PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER

DINAC GEL

DICLOFENAC GEL BP 1% w/w

Read all of this leaflet carefully before you starts giving 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, health care worker or pharmacist.
- Do not pass it on to others. It may harm them, even if their symptoms are the same.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care worker or pharmacist

In this leaflet:

1. What **DINAC GEL** is and what it is used for
2. What you need to know before you use **DINAC GEL**
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4. Possible side effects
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1. What DINAC GEL is and what it is used for

DINAC GEL contains Diclofenac Diethylamine equivalent to Diclofenac Sodium.

Diclofenac is an acetic acid nonsteroidal antiinflammatory drug (NSAID) with analgesic and antipyretic properties, for topical use.

DINAC GEL is indicated for the relief of the pain and reduces swelling caused by a variety of local conditions, usually affecting the joints, ligaments, tendons and muscles, amenable to topical treatment, such as the knees and those of the hands. These include, Sprains, soft tissue injuries, rheumatism of soft tissues and mild arthritis.

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

Do not apply DINAC GEL

- are in the last 3 months of your pregnancy (see also pregnancy and breast-feeding section)
- have an allergy (hypersensitivity) to any of the ingredients in the product (see Section 6 'What DINAC GEL contains').
- have ever had an allergic reaction to diclofenac or other medicines used to treat pain, fever or inflammation, such as aspirin (acetyl salicylic acid) or ibuprofen.
  Symptoms of an allergic reaction to these medicines may include: asthma, wheezing or shortness of breath; skin rash or hives; swelling of the face or tongue; runny nose.

  This medicine is not recommended for use in children under 14 years of age.

Take special care with DINAC GEL

- Do not apply the gel to skin that has (i) a rash or eczema (ii) cuts or open wounds. Stop the treatment if a skin rash develops after applying the product.
- Avoid applying on large areas of skin and over a prolonged period of time, unless under medical advice.
- Due to an increased possibility of side effects, take care if you are using any other medicine containing diclofenac or painkillers known as NSAIDs, such as aspirin or ibuprofen.
- Be careful when sunbathing or using sun lamps as your skin may be more sensitive to sunlight.
- If you have a stomach or duodenal ulcer (or a history of), tell your doctor or pharmacist before using the gel.
- Do not smoke or go near naked flames – risk of severe burns. Fabric (clothing, bedding, dressings etc.) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

Taking other medicines

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

Pregnancy and breast-feeding

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. DINAC GEL must not be used during the last 3 months of pregnancy, as it could harm your unborn child or cause problems at delivery. DINAC 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. DINAC GEL should only be used under medical advice during breast-feeding as diclofenac passes into breast milk in small amounts. However, DINAC 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. Consult your doctor or pharmacist for further information if you are pregnant or breast-feeding.

Driving and using machines

DINAC GEL, when used as directed, is not expected to have any effect on your ability to drive or use machines.

Important information about some of the ingredients of DINAC GEL

The gel formulation contains propylene glycol and Butylated Hydroxytoluene, which may cause mild localised skin irritation in some people.

3. How to use DINAC GEL

- Always use DINAC GEL exactly as your doctor has told you.
- The gel is only for use on your skin. Do not use it in your mouth. Inform your doctor immediately in case of accidental swallowing.
- Do not put DINAC GEL in your eyes. If this happens, rinse your eyes well with clean water. See your doctor or pharmacist if any discomfort persists.

Adults:

1. Take the tube out of the carton:

a. For the aluminium tube: Before first use, pierce the sealing membrane of the tube with the spiked top of the cap. Do not use if seal is broken.

2. Gently squeeze out a small amount of gel from the tube and apply to the painful or swollen area 3 to 4 times a day, slowly rubbing into the skin.

3. The amount needed will vary depending on the size of the painful or swollen area; an amount ranging in size from a 1 penny to a 2 pence piece will usually be sufficient. You may notice a slight cooling effect when you rub the gel in.
4. Do not rub the gel into cuts, open wounds or any other area where the skin is abnormal. After rubbing the gel into the skin, do not cover with bandages or sticking plaster.
5. Be careful not to get the gel in your eyes. If this happens, rinse your eyes with clean water and tell your doctor.
6. Wash your hands after rubbing in DINAC GEL, unless your hands are the site being treated. Replace the cap.
7. Allow at least four hours between applications of the gel. Do not apply more than 4 times in any 24 hour period.

This medicine is not recommended for use in children under 14 years of age.

Do not use DINAC GEL for more than:

- 2 weeks for muscle and joints injuries (e.g. sprains, strains, bruises) or tendonitis.
- If you are using the gel for arthritis, your doctor may wish to review your treatment regularly.

If symptoms do not improve within this time, or they get worse, consult your doctor. In children aged 14 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patient/parents of the adolescent is/are advised to consult a doctor.

If you use more DINAC GEL than you should

If you or a child accidentally swallows DINAC GEL, contact your doctor or accident and emergency department immediately.

If you forget to use DINAC GEL

If you miss your application of DINAC GEL at the correct time, apply it as soon as you remember then carry on as normal. Do not apply a double quantity to make up for a forgotten application. If you have any further questions on the use of this product, ask your pharmacist.

4. Possible side effects

Like all medicines, DINAC GEL can cause side effects, although not everybody gets them.

Some rare and very rare side effects might be serious

If you experience any of the following signs of allergy, STOP using DINAC GEL and tell a doctor or pharmacist immediately:

Skin rash with blisters; hives (may affect between1 and 10 in every 10,000 people).Wheezing, shortness of breath or feeling of tightness in the chest (asthma) (may affect less than 1 in every 10,000 people).

Swelling of the face, lips, tongue or throat (may affect less than 1 in every 10,000 people).

Other side effects which may occur are usually mild, passing and harmless (if you are concerned, tell a doctor or pharmacist)

Common side effects (may affect between 1 and10 in every 100 people)

Skin rash, itching, reddening or smarting of the skin

Very rare side effects (may affect less than 1 in every 10,000 people)

The skin may be more sensitive to the sun. Possible signs are sunburn with itching, swelling and blistering.

Some side effects have unknown frequency (cannot be estimated from available information):

Local application site irritation, peeling of the skin and skin discolouration.

5. How to store Diclofenac Gel BP 1% w/w

Keep out of the sight and reach of children.

Store in a cool place, below 25°C

Do not use DINAC GEL after the expiry date stated on the carton and tube.

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

Medicines should not be disposed of via waste water 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 DINAC GEL contains

The active substance is Diclofenac Diethylamine (1.16%) equivalent to 1 g of Diclofenac Sodium in each 0.2 g of diclofenac sodium in each 20 g of gel in the 20 g tube.

The other ingredients are Carbomer-940, Propylene glycol, Butylated Hydroxytoluene, Disodium Edetate, Diethylamine, Isopropyl alcohol.

What Diclofenac Gel BP 1% w/w looks like and contents of the pack:

Diclofenac Gel BP 1% w/w- Dinac Gel is Clear Transparent Gel.

Contents of the pack: 20 g Collapsible aluminium tube in a printed carton with a printed insert.

Manufactured by:

S Kant
HEALTHCARE Ltd.

1802-1805, G.I.D.C., Phase III,

Vapi - 396 195. Gujarat, INDIA.