Not to be sold by retail without the prescription of a Registered Medical Practitioner

Diclofenac, Linseed Oil, Methyl Salicylate, Menthol, Capsaicin Gel
DICLOTAL®-FORTE Gel

COMPOSITION
Diclofenac Diethylamine BP ……... 1.16% w/w
(equivalent to Diclofenac Sodium 1% w/w)
Linseed Oil BP ……..…..... 3% w/w
Methyl Salicylate IP ……..……..... 10% w/w
Menthol IP ..... 5% w/w
Capsaicin USP ..... 0.025% w/w
Benzyl Alcohol IP ……..……... 1% w/w
(As Preservative)
Gel Base ……..… q.s.

DOSAGE FORM
Gel for topical use.

INDICATIONS
DICLOTAL-FORTE Gel is indicated for the local symptomatic relief of pain and inflammation occurring due to musculoskeletal disorders (MSDs), sprains and strains, knee pain/arthritis, low back pain, etc.

DOSE AND METHOD OF ADMINISTRATION
For topical administration.
Adults and children above 14 years of age: Gel should be rubbed gently into the skin. Depending on the area of the affected site, 2 to 4 gram of gel should be applied 3 to 4 times daily. Total dose of diclofenac-containing topical preparation should not exceed 32 gram per day. After application, the hands should be washed unless they are the site being treated.
In the treatment of osteoarthritis, therapy should be reviewed after 4 weeks while in other indications, it is recommended that the treatment be reviewed after 14 days.
Or, as prescribed by the physician.

USE IN SPECIAL POPULATIONS
Pregnant Women
The systemic concentration of diclofenac is lower after topical administration, compared to oral formulations. But, due to lack of safety data in pregnant women and fetus, use of diclofenac-containing topical preparations are not indicated during pregnancy. This applies in particular to

the third trimester of pregnancy, owing to the possibility of uterine inertia and/or premature closure of the ductus arteriosus.

Lactating Women

Like other non-steroidal anti-inflammatory drugs (NSAIDs), diclofenac passes into breast milk in small amounts. However, at therapeutic doses no effects on the breast-feeding infants are anticipated. Because of a lack of controlled studies in lactating women, this product should be used during lactation only if clearly needed and under medical supervision. Even if it is used, gel should neither be applied on the breasts of nursing mothers nor elsewhere on large areas of the skin or for a prolonged period of time.

Paediatric Patients

Safety and effectiveness of DICLOTAL-FORTE Gel in children below 14 years of age have not been established.

Geriatric Patients

No overall differences in effectiveness or safety have been observed between the elderly population and younger subjects, but greater sensitivity to the effect of NSAIDs in some older individuals cannot be ruled out.

CONTRAINDICATIONS

DICLOTAL-FORTE Gel is contraindicated in the following:

- Known or suspected hypersensitivity to diclofenac or aspirin or other NSAIDs, linseed oil, methyl salicylate, menthol, capsaicin or to any other component of the formulation.
- Concomitant use of oral diclofenac or other NSAIDs/aspirin.
- In patients with aspirin or salicylate idiosyncrasy.
- Patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other NSAIDs.
- In the setting of coronary artery bypass graft (CABG) surgery.

WARNINGS

The possibility of systemic adverse events from application of this topical therapy cannot be excluded if this product is used on large areas of skin and over a prolonged period of time.

Concomitant Use of Oral NSAIDs: Concomitant use of oral NSAIDs with DICLOTAL-FORTE Gel should be best avoided, as incidence of adverse effects of NSAIDs may increase, particularly systemic side effects.

Skin Reactions: NSAIDs, including diclofenac, can cause serious skin adverse events such as exfoliative dermatitis, Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. These serious events may occur without warning. Patients should be

informed about the signs and symptoms of serious skin manifestations, and the use of the drug should be discontinued at the first appearance of skin rash or any other signs of hypersensitivity.
Sun Exposure: Patients should minimize or avoid exposure to natural or artificial sunlight on treated areas because studies in animals indicated topical diclofenac treatment resulted in an earlier onset of ultraviolet light-induced skin tumors. The potential effects of diclofenac gels on skin response to ultraviolet damage in humans are not known.

PRECAUTIONS

- FOR EXTERNAL USE ONLY.
- NOT FOR VETERINARY USE.
- Discontinue the treatment if a skin rash develops after applying this product.
- Avoid showering/bathing for at least 1 hour after the application.
- Avoid wearing of clothing or gloves for at least 10 minutes after applying the gel.
- Do not apply gel to open skin injuries/wounds, irritated skin, infections, skin abrasions.
- Avoid contact of gel with eyes and mucous membranes.
- Do not apply external heat and/or occlusive dressings to treated joints.
- Avoid exposure of the treated joint(s) to natural or artificial sunlight.
- Avoid concomitant use of gel on the treated skin site with other topical products, including sunscreens, cosmetics, lotions, moisturizers, insect repellants, or other topical medications.
- Should not be co-administered with other products containing diclofenac.
- Convulsions have been reported rarely with methyl salicylate, thus, use of this product should be avoided in such cases.

DRUG INTERACTIONS

Since systemic absorption of diclofenac from topical application of the gel is very low, drug interactions are very unlikely. The following drug interactions have been observed rarely.
Oral NSAIDs: Concomitant administration of DICLOTAL-FORTE Gel with oral diclofenac or other NSAIDs/aspirin is generally not recommended because of the potential for increased risk of GI events including ulceration, bleeding, and perforation.
Anticoagulants: Concomitant use of anticoagulants and diclofenac has a risk of serious GI bleeding higher than use of either drug alone.

UNDESIRABLE EFFECTS

Local: This preparation is usually well tolerated. Commonly/occasionally reported adverse reactions are application site reactions, including skin irritation, rash, dermatitis, pruritus, erythema, paresthesia, vesicles, papules, redness or swelling, burning or stinging sensation.
Skin photosensitivity, desquamation, discolouration and bullous or vesicular eruptions have been reported in isolated cases. Patients should be warned against excessive exposure to sunlight in order to reduce the incidence of photosensitivity.

This product may cause hypersensitivity/allergic reactions in some individuals with sensitive skin. If hypersensitivity/allergic reactions develop or if any of the above effects/reactions persist or worsen, discontinue use of the drug and seek immediate medical attention.

General: The possibility of systemic adverse events from topical application of this product cannot be excluded if the preparation is used (either accidently or deliberately) on large areas of skin and over a prolonged period which is usually not recommended. Asthma has been reported, *albeit* rarely, in patients using topical NSAID preparations.

OVERDOSE

Symptoms: Overdose with DICLOTAL-FORTE Gel is very unlikely, due to its low systemic absorption. No event of accidental ingestion has been reported in the literature. However, as it contains diclofenac, undesirable effects similar to those observed following an overdose of diclofenac tablets can be expected if it is inadvertently ingested. Symptoms following acute oral NSAID overdose are usually limited to lethargy, drowsiness, nausea, vomiting, and epigastric pain, which are generally reversible with supportive care. GI bleeding, hypertension, acute renal failure, respiratory depression, and coma may occur. Anaphylactic reactions have been reported with therapeutic intake of NSAIDs, and may occur after an overdose.

When accidentally ingested by oral route large doses of linseed oil may cause loose stools and diarrhea.

Salicylate intoxication can occur after ingestion or topical application of methyl salicylate. Mild chronic salicylate intoxication or salicylism usually occurs only after repeated use of large doses. Salicylism can also occur following excessive topical application of salicylates.

Ingestion of significant quantities of menthol is reported to cause symptoms such as severe abdominal pain, nausea, vomiting, vertigo, ataxia, drowsiness, and coma.

In overdose, capsaicin can cause burning or stinging pain to the skin and, if ingested in large amounts by adults or small amounts by children, can produce nausea, vomiting, abdominal pain, and burning diarrhea.

Treatment: Management of overdose essentially consists of supportive and symptomatic measures. Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, GI irritation, and respiratory depression. Gastric decontamination and the use of activated charcoal should be considered, especially within a short time of ingestion. Specific therapies such as forced diuresis, dialysis or haemoperfusion are probably of no help in eliminating NSAIDs due to their high rate of protein binding and extensive metabolism.

PHARMACODYNAMICS

Diclofenac

Diclofenac, an NSAID, exhibits anti-inflammatory, anti-nociceptive/analgesic, and antipyretic effects. Mechanism of action of diclofenac is similar to that of other NSAIDs. Diclofenac

inhibits the enzyme cyclooxygenase (COX), an early component of the arachidonic acid cascade, resulting in the reduced formation of prostaglandins, thromboxanes and prostacylin.

Linseed Oil

Linseed oil (flaxseed oil), is a colourless to yellowish oil obtained from the dried, ripened seeds of the flax plant. Linseed oil is a rich source of α-linolenic acid (an omega-3 fatty acid) – a natural anti-inflammatory agent. Linseed oil has anti-inflammatory and analgesic properties. Linseed oil softens skin and soothes skin irritation.

Methyl Salicylate

Methyl salicylate is a salicylic acid derivative. Methyl salicylate shares the actions of salicylates. Salicylates inhibit COX, thereby reducing the formation of prostaglandins and block the inflammatory process and pain. Methyl salicylate is a rubefacient. It produces reddening of the skin by dilatation of the blood vessels and gives a soothing feeling of warmth. Methyl salicylate also produces counterirritant effects. Irritation of the sensory nerve endings alters pain in the underlying muscle or joints that are served by the same nerves. Upon topical application of gel, methyl salicylate is absorbed through the skin and it relieves pain in arthritic conditions and painful musculoskeletal disorders.

Menthol

When menthol is rubbed on the skin, it acts as a rubefacient and causes localized vasodilatation; which gives feelings of comfort and warmth. When applied gently on the skin, menthol acts as an anti-pruritic agent and creates a feeling of coolness, and a mild local anesthetic effect. Menthol has good soothing effect and acts as a demulcent. Menthol also acts as a penetration enhancer, increasing the penetration of topically-applied drugs and providing a faster onset of action.

Capsaicin

Capsaicin is a colorless and odorless compound found in chili peppers, which creates a burning sensation when applied locally. Capsaicin is used to treat minor aches and pains of the muscles and joints (e.g., arthritis, backache, sprains). Capsaicin is also useful in diabetic nerve pain (neuropathy). Capsaicin works by decreasing levels of certain natural substances found in the body (e.g., substance P) that help pass pain signals to the brain.

PHARMACOKINETICS

Diclofenac

When DICLOTAL-FORTE Gel is applied locally, diclofenac sodium is absorbed through the skin. In healthy volunteers, approximately 6% of the applied dose is absorbed as determined by urinary excretion of diclofenac and its hydroxylated metabolites. Following local application of gel, diclofenac penetrates into the inflamed areas. After topical administration of gel to hand and

knee joints, diclofenac can be measured in plasma, synovial tissue, and synovial fluid. Maximum plasma concentration of diclofenac is about 100 times lower than following oral administration of diclofenac.

Linseed Oil

Pharmacokinetic properties of linseed oil after topical application are not known.

Methyl Salicylate

The absorption of topical salicylates is proportional to the surface area involved, duration of exposure, concentration and skin integrity. Per-cutaneous absorption is enhanced by exercise, heat, occlusion, or disruption of the integrity of the skin or application to large areas of skin. Both the rate and extent of absorption increases after repeated application, increasing the bioavailability. Methyl salicylate is extensively metabolized to salicylic acid in the dermal and subcutaneous tissues after topical application. At therapeutic levels, the half-life of salicylates is 2 to 4 hours. As salicylate level reaches the toxic range, the half-life can be greater than 18 hours.

Menthol

After absorption, menthol is excreted in the urine and bile as a glucuronide.

Capsaicin

No pharmacokinetic data is available for topical use of capsaicin.

INCOMPATIBILITIES

None known.

SHELF-LIFE

Expiry date as mentioned on the product pack.

PACKAGING INFORMATION

30 g tube.

STORAGE AND HANDLING INSTRUCTIONS

Store below 30°C. Do not freeze.
Replace the cap tightly after each use.
Keep out of reach of children.

Last updated: March 2020.