

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICATION

Traumon Gel 10%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Traumon Gel 10%

1 g of gel contains 100 mg Etofenamate.

Other components with known effects

Propylene glycol (E1520): This medicine contains 51 - 99 mg propylene glycol in a 5 - 10 cm long gel line, which corresponds to 30 mg propylene glycol per 1 g Traumon Gel 10%.

For a complete list of other components, see section 6.1.

3. DOSAGE FORMS

Traumon Gel 10%: Gel

Clear to slightly opalescent, colourless to slightly yellowish gel

4. CLINICAL INFORMATION

4.1. Scope of use

For the external symptomatic treatment of pain;

- in cases of acute strains, sprains or bruises in the limbs due to blunt traumas, e.g. sports injuries;
- soft tissues close to joints (e.g. bursas, tendons, ligaments and joint capsules), for osteoarthritis of the knee joint.

4.2. Dosage and application

Traumon Gel 10%

Three times daily, thinly apply a 10 cm long line of *Traumon Gel 10%* (approx. 3.3 g per application) to the affected parts of the body and lightly rub it.

Only for application on the skin! Do not ingest!

Let the *Traumon Gel 10%* dry on the skin for a few minutes before applying a bandage. Application on an occlusive dressing is not recommended.

In the case of blunt injuries (e.g. sports injuries), application for a week is usually sufficient. The therapeutic benefit of an application beyond this period has not been established.

In cases of rheumatic diseases, a duration of treatment of 3 - 4 weeks is enough in most cases. If symptoms persist, consult a doctor, who will decide how to proceed.

4.3. Contraindications

Do not use the *Traumon Gel 10%*

- if you are hypersensitive to the active substance etofenamate, the main metabolite flufenamic acid or any of the other ingredients listed in section 6.1;
- if you have a history of hypersensitivity reactions (e.g. asthma, bronchospasms, rhinitis, angioedema or urticaria) after taking acetylsalicylic acid or other non-steroidal anti-inflammatory drugs/anti-inflammatory drugs (NSAIDs);
- on open injuries, inflammation or skin infections, as well as on eczema;
- on eyes, lips or mucous membranes;
- in the last trimester of pregnancy;
- for children and adolescents.

4.4 Special warnings and precautions for use

Traumon Gel 10% may only be used under certain precautionary measures and under direct medical supervision in

- Patients suffering from asthma, hay fever, swelling of the nasal mucosa (so-called nasal polyps) or chronic obstructive respiratory diseases or chronic respiratory infections (especially coupled with hay fever-like symptoms). When using *Traumon Gel 10%*, these patients are more at risk of asthma attacks (so-called analgesic intolerances/analgesic asthma), localised swelling of the skin and mucous membranes (so-called Quincke's edema) or urticaria than other patients;
- Patients who are also hypersensitive (allergic) to other substances, such as skin reactions, itching or hives.

Direct sunlight and solarium visits should be avoided during treatment and 2 weeks thereafter.

The occurrence of systemic side effects from the use of *Traumon Gel 10%* cannot be excluded if the medicine is used on large skin areas over a long period of time.

Children should not come into contact with the skin areas where the medicine has been applied.

Traumon Gel 10% can cause discolouration or changes in the surface of polished furniture or plastics. Therefore, if necessary, wash your hands after rubbing the gel or avoid contact with the above-mentioned objects.

Propylene glycol can cause skin irritation.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions are known with the intended use of *Traumon Gel 10%*.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is insufficient experience in humans regarding the safety of using etofenamate during pregnancy. Since the influence of prostaglandin synthesis inhibition during pregnancy is unclear, *Traumon Gel 10%* should only be used in the 1st and 2nd trimesters of pregnancy after careful consideration of the benefit-risk balance. The maximum daily dose should not be exceeded. (See section 4.2)

In the last trimester of pregnancy, the use of *Traumon Gel 10%* is contraindicated.

During the last trimester of pregnancy, the mechanism of affection could inhibit labour, prolong pregnancy and childbirth, cardiovascular (premature occlusion of the ductus Botalli, pulmonary hypertension) and renal (oliguria, oligoamnion) toxicity in the child, increased tendency of bleeding in the mother and child and increased edema formation in the mother.

Lactation

Since etofenamate passes into breast milk, prolonged use of *Traumon Gel 10%* during breastfeeding should be avoided if possible, and the daily dose should not be exceeded. Breastfeeding women should not use the medication in the breast area, so as to avoid ingestion by the infant.

Wash hands after applying *Traumon Gel 10%* to avoid the infant coming in contact with the medication.

4.7 Impact on the ability to drive and operate machines:

Traumon Gel 10% has very little to no influence on the ability to drive and to operate machines.

4.8 Side effects

The following categories are used for the frequency of side effects:

Very frequent	$\geq 1/10$
Frequent	$\geq 1/100$ to $< 1/10$
Occasional	$\geq 1/1,000$ to $< 1/100$
Rare	$\geq 1/10,000$ to $< 1/1,000$
Very rare	$< 1/10,000$
Unknown	Frequency cannot be estimated from the available data

System organ class	Frequency	Side effect
Skin ailments and subcutaneous tissue disorders	Occasional	Dermatitis such as erythema, itching, burning, rash with pustules or wheals
	Very rare	Swelling
	Unknown	Photosensitisation
Immune system disorders	Rare	Hypersensitivity reactions, Localised allergic reactions (contact dermatitis)

Description of selected side effects

Hypersensitivity reactions have been reported after systemic use of NSAIDs. These can be (a) non-specific allergic reactions and anaphylaxis (b) respiratory reactivity with asthma, increased asthma, bronchospasms or dyspnea, or (c) various skin reactions, including rashes of various types, pruritus, urticaria, purpura, angioedema and on rare occasions exfoliative and bullous dermatoses (including toxic epidermal necrolysis, Stevens-Johnson syndrome and erythema multiforme). Seek immediate medical attention if any one of these symptoms arise, which could be possible after the first application.

If *Traumon Gel 10%* is applied over a large skin area and used over a longer period of time, there is a possibility of experiencing side effects after the systemic use of medicines containing etofenamate that affect a certain organ system or the entire being.

Report suspicion of side effects

The reporting of suspected adverse reactions that should occur after authorisation of the medicine is important, because this enables continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system at www.medicinesauthority.gov.mt/adrportal

4.9 Overdose

In case of unintended use:

If the contents of a tube of *Traumon Gel 10%* or more applied to the entire surface of the body within a short time, you may experience headache, dizziness or upper abdominal discomfort.

As a countermeasure, washing off the *Traumon Gel 10%* with water is recommended. There is no specific antidote.

5. PHARMACOLOGICAL CHARACTERISTICS

5.1. Pharmacodynamic characteristics

Pharmacotherapeutic group: Non-steroidal anti-inflammatory drugs for topical use

ATC Code: M02AA06

Etofenamate is a non-steroidal anti-inflammatory analgesic that has been shown to be

effective in inhibiting prostaglandin synthesis in typical animal inflammation models.

5.2. Pharmacokinetic characteristics

Plasma level

When subjects were given 300 mg etofenamate in the form of *Traumon Gel 10%*, maximum flufenamic acid plasma levels were measured between 12 and 24 hours after application (21-28 ng/ml).

Protein binding

Protein binding is between 98% - 99%.

Metabolism and elimination

Etofenamate elimination occurs renally in the form of numerous metabolites of flufenamic acid (hydroxylation, ether and ester cleavage) and their conjugates, 55%.

Enterohepatic circulation is likely.

After topical application, an elimination half-life of approximately 3.3 hours was observed.

Etofenamate is excreted in breast milk in low concentrations as flufenamic acid.

Bioavailability

The bioavailability of preparations containing etofenamate is subject to both high interindividual and intraindividual fluctuations, which are essentially due to the application site, skin moisture and other factors. After cutaneous application, the relative bioavailability, that is the systemically available portion of the dose, in the order of magnitude of other etofenamate preparations (up to 20%).

5.3. Pre-clinical safety data

In case of topical application of etofenamate, the absorption rate must be taken into account when evaluating the toxicological data (see pharmacokinetics).

Acute toxicity

Studies on the acute toxicity of etofenamate were carried out on rats, mice, guinea pigs and rabbits with different applications. Oral application indicated higher toxicity as compared to cutaneous application. The intoxication chart characteristics are concentrated in the gastrointestinal tract, with diarrhoea and weight loss. These symptoms usually only appear a few days after application. Fatalities occurred between the 2nd and 14th day. After administering sub-lethal doses, the animals recovered within 14 days. The autopsy revealed peritonitis and ascites.

Sub-chronic and chronic toxicity

Sub-chronic toxicity tests were carried out on various animal species. Studies of one year duration and oral use were carried out in rats (7, 27, 100 mg/kg body weight/day) and monkeys (7, 26, 100 mg/kg body weight/day). In rats below 100 mg/kg body weight/day, bleeding and ulcers developed in the gastrointestinal area, with subsequent peritonitis and increased mortality.

The high dose led to a reduction in body weight, thymus weight and haemoglobin in monkeys.

Mutagenic and tumorigenic potential

The *in vitro* and *in vivo* studies on the induction of gene and chromosome mutations were negative. A mutagenic effect appears to be sufficiently excluded.

In long-term studies with oral use in rats (7, 21, 63 mg/kg body weight/day) and mice (15, 45, 140 mg/kg body weight/day), there was no evidence of etofenamate's tumorigenic potential.

Local tolerance

See point 4.8. "Side effects"

Reproductive toxicity

Etofenamate crosses the placenta.

There is no experience regarding human application. In animal experiments, the embryotoxic dose was below the maternally toxic one. From a dose of 21 mg/kg body weight orally (days 6 - 15 p.c.), the rat showed increased dilatation of the renal pelvis and an increased incidence of 14 rib pairs from 7 mg/kg body weight orally (days 6 - 15 p.c.) in young animals of treated mother animals.

Etofenamate is excreted in breast milk as flufenamic acid. The concentrations in breast milk are low, so that short-term and small-scale dermal treatment of the mother with etofenamate should not be regarded as an obstacle to breastfeeding.

6. PHARMACEUTICAL DATA

6.1. List of other components

Traumon Gel 10%

α -Hexadecyl/(Z)-octadec-9-en-1-yl]- ω -hydroxypoly(oxyethylene)-8, Macrogol 400, sodium hydroxide, Carbomer (average viscosity 50000 mPa · s), isopropyl alcohol, Propylene glycol, purified water

6.2. Incompatibilities

There are no known incompatibilities.

6.3. Shelf life

Traumon Gel 10%

Shelf life is 5 years.

After opening the tube, *Traumon Gel 10 %* have a shelf life of 12 weeks.

6.4. Special precautions for storage

No special storage conditions are required for these medications.

6.5. Type and content of the containers

Traumon Gel 10%

Original packaging of 50 g gel

Original packaging of 100 g gel

Packaging for hospitals

Not all package sizes may be marketed.

6.6. Special precautions for disposal

No special requirements

7. MARKETING AUTHORISATION HOLDER

Viartis Healthcare Limited
Damastown Industrial Park,
Mulhuddart,
Dublin 15, DUBLIN,
Ireland

8. MARKETING AUTHORISATION NUMBER

MA1507/02301

9. Date of approval/renewal of approval

18th January 2008/30th November 2012

10. DATE OF LAST REVISION OF TEXT

November 2022

11. SALES RESTRICTIONS

Available only in pharmacies