Vurdon® Diclofenac sodium

GR. tab 25mg/tab, GR. tab 50mg/tab, S.R.F.C. tab 100mg/tab,
Supp 50mg/supp, Supp 100mg/supp, Inj. Sol. 75mg/3ml amp

Composition:
Active Ingredient: Diclofenac sodium.
Excipients:
- ***GR. TAB 25MG/TAB & GR. TAB 50MG/TAB:***
  Starch, Magnesium stearate, Eudragit L, Lactose, Polyvidone.
- ***S.R.F.C. TAB 100MG/TAB:***
  Coat: Iron oxide red E172, Opadry Y-1-7000. ***Components of Opadry Y-1-7000:*** Hypromellose (Methocel E5 premium), Titanium dioxide E171, Macrogol 400. ***Core:*** Sucrose, Cetostearyl alcohol, Polyvidone, Silicon dioxide colloidal (aerosil), Talc purified, Magnesium stearate.
- ***SUPP 50MG/SUPP & SUPP 100MG/SUPP:***
  Myritol, Hard fat.
- ***INJ. SOL. 75MG/3ML AMP:***
  Macrogol 400, Ethanol, Benzyl alcohol, Sodium metabisulfite E223, Edetate disodium, Propylene glycol (PG 1.2), Water for injection.

Drug Formulation:
Gastro-resistant tablets, Slow Release Film Coated tablets, Suppositories, Injection Solution.
Concentration of active ingredient:
- ***GR. TAB 25MG/TAB:*** Each **Vurdon®** 25mg gastro-resistant coated tablet contains Diclofenac Sodium 25mg.
- ***GR. TAB 50MG/TAB:*** Each **Vurdon®** 50mg gastro-resistant tablet contains Diclofenac Sodium 50mg.
- ***S.R.F.C. TAB 100MG/TAB:*** Each **Vurdon®** 100mg slow release film coated tablet contains Diclofenac Sodium 100mg.
- ***SUPP 50MG/SUPP:*** Each **Vurdon®** 50mg suppository contains Diclofenac Sodium 50mg.
- ***SUPP 100MG/SUPP:*** Each **Vurdon®** 100mg suppository contains Diclofenac Sodium 100mg.
- ***INJ. SOL. 75MG/3ML AMP:*** Each 3 ml ampoule of **Vurdon®** Injection Solution 75mg/3ml Amp contains Diclofenac Sodium 75mg.

Presentation*:
- ***GR. TAB 25MG/TAB:*** Carton box which contains 30 or 100 **Vurdon®** 25mg gastro-resistant tablets in blisters.
- ***GR. TAB 50MG/TAB:*** Carton box which contains 20 or 100 **Vurdon®** 50mg gastro-resistant tablets in blisters.
- ***S.R.F.C. TAB 100MG/TAB:*** Carton box which contains 10 or 1000 **Vurdon®** 100mg slow release film coated tablets in blisters.
- ***SUPP 50MG/SUPP:*** Carton box which contains 10 **Vurdon®** 50mg suppositories in plastic cases.
- ***SUPP 100MG/SUPP:*** Carton box which contains 10 **Vurdon®** 100mg suppositories in plastic cases.
- ***INJ. SOL. 75MG/3ML AMP:*** Carton box which contains 5, 6 or 50 ampoules (3 ml each) in plastic trays.

***Not all pack sizes may be marketed**

Therapeutic Category:
Non-Steroidal Anti-Inflammatory Drugs (NSAIDS).
Marketing Authorisation Holder and Manufacturer:
HELP S.A., 10 Valaoritou str., GR144 52 Metamorphosis, Attica, Greece, Tel.: +30 210 2815353, +30 210 2843479

WHAT YOU SHOULD KNOW ABOUT THE MEDICINE YOUR DOCTOR HAS PRESCRIBED

General Information:
Diclofenac relieves from the symptoms of inflammation such as swelling and pain, without having an impact on the cause of inflammation.
Therapeutic Indications:
- Chronic inflammatory arthropathies (rheumatoid arthritis, ankylosing spondylitis, psoriatric arthritis etc.)
- Degenerative arthropathies of peripheral joints and spine.
- Arthritis due to deposits of crystals (monosodium urate, calcium diphosphate, calcium phosphate, calcium oxalate)
- Acute musculoskeletal disorders (periathritis, tenonditis, traumatic injuries)
- Primary dysmenorrhoea
- Migraine attacks
- Ureteral colics

Contraindications:
Do not take/use **Vurdon®** if:
- You have active peptic ulcer or intestinal ulcer.Have ever had an allergic reaction (e.g. rash or wheezing) to medicines containing diclofenac, acetylsalicylic acid (aspirin), ibuprofen or other non-steroidal anti-inflammatory drugs.
- Have ever had an allergic reaction to any of the excipients of this medicine
- You have blood in your stool or black stool
- Suffer from hepatic porphyria
- You are pregnant or plan to become pregnant or breast-feeding.

Diclofenac should not be given to children under 14 years of age.
You should tell your doctor if you have any of the above, because diclofenac may not be suitable for you.
Special warnings and precautions during use:
General:
Medicines like **Vurdon®** could be related to a small increase in the risk for a heart attack ("myocardial infarction") or stroke. This risk is more likely to occur in high doses and prolonged therapy. You should not exceed the recommended dose or duration of therapy. If you have problems with your heart, a previous history of a stroke or if you think you are in danger of developing such conditions (if for example you have high blood pressure, diabetes or high cholesterol levels or if you are a smoker) you must discuss your therapy with your doctor or pharmacist.
Before taking/using **Vurdon®** you should tell your doctor if:
- You have ever had in the past any problems in your stomach or intestine or experienced any discomfort or burning sensation in the stomach after you have taken an NSAID.
- If you suffer from any of the following: asthma, heart, hepatic or renal disease, high blood pressure, haemmorhagic or other haemological disorder

Your doctor will take these conditions under consideration before and during your therapy.
Warnings about containing excipients:
Vurdon® injection contains 6 vol % ethanol (alcohol), i.e. up to 141 mg per dose (1 ampoule), equivalent to 3.6 ml beer, 1.5 ml wine per dose. Harmful for those suffering from alcoholism. To be taken into account in pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy. Vurdon injection contains 40mg benzyl alcohol per ml. It must not be given to premature babies or neonates. It may cause toxic reactions and allergic reactions in infants and children up to 3 years old. **Vurdon®** injection contains sodium metabisulphite. It may rarely cause severe hypersensitivity reactions and bronchospasm.
Vurdon® GR tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
Elderly:
The effect of diclofenac is higher in elderly patients, than in other adults. The elderly should receive the lowest effective dose for their condition. It is important for the elderly to inform their doctor immediately if they experience any adverse reactions.
Pregnancy:
You must tell your doctor if you are pregnant or plan to become pregnant. Diclofenac use is contraindicated during pregnancy.
Lactation:
You must tell your doctor if you are breastfeeding. Diclofenac use is contraindicated when breastfeeding.
Children:
Diclofenac use is contraindicated in children under 14 years of age. **Vurdon®** injection, in particular, contains benzyl alcohol and therefore it must never be administered in premature babies or newborns. It can cause toxic reactions in infants and children up to 3 years old.
Effects on ability to drive and use machines:
Patients who experience dizziness, drowsiness or visual disturbances, while taking NSAIDs should refrain from driving or operating machinery. You should tell you doctor immediately if you experience any of these symptoms.
Interactions with other medicinal products and other forms of interaction:
You should tell your doctor if you are taking any other drugs, except diclofenac because it may be necessary to change the dose or stop taking one of them. This applies for prescribed medicines and those obtained without a prescription (OTC).

The action of the following medicinal products or substances can be affected from **Vurdon®**:
- Lithium, Digoxin, Methotrexate and Cyclosporine
- Antidiabetic medicines, except insulin
- Diuretics
- Medicines used to prevent blood clotting (anticoagulants) such as warfarin
- Other NSAIDS such as acetylsalicylic acid (aspirin) or ibuprofen
- Some medicines used for the treatment of infections (Quinolone antimicrobials)
- Corticosteroids
- Antihypertensives

Dosage:
You should make sure that you take/use **Vurdon®** regularly and exactly as directed by your doctor. This will help you get the best results and reduce the risk of adverse effects. Depending on your condition you may need treatment for a few days, a few weeks or longer. If you have any doubt about the treatment, ask your doctor.
Adults
The dosage should be individualised according to the condition and the patient's response. The usual starting dose is 75 to 150mg of Diclofenac daily in divided doses. Maintenance dose is 50 to 100 mg of Diclofenac daily in divided doses and the duration of treatment is determined by the doctor and the patient's response. For the management of acute episodes that require short term treatment, the formulations preferred are those inducing rapid absorption.
For the management of migraine attacks, the recommended dose is 100mg of Diclofenac administered as suppositories at the first sign of an upcoming attack. If necessary an additional 50mg can be administered during the day. The total daily dose should not exceed that of 150 mg.
For severe migraine episodes, Diclofenac is administered as an I.M. injection, with an initial dose of 75 mg, followed, if necessary in the same day, by Diclofenac in the form of a suppository. The total daily dose should not exceed that of 150 mg.
For the management of ureteral colic, the use of Diclofenac as an I.M. injection is recommended in doses of up to 150mg. The duration of treatment should not exceed 2 days. Treatment in the elderly and in patients with heart, hepatic, renal problems should be initiated with the lowest dose and should be continued with the lowest effective dose.
Children
Diclofenac use is not recommended in children.
Method of Administration:
The suppositories are wrapped in plastic cases. Before inserting the suppository remove the plastic case that wraps the suppository completely and moisten the suppository with cold water. Lie on your side and using your finger, push the suppository in the rectum as far as possible. If the suppository is too soft to insert, freeze it in the fridge for a few minutes or keep it under cold water before removing the plastic case. Do not break the suppositories because incorrect storage conditions can lead to uneven distribution of the active substance. It is best to empty your bowels first before you use a suppository.
Gastro-resistant & Slow release film coated tablets should be taken whole with a glass of water or other liquid. Gastro-resistant tablets are best to be taken before meals or on an empty stomach. Slow release film coated tablets are best to be taken during meals.
Management of Overdose:
If you accidentally receive much more gastro-resistant tablets than those prescribed to you, you should immediately visit your doctor.
What you should do in case you have omitted a dose:
If you forget to take a dose take it as soon as you remember. If however the time for the next dose approaches, for example if less than half the time between doses remains, do not take the missed dose but return to your usual dosage regime normally.
Undesirable effects:
Like all medicines **Vurdon®** can sometimes cause side effects, besides its desired action. These effects include stomach discomfort, malaise, burning sensation in the stomach vomiting, diarrhoea, abdominal cramps, flatulence, loss of appetite, headache, dizziness and skin rashes.
Medicines like diclofenac can sometimes be associated with a small increased risk of arterial thrombolytic events (for example myocardial infarction or stroke).
Rare side effects, occurring in less than 1% of patients treated: haematemesis, black stools, stomach or intestinal ulcer, haemmorhagic diarrhoea, constipation, drowsiness, tingling sensation in the limbs, disorientation, visual disturbances (e.g. blurred vision or diplopia), impaired hearing, tinnitus, insomnia, irritability, anxiety, depression, panic attacks, urticaria, serious skin reactions, hair loss, photosensitivity, skin bleeding, impaired renal function leading to swelling of the face, legs and lower legs, acute oliguria, haematuria, hepatic disorders resulting in yellowing of the skin or eyes, sometimes with fever or swelling and tenderness of the upper right part of the abdomen, symptoms of severe haematological disorders such as persistent sore throat and fever, allergic reactions such as wheezing, shortness of breath or fainting, high blood pressure. Other undesirable effects, except those listed above, can also occur in some patients.
If you notice any of the following symptoms STOP taking/ using Vurdon® and tell your doctor IMMEDIATELY:
- Stomach discomfort, burning sensation in the stomach or pain in the upper abdomen
- Haematemesis, black stools or haematuria
- Skin problems such as rash or itching
- Wheezing
- Yellowing of the skin or eyes
- Persistent sore throat or fever
- Swelling of the face, legs and lower legs
- Severe headache
- Chest pain with cough

Inform your doctor or pharmacist if these side effects get serious or if you notice any other side effects, not listed above.
If you take/use this medicine for more than a few weeks, you should visit your doctor for regular checks to make sure that no side effects remain unnoticed.
Expiry Date:
Do not use this product after the expiry date shown on the internal and external packaging.
Special precautions for storage: Do not store above 25°C.
Date of last revision of this data sheet: June 2010.

INFORMATION ON THE RATIONAL USE OF MEDICINES
- This medicine has been prescribed by your doctor only for your specific medical problem. You 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 ON DOCTOR'S PRESCRIPTION

HELP SA - 10, VALAORITOU STR.
GR 144 52 METAMORPHOSIS, ATTIKA, GREECE
TEL.: +30.210.2815353, +30.210.2843479
FACTORY: PEDINI IOANNINA - GREECE - TEL.: +30.2651.092143

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