Y. S. P.

Y. S. P. INDUSTRIES (M) SDN. BHD.
SUMMARY OF PRODUCT CHARACTERISTICS

PRODUCT NAME: VOREN PLUS GEL 10MG/G Prepared on: 18 Jun 2020

1. **Name of the finished pharmaceutical product:**

   Voren Plus Gel 10mg/g

2. **Qualitative and quantitative composition:**

   Diclofenac Sodium 10 mg/g

3. **Pharmaceutical form:**

   Gel

4. **Clinical Particulars:**

   4.1 Therapeutic indication:

   Topical treatment of inflammatory or pain conditions caused by chronic rheumatoid arthritis, degenerative arthritis and soft tissue rheumatism.

   4.2 Posology and method of administration:

   Depending on the size to be treated, apply sufficient amounts of Voren Plus Gel 3 ~ 4 times daily on the affected areas and rub in gently.

   To be dispensed on physician's prescription.

   After assessing the risk/ benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.

   4.3 Contraindication:

   Known hypersensitivity to diclofenac sodium, propylene glycol or to any components of this product.

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4.4 Special warnings and special precautions for use:

1. Voren Plus Gel should be applied only to intact skin surfaces, and not to skin wounds or open injuries. It should not be allowed to come into contact with the eyes or with mucous membranes.
2. NSAIDs may very rarely cause serious cutaneous adverse events such as exfoliative dermatitis, toxic epidermal necrolysis (TEN) and Stevens-Johnson Syndrome (SJS), which can be fatal and occur without warning. These serious adverse events are idiosyncratic and are independent of dose or duration of use. Patients should be advised of the signs and symptoms of serious skin reaction and to consult their doctor at the first appearance of a skin rash or any other sign of hypersensitivity.
3. When Voren Gel is applied to relatively large areas of skin and over a prolonged period, the possibility of systemic side effects cannot be completely excluded. In such cases, the product information on Voren should be consulted.
4. Observational studies have indicated that non-selective NSAIDs may be associated with an increased risk of serious cardiovascular events, principally myocardial infarction, which may increase with dose or duration of use. Patients with cardiovascular disease or cardiovascular risk of an adverse cardiovascular event in patient taking NSAID, especially in those with cardiovascular risk factors, the lowest effective dose should be used for the shortest possible duration. There is no consistent evidence that the concurrent use of aspirin mitigates the possible increased risk of serious cardiovascular thrombotic events associated with NSAID use.
5. NSAIDs may lead to the onset of new hypertension or worsening the pre-existing hypertension and patients taking anti-hypertensive with NSAIDs may have an impaired anti-hypertensive response. Caution is advised when prescribing NSAIDs to patients with hypertension. Blood pressure should be monitored closely during initiation of NSAID treatment and at regular intervals thereafter.
6. Fluid retention and oedema have been observed in some patients taking NSAIDs, therefore caution is advised in patients with fluid retention or heart failure.

7. All NSAIDs can cause gastrointestinal discomfort and rarely serious, potentially fatal gastrointestinal effects such as ulcers, bleeding and perforation which may increase with dose or duration of use, but can occur at any time without warning. Caution is advised in patients with risk factors for gastrointestinal events e.g. the elderly, those with a history of serious gastrointestinal events, smoking and alcoholism. When gastrointestinal bleeding or ulceration occurs in patients receiving NSAIDs, the drug should be withdrawn immediately. Doctors should warn patients about signs and symptoms of serious gastrointestinal toxicity. The concurrent use of aspirin and NSAIDs also increases the risk of serious gastrointestinal adverse events.

WARNINGS
RISK OF GI ULCERATION, BLEEDING AND PERFORATION WITH NSAID Serious GI toxicity such as bleeding, ulceration and perforation can occur at any time, with or without warning symptoms, in patients treated with NSAID therapy. Although minor upper GI problems (eg. 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 adverse events and other risk factors associated with peptic ulcer disease (eg. 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.

4.5 Interaction with other FPPs and other forms of interaction:

No interactions have been reported.

4.6 Pregnancy and lactation:

Safe use of this product during pregnancy and lactation has not been established. Women who suspect pregnancy, pregnant women or nursing mothers should not be given this product unless clearly needed.

4.7 Effects on ability to drive and use machines:

No information available.

4.8 Undesirable effects:

Voren Plus Gel is usually well tolerated. Itching, reddening, smarting of the skin, rashes or skin eruptions may occasionally occur.

4.9 Overdose:

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.

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5. Pharmacological properties:

5.1 Pharmacodynamic properties:

1. Diclofenac Sodium has analgesic and anti-inflammatory properties. It inhibits cyclo-oxygenase which results in a marked reduction in prostaglandin synthesis.

2. Voren Plus Gel is suitable for use in inflammatory and degenerative rheumatic diseases, as well as for the treatment of post traumatic inflammation and swelling.

3. Voren Plus Gel can be easily rubbed on the skin, and due to the aqueous alcoholic base it exerts a soothing and cooling effects.

5.2 Pharmacokinetic properties:

1. After percutaneous application of diclofenac gel, the maximum plasma concentration of diclofenac was less than 10% of that reached after a similar dose given by parenteral administration.

2. Local accumulation of diclofenac by direct transport or diffusion into the knee joint seems unlikely.

3. After topical application fewer adverse effects are to be expected which are otherwise related to the higher drug plasma levels reached after oral or parenteral administration.

5.3 Preclinical safety data:

No information available.

6. Pharmaceutical particulars:

6.1 List of excipients:

a) Propylene Glycol
b) l-Menthol
c) Triethanolamine
d) Isopropyl Alcohol
e) Carbopol
f) Purified Water

6.2 Incompatibilities:

No information available.

6.3 Shelf life:

3 years from the date of manufacture.

6.4 Special precautions for storage:

Keep in an airtight container. Store at temperature below 30°C. Protect from light and moisture.

6.5 Nature and contents of container:

Aluminium tube of 20g & 45g

6.6 Instructions for use and handling <and disposal>:

None has been mentioned.

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7. Marketing authorization holder:

Name : Y. S. P. INDUSTRIES (M) SDN. BHD.

Address : Lot 3, 5 & 7, Jalan P/7, Section 13,
Kawasan Perindustrian Bandar Baru Bangi,
43000 Kajang, Selangor Darul Ehsan,
Malaysia.

8. Number(s) in the national register of finished pharmaceutical products:

MAL 19988492AZ

9. Date of first authorization / ~~renewal of the authorization~~: 05 Oct 2017

10. Date of revision of the text:

18 Jun 2020