Vurdon® Diclofenac Sodium

Gel for external use 1%

Composition:
Active ingredient: Diclofenac diethylammonium equivalent to Diclofenac sodium.
Excipients: Triethylamine, Carbomer, Cetomacrogol 1000, Cetiol LC, Isopropanol, Paraffin liquid, Levanda Vioryl, Propylene glycol. Water (deionised).
Drug formulation: Gel for external use.
Concentration of active ingredient:
Each g of **Vurdon® gel** contains Diclofenac diethylammonium equivalent to Diclofenac sodium 10 mg. Presentation: Box containing **Vurdon® gel** in aluminium tubes of 25 or 100g.
Therapeutic category: Non-steroidal anti-inflammatory drugs.
Manufactured and marketed by:
HELP SA - 10 Valaoritou str., GR144 52 Metamorphosis Attika- Greece.
Tel.: +30.210.2815.353, +30.210.2843.479

WHAT YOU SHOULD KNOW ABOUT THE MEDICINE YOUR DOCTOR HAS PRESCRIBED

General Information:
Diclofenac Diethylammonium is especially formulated for topical administration. The active agent Diclofenac belongs to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDS). Diclofenac Diethylammonium relieves from the symptoms of inflammation like swelling and pain, without having an effect on the cause of inflammation.
Indications:
Vurdon® gel is potentially effective for the local treatment of:
- traumatic inflammation of tendons, ligaments, muscles and joints due to strains, sprains and contusions,
- local manifestations of soft tissue pathology (tendinitis, bursitis, shoulder-hand syndrome, periarthritis),
- local manifestations of degenerative arthropathies (osteoarthritis of peripheral joints and spine) Treatment should not be prolonged beyond two weeks.

Contraindications:
Medicines can help patients, but they can also cause problems when they are not used according to instructions.
Before you use this particular medicine you should let your doctor know:
- if you ever had an allergic reaction or unusual response to this medicine or to any of the substances it contains.
- if you ever had hypersensitivity to acetylsalicylic acid or to other nonsteroidal anti-inflammatory drugs, as well as to Isopropanol or Propylene glycol.

Special precautions and warnings during use:
- **Vurdon® gel** should be applied only to intact, non-diseased skin and not to skin wounds or open injuries. It should not be used with occlusion. It should not be allowed to come into contact with the eyes or mucous membranes, and should never be taken by mouth.
- **Vurdon® gel** contains Propylene Glycol which may cause mild, localized skin irritation in some people. • As there is no experience with the use of **Vurdon® gel** during pregnancy and lactation, this preparation is not recommended for use in such cases.
- As, in cases where **Vurdon® gel** is applied on relatively large skin areas and for prolonged periods, the possibility of systemic effect cannot be completely excluded, patients who have vertigo or other CMS disturbances should avoid driving or operating machinery.
- The likelihood of systemic side effects with topical diclofenac is small compared to the frequency of side effects in patients using oral diclofenac. However when Vurdon gel is applied on relatively large skin areas and for prolonged periods or if the dosage exceeds by far the recommended limits, there is a danger of systemic effect. Therefore it should be used with caution in patients with renal and liver failure, severe hypoalbuminaemia, arterial hypertension, ischaemic heart disease, diabetes mellitus, epilepsy, parkinsonism, psychotic disturbances, latent or active infections, and in persons driving or operating machinery. In cases that Vurdon

is used for such or similar cases the general information of diclofenac should be taken into account.

Interactions with others drugs or substances:
Systemic absorption of **Vurdon® gel** is low and hence the risk of an interaction is small. However, before you take this medicine, you should let your doctor know of any other drugs you may be using. Drugs may also be substances taken without a medical prescription.

Dosage:
This should be individualised for each patient.

Administration: For external use only.

- **Adults:** Depending on the surface area of the painful site, apply by gentle massage 2-4 g **Vurdon® gel** (an amount ranging in volume from that of a cherry to that of a walnut) 3-4 times daily on the painful sites.

The duration of the treatment should not exceed 2 weeks. If no improvement is observed after 7 days of treatment with Vurdon Gel please consult your doctor.
After application, the hands should be washed unless they are the site being treated.

What you should do in case you have omitted a dose:
Continue your treatment normally. Do not double the dose.

Undesirable effects:
Vurdon® gel is usually well tolerated. However, like all medicines it may cause undesirable effects in some cases.
Adverse reactions (Table 1) are ranked under heading of frequency, the most frequent first, using the following convention: common (1/100, < 1/10); uncommon (1/1,000, < 1/100); rare (1/10,000, < 1/1,000); very rare (< 1/10,000), including isolated reports.
Infections and infestations: ***Very rare:*** Rash pustular.
Immune system disorders: ***Very rare cases:*** Hypersensitivity, angioneurotic oedema.
Respiratory, thoracic and mediastinal disorders: ***Very rare:*** Asthma.
Skin and subcutaneous tissue disorders: ***Common:*** Rash, eczema, erythema, dermatitis (including dermatitis contact). ***Rare:*** Dermatitis bullous. ***Very rare cases:*** Photosensitivity reactions (patients should be warned against excessive exposure to sunlight in order to reduce the incidence of photosensitivity)
If you experience any of the following symptoms **STOP using Vurdon® gel and contact your doctor IMMEDIATELY:** Extensive skin rash. Wheezing, difficulty in breathing, swelling on the face.
You should also inform your doctor in case you experience any undesirable effects other than those mentioned in this Leaflet.

Storage instructions for this product: This drug should be kept at temperature <30°C.

Data of last revision of this data sheet: JULY 2008.

INFORMATION ON THE RATIONAL USE OF MEDICINES

• This medicine has been prescribed by your doctor only for your specific medical problem. Your should not give it to other individuals or use it for any other condition, without previous consultation with your doctor. • If during your therapy there is any problem with the medicine, you should notify your doctor or pharmacist. • If you have any questions about the information concerning the drug you are taking or if you need more information about your medical problem, do not hesitate to ask your doctor or pharmacist. •To be effective and safe the prescribed drug should be used according to the instructions given to you. • For your health and safety you must read carefully all the information regarding the drug you have been prescribed. •Do not store medicines in bathroom cupboards; heat and moisture may alter them and make them hazardous to your health. • Do not keep medicines you do not need any more, or those that have expired. • For greater safety keep all medicines out of the reach of children.

THIS MEDICINE IS TO BE TAKEN ONLY BY DOCTOR'S PRESCRIPTION.

help SA

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