Olfen™ 1% Gel

Composition

Active substance

Diclofenac sodium

Excipients

Lactic acid, diisopropyl adipate, isopropyl alcohol, sodium metabisulfite (E223), hydroxyethyl cellulose, hydroxypropyl cellulose, purified water

Pharmaceutical form and active substance quantity per unit

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

Indications/Uses

For the external treatment of pain, inflammation and swelling in:

- injuries of the tendons, ligaments, muscles and joints, e.g. 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, periarthropathies;
- 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/Administration

The product is intended for external use only.

Adults and adolescents aged 12 years and over

Depending on the size of the painful site to be treated, 2-4 g Olfen™ 1% Gel (cherry- to walnut-sized amount sufficient to treat an area of about 400–800 cm²) 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. Wash hands well after use (except in the treatment of osteoarthritis of the fingers).

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; its use is therefore not recommended.

Contraindications

Hypersensitivity to diclofenac or to any of the excipients (e.g. isopropanol or E223 sodium disulphite). In patients in whom acetylsalicylic acid or other non-steroidal anti-inflammatory drugs such as ibuprofen can trigger asthma attacks, angioedema, urticaria or acute rhinitis.

During the 3rd trimester of pregnancy (see advice in the section “Pregnancy, lactation”).

Warnings and precautions

Olfen™ 1% Gel should be applied to intact, non-diseased skin only and not to skin wounds or open lesions. The eyes and mucous membranes should not come into contact with the preparation.
Stop treatment immediately if a skin rash appears after use.
Olfen™ 1% Gel must not be used with airtight, occlusive bandages.
When Olfen™ 1% Gel is used on larger surfaces and for longer than recommended periods (see “Dosage/Administration”), occurrence of systemic side effects cannot be completely ruled out. In such cases, the Information for healthcare professionals for the oral forms of diclofenac should be consulted.

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 “Undesirable effects”.

Pregnancy, lactation

Pregnancy
No controlled studies are available in pregnant women. Hence, Olfen™ 1% Gel should not be used during pregnancy.

Animal studies have not shown direct or indirect harmful effects with respect to pregnancy, embryofetal development, birth or postnatal development (see “Preclinical data”).

Third trimester

Olfen™ 1% Gel is contraindicated in the 3rd trimester of pregnancy due to possible premature closure of the ductus arteriosus, possible suppression of uterine contractions and possible renal dysfunction in the foetus, which may progress to renal failure with oligohydramnios.

Lactation

It is not known whether topically applied diclofenac passes into breast milk. Hence, 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 on ability to drive and use machines

Not applicable.

Undesirable effects

Undesirable effects are listed according to system organ class and frequency. Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.
Frequencies
"Very common" (≥1/10), "common" (≥1/100, <1/10), "uncommon" (≥1/1000, <1/100), "rare" (≥1/10,000, <1/1000), "very rare" (<1/10,000).
Immune system disorders
Very rare: angioedema, hypersensitivity reactions (including urticaria), angio-oedema.
Respiratory, thoracic and mediastinal disorders
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™.
Reporting suspected adverse reactions after authorisation of the medicinal product is very important. It allows continued monitoring of the benefit/risk balance of the medicinal product. To report a safety issue or for queries in relation to drug safety – please send an e-mail to: pv@acino.swiss.

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Overdose

Signs and symptoms

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).

Treatment

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.

Properties/Effects

ATC code

ATC code: M02AA15

Mechanism of action

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. In cases of inflammation of traumatic origin, Olfen™ 1% Gel provides relief from pain and causes regression of oedema.

Pharmacodynamics

Not applicable.

Clinical efficacy

Not applicable.

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 1-2 h. Four of the metabolites, including the two active metabolites, also have a short plasma half-life of 1-3 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 patient groups

Hepatic impairment

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

Renal impairment

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

Preclinical data

Long-term toxicity (or repeat dose toxicity)
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.

Mutagenicity

No teratogenic effects were found in mice, rats or rabbits.

Reproductive toxicity

Diclofenac has no effect on the fertility of the parent animals (rat) or prenatal, perinatal and postnatal development of the progeny.

Phototoxicity

There was no evidence in various studies that diclofenac gel causes phototoxicity or skin sensitisation.

Other information

Do not swallow.

Shelf life

Do not use this medicine after the expiry date ("EXP") stated on the container.

Special precautions for storage

Climatic zone I and II: Do not store above 25° C.
Climatic zone III and IV: Do not store above 30° C.
Store in the original packaging.

Keep out of the sight and reach of children.

Packs

Olfen™ 1% Gel: 20 g, 50 g and 100 g. (D)
Not all pack sizes may be marketed.

Marketing authorisation holder

Acino Pharma AG, Liesberg, Switzerland

Date of information

April 2019