Olfen™

Olfen™ 1% Gel

Non-steroidal anti-inflammatory agent for topical application

Composition

Active substance
Diclofenac sodium.
Excipients
Antioxidant E223 (sodium disulphite); excipients for gel.

Pharmaceutical form and quantity of active pharmaceutical ingredient per unit

1 g gel contains diclofenac sodium 10 mg as active substance.

Indications / Possible areas of use

For the external treatment of pain, inflammation and swelling in:
- sprains, contusions, strains and back pain following sport or accidents;
- localised forms of soft tissue rheumatism, such as tendinitis (tennis elbow), shoulder-hand syndrome, bursitis, peri-arthropathies;
- and for the symptomatic treatment of osteoarthritis of small and medium-sized joints close to the skin surface, such as finger joints or knees.

Dosage/Use

Adults and adolescents aged 12 years and over
Depending on the size of the painful site to be treated, 24 g Olfen 1% Gel (cherry-to walnut-sized amount sufficient to treat an area of about 400-800 cm^2) should be applied 3-4 times daily to the affected parts of the body and rubbed in gently.
The duration of use depends on the indication and the success of treatment. It is recommended to reassess the treatment after 2 weeks if the symptoms have not improved. Olfen 1% Gel should not be used for more than 14 days. The hands should be washed well after use (except in the treatment of osteoarthritis of the fingers). Olfen 1% Gel can also be used as adjuvant therapy together with other dosage forms of Olfen.

Children under 12 years
So far, the use and safety of Olfen 1% Gel have not been systematically tested in children under 12 years of age and its use is not recommended.

Contraindications

Hypersensitivity to diclofenac or to any of the excipients (e.g. isopropanol or E223 sodium disulphite).
Olfen 1% Gel is contraindicated in patients in whom acetylsalicylic acid or other non-steroidal anti-inflammatory drugs such as ibuprofen can trigger asthma attacks, urticaria or acute rhinitis.
Olfen 1% Gel is contraindicated during the 3rd trimester of pregnancy (see advice in the section "Pregnancy/ Breast-feeding").

Warnings and precautionary measures

Olfen 1% Gel should be applied to intact skin surfaces only and not to skin wounds or open lesions. The eyes and mucous membranes should not come into contact with the preparation.
Olfen 1% Gel must not be used with airtight, occlusive bandages.

Interactions
Due to the low systemic absorption in topical use, the likelihood of interactions is very low. See also the last paragraph of the section "Adverse effects".

Pregnancy/Breast-feeding
Pregnancy
No controlled studies are available in pregnant women. Olfen 1% Gel should therefore not be used during pregnancy. Olfen 1% Gel is contraindicated in the 3rd trimester of pregnancy due to possible premature closure of the ductus arteriosus and possible suppression of uterine contractions. Animal studies have not shown direct or indirect harmful effects with respect to pregnancy, embryofetal development, birth or postnatal development (see "Preclinical data").

Breast-feeding
It is not known whether topically applied diclofenac passes into breast milk. Therefore, Olfen 1% Gel should not be used in breast-feeding mothers. Where it is strictly indicated, Olfen 1% Gel should not be used in the area of the breast, over large areas of skin or for prolonged periods.

Effects ability to drive and to use machinery
Not applicable.

Adverse effects
Frequency
"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).

Immune system disorders
Very rare: hypersensitivity reactions (including urticaria), angio-oedema.

Respiratory organs
Very rare: asthma

Skin and subcutaneous tissue disorders:
Common: skin rash, eczema, reddening, dermatitis (including contact dermatitis), pruritus.
Rare: bullous dermatitis
Very rare: photosensitisation, pustular skin rash.

The likelihood of systemic side effects occurring during topical administration of diclofenac is low compared with the frequency of side effects during oral treatment with diclofenac.

When Olfen 1% Gel is used on relatively large areas and for a prolonged period of time, the occurrence of systemic side effects cannot entirely be ruled out. In such cases, the professional information should be consulted for the oral forms of Olfen.

Overdose
Due to the low systemic absorption of diclofenac when used topically, an overdose is very unlikely.

Adverse effects similar to those of an overdose with diclofenac tablets are to be expected following inadvertent ingestion of Olfen 1% Gel (1 tube of 100 g is equivalent to 1 g diclofenac sodium). Should significant systemic side effects occur as a result of improper use or accidental overdose (e.g. in children), the general therapeutic measures customary for treating intoxication with non-steroidal anti-inflammatory agents must be taken.
Gastric lavage and treatment with activated charcoal may be considered, particular shortly after ingestion.

Characteristics/Effects
ATC code: M02AA15
Mechanism of action and pharmacodynamics
Diclofenac is a non-steroidal antic-inflammatory drug (NSAID) with marked analgesic, anti-inflammatory and antipyretic properties.
Olfen 1% Gel is an anti-inflammatory and analgesic preparation for external use.
The colourless, non-greasy gel can be rubbed into skin easily and possesses a soothing, cooling effect due to the aqueous alcoholic base.
The demonstrated inhibition of prostaglandin biosynthesis by diclofenac is regarded as an important component of its mechanism of action.

Pharmacokinetics
Absorption
The amount of diclofenac absorbed through the skin is proportional to the duration of skin contact and to the area of skin covered with diclofenac gel and is dependent on the total topical dose and the hydration of the skin. After topical application of 2.5 g diclofenac gel per 500 cm² of skin, about 6% of the diclofenac dose is absorbed, as determined by total elimination via the kidney compared with diclofenac tablets. The absorption of diclofenac is increased three-fold by an occlusive bandage for 10 hours.

Distribution
Following topical administration of Olfen 1% Gel to hand and knee joints, diclofenac is detectable in plasma, synovial tissue and synovial fluid.
Peak plasma concentrations of diclofenac are about 100 times lower after topical application of Olfen 1% Gel than after oral administration of Olfen tablets. Diclofenac is 99.7% bound to serum proteins, primarily albumin (99.4%).

Metabolism
Biotransformation of diclofenac is partly by glucuronidation of the intact molecule, but mainly by single and multiple hydroxylation followed by glucuronidation of most of the resultant phenolic metabolites. Two of these phenolic metabolites are biologically active, although to a much lesser extent than diclofenac.

Elimination
Total systemic clearance of diclofenac from plasma is 263 ± 56 mL/min (mean ± standard deviation) and the terminal plasma half-life is 12 h. Four of the metabolites, including the two active metabolites, also have a short plasma half-life of 13 h. One metabolite, 3'-hydroxy-4'-methoxy- diclofenac, has a much longer half-life. However, this metabolite is practically inactive.
Diclofenac and its metabolites are predominantly eliminated with the urine.

Kinetics in special clinical situations
No accumulation of diclofenac and its metabolites is to be expected in patients with renal failure.

The kinetics and metabolism of diclofenac in patients with chronic hepatitis or compensated liver cirrhosis are the same as in patients without liver disease.

Preclinical data
Preclinical data from acute and repeated dose toxicity, genotoxicity, mutagenicity and carcinogenicity studies with diclofenac indicated no specific hazard for humans at the recommended therapeutic dosages. No teratogenic effects were found in mice, rats or rabbits. Diclofenac has no effect on the fertility of the parent animals (rat) or prenatal, perinatal and postnatal development of the progeny.
There was no evidence in various studies that diclofenac gel causes phototoxicity or skin sensitisation.

Other instructions
Shelf life
This medicine may only be used up until the expiry date stated on the pack (EXP).

Special storage instructions
Climatic zone I and II: Do not store above 25° C.
Climatic zone III and IV: Do not store above 30° C.
Do not swallow.
Keep out of the sight and reach of children.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Presentation
Olfen 1% Gel: tubes of 20 g, 50 g and 100 g; not all pack sizes may be marketed.

Date of information
August 2014

Manufactured by Sofarimex S.A., Cacém, Portugal
for Acino Pharma AG, Liesberg, Switzerland

To report a safety issue or for queries in relation to drug safety – please send an e-mail to: pv@acino-pharma.com