SUMMARY OF PRODUCT CHARACTERISTICS
ETOVAC GEL (Diclofenac Sodium Gel 10 mg/g)

1. NAME OF THE MEDICINAL PRODUCT

ETOVAC GEL (Diclofenac Sodium Gel 10 mg/g)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of gel contains:
Diclofenac sodium …… 10 mg
Methyl Salicylate BP …… 1000 mg
Menthol BP …… 50 mg
Linseed Oil BP …… 30 mg

Excipients with known effect:
Contains propylene glycol and benzyl alcohol. For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gel for cutaneous use (topical gel).
White coloured gel.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the short-term local symptomatic treatment of the following musculoskeletal inflammatory conditions:

- Acute soft-tissue injuries, including sprains, strains and sports injuries.
- Localised forms of soft tissue rheumatism such as tendinitis (e.g. tennis elbow) and bursitis.

For the short-term (up to 3 weeks) relief of pain in non-serious arthritis (i.e. mild and localised forms of osteoarthritis) of the knees or fingers. Relief of osteoarthritic pain builds up gradually over the first few days of treatment; a significant effect can be expected after one week of application.

4.2 Posology and method of administration

Adults and adolescents aged 12 years and over
Diclofenac gel is applied locally to the skin 3 or 4 times daily and rubbed in gently. The amount needed depends on the size of the painful site. For example, 2 to 4 g of gel (a quantity ranging in size from a cherry to a walnut) is sufficient to apply to an area of about 400–800 cm². After application, the hands should be washed, unless they are the site being treated. The gel should never be taken by mouth. The gel may be used with non-occlusive bandages but should not be used with occlusive dressings. The duration of treatment depends on the indication and the response obtained. The gel should not be used for more than 14 days for soft tissue injuries or soft tissue rheumatism, or 21 days for osteoarthritis pain, unless recommended by a doctor. When used without medical prescription, patients should consult their doctor or pharmacist if the condition does not improve within 7 days, or if it gets worse.

Children
ETOVAC GEL is not recommended for use in children below 12 years of age, as safety and efficacy in this age group have not been established.

Elderly
No dose adjustment is required for elderly patients.

Method of administration
For cutaneous use only. Apply topically to the affected area. Avoid contact with the eyes and mucous membranes. Do not apply to broken or damaged skin.

4.3 Contraindications

- Known hypersensitivity to diclofenac sodium or to any of the excipients listed in section 6.1.
- Patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs).
- Third trimester of pregnancy (see section 4.6).
- Active or history of gastrointestinal bleeding, ulceration or perforation related to previous NSAID therapy.

4.4 Special warnings and precautions for use

Systemic side effects

The likelihood of systemic side effects occurring following topical application of diclofenac is small compared with the frequency of side effects following oral diclofenac. However, the possibility of systemic side effects cannot be excluded, particularly when the gel is applied to relatively large areas of skin or for prolonged periods exceeding 3 weeks. In cases where such usage is envisaged, the systemic risks associated with oral NSAID therapy should be taken into consideration.

Topical side effects

ETOVAC GEL should be applied only to intact, healthy skin and not to skin wounds, infections, exudative dermatoses or open injuries. It should not be allowed to come into contact with the eyes or mucous membranes and should not be ingested. Discontinue treatment if a skin rash develops after applying the product.

Propylene glycol and benzyl alcohol

This medicinal product contains propylene glycol and benzyl alcohol, which may cause mild, localised skin reactions (e.g. contact dermatitis) in some patients.

Use in gastrointestinal disorders

In general, topical NSAIDs should be used with caution in patients with a history of or active gastrointestinal ulceration or bleeding. If gastrointestinal bleeding or ulceration occurs, ETOVAC GEL should be withdrawn.

Cardiovascular and cerebrovascular effects

Appropriate monitoring and advice are required for patients with hypertension and/or mild to moderate congestive heart failure as fluid retention and oedema have been reported in association with NSAID therapy.

Renal effects

Renal function may be impaired following treatment with NSAIDs, particularly in patients who are volume-depleted or receiving diuretics. As ETOVAC GEL is a topical preparation with low systemic absorption, clinically relevant renal effects are less likely; however, caution is required in patients with severe renal impairment.

Use in pre-existing asthma

Reactions to NSAIDs such as asthma exacerbations (so-called intolerance to analgesics/analgesic-asthma), Quincke's oedema or urticaria are more frequent in patients with asthma, seasonal allergic rhinitis, swelling of the nasal mucosa (nasal polyps), chronic obstructive pulmonary disease or chronic infections of the respiratory tract. Special precaution is recommended in such patients. This applies also for patients who are allergic to other substances, e.g. with skin reactions, pruritus or urticaria.

Use under dressings

ETOVAC GEL can be used with non-occlusive bandages but should not be used under occlusive dressings. Occlusion over a period of 10 hours leads to a 3-fold increase in the amount of diclofenac absorbed.

Hepatic impairment

In patients with chronic hepatitis or non-decompensated cirrhosis, the kinetics and metabolism of diclofenac are the same as in patients without liver disease. In severe hepatic impairment, caution is required.

Paediatric use

ETOVAC GEL is not recommended for use in children under 12 years of age, as safety and efficacy in this age group have not been established.

4.5 Interaction with other medicinal products and other forms of interaction

Due to the low systemic absorption of diclofenac from topical application, clinically significant drug interactions are unlikely. However, the following should be considered:

Anticoagulants and antiplatelet agents:

The concurrent use of NSAIDs and warfarin has been associated with severe, sometimes fatal, haemorrhage. The mechanism may involve enhanced bleeding from NSAID-induced gastrointestinal ulceration or an additive effect on platelet function. Isolated reports of suspected interaction of topical NSAID formulations with oral anticoagulants have been received. Since systemic absorption of diclofenac from topical application of the gel is very low, such interactions are very unlikely. Nevertheless, this possibility should be borne in mind.

Other NSAIDs:

Concomitant use of ETOVAC GEL with other topical or systemic NSAIDs may increase the risk of adverse reactions. Concurrent use should be avoided.

Cyclosporin and tacrolimus:

NSAIDs may increase the nephrotoxicity of ciclosporin and tacrolimus. Caution should be exercised when any NSAID, including topical formulations used over large areas or for prolonged periods, is administered together with ciclosporin or tacrolimus.

4.6 Fertility, pregnancy and lactation

Pregnancy

Inhibition of prostaglandin synthesis may adversely affect pregnancy and/or embryonal/foetal development.

First and second trimesters of pregnancy:

Diclofenac should not be used during the first two trimesters of pregnancy unless clearly necessary. If diclofenac is used by a woman attempting to conceive, or during the first or second trimester of pregnancy, the dose should be kept as low and the duration of treatment as short as possible.

Third trimester of pregnancy:

Diclofenac is contraindicated during the third trimester of pregnancy. All prostaglandin synthesis inhibitors may expose the foetus to cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension), renal dysfunction (which may progress to renal failure with oligohydramnios), and possible prolongation of bleeding time. The mother and the neonate may experience inhibition of platelet aggregation even at low doses. At the end of pregnancy, prostaglandin synthesis inhibitors may expose the mother to risk of uterine inertia and delay in parturition.

Breast-feeding

It is not known whether topically applied diclofenac is excreted in breast milk. ETOVAC GEL should only be used during breast-feeding if the expected benefit to the mother clearly outweighs the potential risk to the infant. If used, the gel should not be applied to the breasts or to large areas of skin, nor should it be used for a prolonged period.

Fertility

Diclofenac had no influence on the fertility of parent animals in rats. There was no evidence that diclofenac had a teratogenic potential in mice, rats or rabbits. The prenatal, perinatal and postnatal development of the offspring was not affected at clinically relevant exposures.

4.7 Effects on ability to drive and use machines

Cutaneous application of the gel is unlikely to influence the ability to drive and use machines. The possibility of systemic effects should be considered if the product is used over large areas or for prolonged periods.

4.8 Undesirable effects

Summary of the safety profile

The most frequently reported adverse reactions are local skin reactions at the site of application. Systemic adverse reactions are uncommon with topical use at recommended doses.

Tabulated list of adverse reactions

Adverse reactions are listed by MedDRA System Organ Class and frequency using the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000).

System Organ Class	Very common ≥1/10	Common ≥1/100	Uncommon ≥1/1,000	Rare ≥1/10,000	Very rare <1/10,000
Immune system disorders			Hypersensitivity reactions		Angioneurotic oedema
Respiratory disorders					Asthma (in susceptible patients)

System Organ Class	Very common ≥1/10	Common ≥1/100	Uncommon ≥1/1,000	Rare ≥1/10,000	Very rare <1/10,000
Skin and subcutaneous tissue disorders		Rash Erythema Eczema Pruritus Dermatitis (including contact dermatitis)	Dermatitis bullosa	Photosensitivity reaction Desquamation Skin discoloration	Pustular rash
Gastrointestinal disorders			Nausea Abdominal discomfort (with extensive use)		

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

4.9 Overdose

The low systemic absorption of topical diclofenac renders overdosage extremely unlikely. However, undesirable effects similar to those observed following an overdose of an oral NSAID can be expected if the gel is inadvertently ingested. One tube of 30 g of ETOVAC GEL contains 300 mg diclofenac sodium.

Treatment: In the event of accidental ingestion resulting in significant systemic side effects, general therapeutic measures normally adopted to treat poisoning with NSAIDs should be used, including gastric lavage and symptomatic and supportive therapy. There is no specific antidote. Forced diuresis, alkalisation of urine, haemodialysis, or haemoperfusion may not be useful due to the high degree of protein binding of diclofenac.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical products for joint and muscular pain; anti-inflammatory preparations, non-steroids for topical use. ATC code: M02AA15.

Mechanism of action

Diclofenac is a non-steroidal anti-inflammatory drug (NSAID) with pronounced analgesic, anti-inflammatory and antipyretic properties. Inhibition of prostaglandin synthesis is the primary mechanism of action. Diclofenac inhibits cyclo-oxygenase (COX-1 and COX-2) enzymes, thereby reducing the synthesis of prostaglandins, prostacyclins and thromboxanes from arachidonic acid. ETOVAC GEL is an anti-inflammatory and analgesic preparation designed for external application. In inflammation and pain of traumatic or rheumatic origin, the gel has been shown to relieve pain, reduce oedema, and shorten the time to return of normal function. Due to its aqueous-alcoholic base, the gel also exerts a soothing and cooling effect.

5.2 Pharmacokinetic properties

Absorption

When diclofenac gel is applied locally, the active substance is absorbed through the skin. The amount of diclofenac absorbed through intact skin is proportional to the contact time and skin area covered with the gel, and depends on the total topical dose and the hydration of the skin. Absorption amounts to about 6% of the dose of diclofenac after topical application of 2.5 g of the gel per 500 cm² of skin, determined by reference to the total renal elimination compared to oral administration. Occlusion over a period of 10 hours leads to a 3-fold increase in the amount of diclofenac absorbed.

Distribution

After topical administration of diclofenac gel to hand and knee joints, diclofenac can be measured in plasma, synovial tissue, and synovial fluid. Maximum plasma concentrations of diclofenac after topical administration are approximately 100 times lower than after oral administration of the same quantity of diclofenac. Diclofenac is highly bound to serum proteins (99.7%), predominantly to albumin (99.4%).

Biotransformation

The biotransformation of diclofenac involves partly glucuronidation of the intact molecule, but mainly single and multiple hydroxylation and methoxylation, resulting in several phenolic metabolites, most of which are converted to glucuronide conjugates. Two of these phenolic metabolites are biologically active, however to a much smaller extent than diclofenac. Metabolism of diclofenac following topical and oral administration is similar.

Elimination

The total systemic clearance of diclofenac from plasma is 263 ± 56 mL/min (mean value ± SD). The terminal plasma half-life is 1 to 2 hours. Four of the metabolites, including the two active ones, also have short plasma half-lives of 1–3 hours. One metabolite, 3′-hydroxy-4′-methoxy-diclofenac, has a much longer plasma half-life but is virtually inactive. Diclofenac and its metabolites are excreted mainly in the urine.

5.3 Preclinical safety data

Preclinical data from acute and repeated dose toxicity studies, as well as from genotoxicity, mutagenicity and carcinogenicity studies with diclofenac, revealed no specific hazard for humans at the intended therapeutic doses. The gel was well tolerated in a variety of dermal studies. There was no potential for phototoxicity and diclofenac gel caused no skin sensitisation in standard predictive tests.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbopol 934

Propylene glycol

Benzyl alcohol

Chlorocresol

Sodium methyl paraben

Sodium propyl paraben

Butylated hydroxytoluene (BHT)

Butylated hydroxyanisole (BHA)

Triethanolamine

Polysorbate 80 (Tween-80)

Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30°C in a cool, dry place. Do not freeze. Keep out of the reach and sight of children.

6.5 Nature and contents of container

Aluminium laminated tube (LDPE/aluminium/HDPE). Pack size: 30 g.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements. The product is for external use only.

7. MARKETING AUTHORISATION HOLDER

PROMED PHARMACEUTICALS LTD

P.O. Box 22953-00100, Nairobi, Kenya.

8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2025/CTD9915/22300

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03.11.2025

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