaria (itchy, raised, red or skin-coloured welts) or acute rhinitis (runny, stuffy nose) appears after the use of acetylsalicylic acid (aspirin) or other nonsteroidal anti-inflammatory medicines.
- If you are in the last 3 months of your pregnancy.
- If you have porphyria (a rare hereditary disease in which there is abnormal metabolism of the blood pigment haemoglobin with symptoms such as dark urine, mental disturbances and extreme sensitivity of the skin to light).
- If you are using other medicine containing diclofenac.
- If you are using other oral NSAIDs such as aspirin or ibuprofen.
- If you have heart failure.
- If you have a history of NSAID related GI complications including bleeding or perforation.
- If you currently have ongoing or previous problems with ulcers or bleeding in the digestive area.
- If your kidney is not functioning normally.

Warnings and precautions

Take special care with DICOREN GEL:

- DICOREN GEL may cause systemic side effects if it is used on large areas of the skin and for a long time (see section 3, If you use more DICOREN GEL than you should).
- If serious skin reactions develop while using DICOREN GEL, stop using DICOREN GEL and consult your doctor immediately. These reactions can be life-threatening. Serious skin reactions include

- Stevens-Johnson syndrome, a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals
- exfoliative dermatitis and toxic epidermal necrolysis, causing extensive peeling of the skin.
- DICOREN GEL can only be applied on healthy skin. Do not apply DICOREN GEL on open wounds.
- Avoid contact with your eyes or mucous membranes (e.g. mouth).
- Do not ingest (eat) DICOREN GEL.
- The area treated with DICOREN GEL should not be exposed to sunlight.
- DICOREN GEL can be used with non-occlusive (allowing air and liquids to pass through) bandages but should not be used with an airtight occlusive (not allowing air and liquids to pass through) dressing.

Children under 12 years of age:

The safety and efficacy of DICOREN GEL in children under the age of 12 years have not been established. Do not use DICOREN GEL in children under the age of 12 years.

Other medicines and DICOREN GEL

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently taking:

- Diuretic medicines (used to treat high blood pressure and heart failure).
- Lithium (used to treat certain mental illnesses such as bipolar disorder or some types of depression).
- Digoxin (used to treat heart failure and a fast heartbeat).
- Anticoagulant medicines (used to thin your blood and prevent blood clots from forming).
- Antidiabetic medicines (used to treat diabetes). Your doctor may need to adjust the dosage of your antidiabetic medicine.
- Ciclosporin (immunosuppressive medicine used to treat organ rejection post-transplant).

- Methotrexate (used to treat cancer, psoriasis (skin disorder that caused the skin cells to multiply up to 10 times faster) and rheumatoid arthritis (inflammation in the joints)).
- Quinolone antimicrobials (broad-spectrum antibiotics).
- Other NSAIDs and steroids (used to reduce inflammation in the body and may also be used to treat pain and reduce fever).
- Mifepristone (used to cause an abortion during the early part of a pregnancy).
- Anti-hypertensive medicines (used to treat high blood pressure).

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before using DICOREN GEL.

DICOREN GEL is not for use during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery.

Mothers using DICOREN GEL should not breastfeed their babies as diclofenac passes into breastmilk.

DICOREN GEL should not be applied on the breasts of nursing mothers.

Consult your doctor or pharmacist for further information if you are pregnant or breastfeeding.

Driving and using machines

DICOREN GEL has no or minor influence on your ability to drive a vehicle and use machines.

DICOREN GEL contains propylene glycol

DICOREN GEL contains 200 mg/g propylene glycol, which may cause skin irritation.

3. How to use DICOREN GEL

Do not share your medicines with any other person.

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

Adults and children 12 years and older

For cutaneous use only.

Apply 2 g to 4 g (quantity as large as a cherry or a walnut) DICOREN GEL three to four times a day to the affected area and rub in gently.

After application, wash your hands, unless they are the site being treated.

The duration of treatment will be determined by the indication and the response to the treatment.

It is recommended that treatment be reviewed after 2 weeks.

If you use more DICOREN GEL than you should

Overdose with DICOREN GEL is unlikely due to the low systemic absorption. If DICOREN GEL is accidentally ingested you can experience side effects such as nausea, vomiting, diarrhoea or stomach pain.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to use DICOREN GEL

Use DICOREN GEL at the next scheduled time.

Do not use a double dose to make up for forgotten individual doses.

4. Possible side effects

DICOREN GEL can have side effects.

Not all side effects reported for DICOREN GEL are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DICOREN GEL, please consult your health care provider for advice.

If any of the following happens, stop using DICOREN GEL and tell your doctor immediately or go

to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to DICOREN GEL. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Scaly, leathery patches of skin.
- Redness of the skin, either in a limited area or all over.
- Itching.
- Headaches and nervousness.
- Dizziness.
- Pain in upper, middle region of stomach.
- Nausea, vomiting and diarrhoea.

Less frequent side effects:

- Fluid-filled blisters that are often located along creases in the skin.
- Increased sensitivity of your skin to the sun.
- Small bumps or rash on the skin that contain fluid or pus.
- Allergy (including allergic skin reaction).
- Asthma or any lung infections such as pneumonia.
- Leucopenia (condition with too few white blood cells).
- Thrombocytopenia (reduction in blood platelets, which increases risk of bleeding or bruising; too few platelets).
- Aplastic anaemia (serious reduction of blood cells (due to failure of the bone marrow that can

cause weakness, bruising or make infections more likely).

- Haemolytic anaemia (lack of red blood cells due to destruction of circulating cells; reduction in red blood cells which can make the skin pale yellow and cause weakness or breathlessness).
- Agranulocytosis (severe decrease in a particular type of white blood cells which makes infections more likely).
- Psychiatric disorders such as disorientation, sleeplessness, irritability, depression, nightmares and psychotic reactions.
- Tiredness.
- Disturbances of sensation (including numbness; tingling; pins and needles; cold, warmth, tingling pressure of the skin).
- Memory disturbance.
- Convulsions.
- Anxiety.
- Tremors.
- Aseptic meningitis (infection of the brain membranes).
- Sleepiness.
- Taste disturbances.
- Damage to the heart and blood vessels.
- Disturbances in vision.
- Impaired hearing or ringing in the ears.
- Rapid irregular action of the heart; irregular heart beat.
- Inflammation of blood vessels, often with skin rash.
- High blood pressure.
- Internal bleeding of the stomach or intestines.
- Signs of internal bleeding from the upper portion of your digestive tract.
- Blood in stools.
- Bloody diarrhoea.
- Stomach and duodenal ulcers with or without bleeding.

- Lower gut disorders such as chronic disease affecting colon (large bowel), inflammation of last part of small bowel).
- Mouth ulcers and inflammation of the mouth.
- Disease of the liver (with or without jaundice – a condition with yellow pigmentation of skin and eyes; yellowing of the skin or whites of the eyes caused by liver or blood problems).
- Liver disorder or failure.

Side effects with frequency unknown:

- Burning sensation at the site of application.
- Dry skin.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on the SAHPRA website.

By reporting side effects, you can help provide more information on the safety of DICOREN GEL.

5. How to store DICOREN GEL

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Do not use DICOREN GEL after the expiry date on the tube and carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What DICOREN GEL contains:

The active substance is diclofenac sodium.

Each gram gel contains 10 mg diclofenac sodium.

The other ingredients are carbopol 940, isopropyl alcohol, *l*-menthol powder, propylene glycol (E1520), purified water, triethanolamine.

What DICOREN GEL looks like and contents of the pack

A colourless, transparent gel.

Aluminium tube with sealed membrane over the opening, closed with a white HDPE piercer cap, packed in an outer cardboard carton.

Pack sizes: 20 g and 45 g.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to corresponding Professional Information

Request via the email address: info@lebasi.co.za