VOLNAC-M GEL 1% w/w

Composition:
Each gram of gel contains
Diclofenac sodium 1% w/w with menthol 0.2% w/w added.

Description:
A clear, colourless to light pink-orange, smooth gel.

Pharmacodynamics:
Diclofenac sodium is non-steroidal anti-inflammatory drug (NSAID) with marked analgesic, antipyretic and anti-inflammatory properties. It inhibits cyclo-oxygenase which results in a marked reduction in prostaglandin synthesis. Diclofenac inhibits the enzyme, cyclooxygenase (COX), an early component of the arachidonic acid cascade, resulting in the reduced formation of prostaglandins, thromboxanes and prostacylin.

Pharmacokinetics:
Diclofenac is absorbed through the skin. The topical application of diclofenac sodium allows the percutaneous absorption of therapeutic concentrations of the active to penetrate to, and accumulate at, the target site of action. The dose to be delivered in a concentration of a 1% gel, is comparable to the normal daily doses of oral administration. As with other percutaneously applied NSAIDs, it is the concentration reached at the target area that is important for the therapeutic action rather than the plasma concentration. Hence, the systemic load produced by oral parenteral administration can be avoided through local application.

Indication:
Topical application in the treatment of inflammatory conditions or pain caused by chronic rheumatoid arthritis, degenerative arthritis and soft tissue arthritis

Recommended dose:
Depending on the size of the painful site to be treated, apply 2 – 4g of diclofenac gel 3 to 4 times daily to the affected areas and rub in gently. After assessing the risk/ benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.

Route of administration:
Topical administration

Contraindication:
Hypersensitivity to Diclofenac sodium and NSAID.

VOLNAC-M should not be administered in patients who have experienced asthma, urticaria. VOLNAC-M is contraindicated in the setting of coronary artery bypass graft (CABG) surgery.

Warning and precautions:
VOLNAC-M should be applied only to intact skin and not to skin wounds or open injuries. It should not be allowed to come into contact with the eyes or mucous membranes and should never be taken by mouth. If eye contact occurs, they should immediately wash out the eye with water and consult a physician if irritation persists for more than an hour.
The product should not be used with occlusion.
Undesirable effects may be reduced by using the minimum effective dose for the shortest possible duration. If treated with NSAIDs long-term should undergo regular medical supervision to monitor for adverse events.
Diclofenac should be used with great caution in patients with a history of peptic ulceration or inflammatory bowel disease, gastrointestinal bleeding, hepatic or oral insufficiency or bleeding diathesis. Circulating levels of active drug are low but the theoretical increased risk in patients should be considered.
Severe cutaneous reactions, including Stevens - Johnson syndrome and toxic epidermal necrolysis (Lyell's syndrome), have been reported with diclofenac sodium. Patients treated with diclofenac sodium should be closely monitored for signs of hypersensitivity reactions. Discontinue diclofenac sodium immediately if rash occurs.

RISK OF GI ULCERATION, BLEEDING AND PERFORATION WITH NSAID
Serious GI toxicity such as bleeding, ulceration and perforation can occur at anytime, with or without warning symptoms, in patients treated with NSAID therapy. Although minor upper GI problems (e.g. dyspepsia) are common, usually developing early in therapy, prescribers should remain alert for ulceration and bleeding in patients treated with NSAIDs even in the absence of previous GI tract symptoms.
Studies to date have not identified any subset of patients not at risk of developing peptic ulceration and bleeding. Patients with prior history of serious GI events and other risk factors associated with peptic ulcer disease (e.g. alcoholism, smoking, and corticosteroid therapy) are at increased risk. Elderly or debilitated patients seem to tolerate ulceration or bleeding less than other individuals and account for most spontaneous reports for fatal GI events.

Interaction with other medicaments:
Systemic absorption of diclofenac sodium is low and hence the risk of an interaction is small. There are no known interactions with VOLNAC-M GEL.

Pregnancy and lactation:
This product should be avoided in late pregnancy, because it may cause premature closure of the ductus arteriosus.

Effects on Ability to Drive and Use Machine:
None Known

Side effects:
VOLNAC-M is usually well tolerated. Local allergic skin reactions (exanthema, erosion, erythema, eczema and ulceration) may occasionally occur.
Although systemic absorption of VOLNAC-M is low in comparison to oral forms of diclofenac, the possibility of systemic side-effects cannot be excluded.
Asthma has been rarely reported in patients using topical NSAID preparations.
Dermatological: Occasional - rashes or skin eruptions
Cases of hair loss, bullous eruptions, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), and photosensitivity reactions have been reported.

Overdose and Treatment:
In the event of significant systemic side effects occurring as a result of improper use or accidental overdosage (eg. children), general therapeutic measures of the kind normally adopted to treat poisoning with non-steroidal anti-inflammatory drugs should be resorted to.

Presentation:
Aluminum tube of 10gm, 15gm, 20gm, and 30gm

Storage:
Store below 30°C

Manufacturer & Product Registration Holder:
Noripharma Sdn. Bhd. 200701034604(792633-A)
Lot 5030 Jalan Teratai,
5 1/2 Mile off Jalan Meru,
41050 Klang,
Selangor, Malaysia.

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