

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Swiss relief spray gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1g of solution contains 40 mg of diclofenac sodium (4%w/w).

Excipients with known effects: 150 mg propylene glycol / gram solution

99.98 mg Soybean lecithin 76% / gram solution

33.32 mg Ethanol anhydrous / gram solution

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution.

A golden-yellow, transparent solution, which turns to a gel-like consistency after administration.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the local symptomatic relief of mild to moderate pain and inflammation following acute blunt trauma of small and medium-sized joints and periarticular structures.

4.2 Posology and method of administration

Posology

Adults

Sufficient solution of Swiss relief Spray Gel should be sprayed onto the skin of the affected site. Depending on the size of area to be treated 4-5 pump strokes (0.8-1.0 g of spray containing 32-40 mg of diclofenac sodium) should be applied 3 times daily in regular intervals. A maximum single dose of 1.0 g of the product should not be exceeded. The maximum daily dose is 15 pump strokes (3.0 g of spray containing 120 mg of diclofenac sodium).

Swiss relief Spray Gel should be massaged gently into the skin. After this the hands should be washed unless they are the site to be treated. After application some minutes for drying should be allowed before dressing or binding the treated area.

The treatment may be discontinued when the symptoms (pain and swelling) have subsided. Treatment should not be continued beyond 7-8 days without review. The patient is requested to consult the doctor if no improvement is seen after 3 days.

Older people

The posology is the same as for adults.

Paediatric population

There are insufficient data on efficacy and safety available for the children and adolescents below 15 years of age.

In children aged 15 years and over, if this product is required for more than 7 days for pain relief or if the symptoms worsen the patient/parents of the adolescent is/are advised to consult a doctor.

Patients with hepatic or renal impairment

For the use of Swiss relief Spray Gel in patients with hepatic or renal insufficiency see section 4.4.

Method of administration

For cutaneous use only.

4.3 Contraindications

- Hypersensitivity to diclofenac, peanut, soya or to any of the excipients listed in section 6.1.
- Hypersensitivity to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).
- Patients in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory agents (NSAIDs).
- Use on open injuries, inflammations or infections of the skin as well as on eczema or mucous membranes.
- During the third trimester of pregnancy.
- Children and adolescents aged less than 15 years.

4.4 Special warnings and precautions for use

The possibility of systemic adverse events from application of Swiss relief Spray Gel cannot be excluded if the preparation is used on large areas of skin and over a prolonged period (see the product information on systemic forms of diclofenac).

Swiss relief Spray Gel should be applied only to intact non-diseased skin, and not to skin wounds or open injuries. It should not be allowed to come into contact with the eyes or mucous membranes and should not be ingested.

Swiss relief Spray Gel can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.

Patients should be warned against exposure to sunlight or solarium radiation in order to reduce the incidence of photosensitivity.

Discontinue the treatment if a skin rash develops after applying the product.

The concomitant use of Swiss relief Spray Gel with oral NSAIDs should be cautioned as the incidence of systemic side effects may increase (see section 4.5).

Undesirable effects may be reduced by using the minimum effective dose for the shortest possible duration. Bronchospasm may be precipitated in patients suffering from or with previous history of bronchial asthma or allergenic disease.

Swiss relief Spray Gel should only be used with caution in patients with a history of peptic ulcer, hepatic or renal insufficiency, bleeding diathesis or inflammatory bowel disease as isolated cases with topical diclofenac have been reported.

Swiss relief Spray Gel contains propylene glycol which may cause skin irritation in some people.

Swiss relief Spray Gel contains peppermint oil which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

Since systemic absorption of diclofenac from a topical application of Swiss relief Spray Gel is very low such interactions are very unlikely. Concurrent acetylsalicylic acid or other NSAIDs may result in an increased incidence of adverse reactions (see section 4.4).

4.6 Fertility, pregnancy and lactation

Pregnancy

The systemic concentration of Swiss relief Spray Gel is lower after topical administration, compared to oral formulations. With reference to experience from treatment with NSAIDs with systemic uptake, the following is recommended:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5%. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal lethality. In addition, increased incidences of various malformations, including cardiovascular, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period.

During the first and second trimester of pregnancy, Swiss relief Spray Gel should not be given unless clearly necessary. If Swiss relief Spray Gel is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low and duration of treatment as short as possible.

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 oligo-hydroamniosis;

The mother and the neonate, at the end of pregnancy, to:

- possible prolongation of bleeding time, an anti-aggregating effect which may occur even at very low doses.
- inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, diclofenac is contraindicated during the third trimester of pregnancy.

Fetal Toxicity

Premature Closure of Fetal Ductus Arteriosus:

Avoid use of NSAIDs, including Swiss relief Spray Gel, in pregnant women at about 28 weeks gestation and later. NSAIDs, including Swiss relief Spray Gel, increase the risk of premature closure of the fetal ductus arteriosus at approximately this gestational age.

Oligohydramnios/Neonatal Renal Impairment:

Use of NSAIDs, including Swiss relief Spray Gel, at about 20 weeks gestation or later in pregnancy may cause fetal renal dysfunction leading to oligohydramnios and, in some cases,

neonatal renal impairment. These adverse outcomes are seen, on average, after days to weeks of treatment, although oligohydramnios has been infrequently reported as soon as 48 hours after NSAID initiation. Oligohydramnios is often, but not always, reversible with treatment discontinuation. Complications of prolonged oligohydramnios may, for example, include limb contractures and delayed lung maturation. In some postmarketing cases of impaired neonatal renal function, invasive procedures such as exchange transfusion or dialysis were required.

If NSAID treatment is necessary between about 20 weeks and 28 weeks gestation, limit Swiss relief Spray Gel use to the lowest effective dose and shortest duration possible. Consider ultrasound monitoring of amniotic fluid if Swiss relief Spray Gel treatment extends beyond 5 days. Discontinue Swiss relief Spray Gel if oligohydramnios occurs and follow up according to clinical practice.

Lactation

Like other NSAIDs, diclofenac passes into breast milk in small amounts. However, at therapeutic doses of Swiss relief Spray Gel no effects on the suckling child are anticipated. Because of a lack of controlled studies in lactating women, the product should only be used during lactation under advice from a healthcare professional. Under this circumstance, Swiss relief Spray Gel should not be applied on the breasts of nursing mothers, nor elsewhere on large areas of skin or for a prolonged period of time (see section 4.4).

4.7 Effects on ability to drive and use machines

Cutaneous application of Swiss relief Spray Gel has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Skin disorders are commonly reported.

Adverse reactions (Table 1) are ranked under heading of frequency, the most frequent first, using the following convention: very common ($\geq 1/10$); common ($\geq 1/100$ to $< 1/10$); uncommon ($\geq 1/1,000$ to $< 1/100$); rare ($\geq 1/10,000$ to $< 1/1,000$); very rare ($< 1/10,000$), or not known (can not to be estimated from available data). Within each frequency grouping, adverse reactions are presented in order of decreasing seriousness.

Table 1

Immune system disorder	
Very rare	Hypersensitivity (including urticaria), angioneurotic oedema
Infections and infestations	
Very rare	Rash pustular
Respiratory, thoracic and mediastinal disorders	
Very rare	Asthma

Skin and subcutaneous tissue disorders	
Common	Rash, eczema, erythema, dermatitis (including dermatitis contact), pruritus*
Rare	Dermatitis bullous
Very rare	Photosensitivity reaction
Not known:	Application site reaction, dry skin, burning sensation

* Pruritus has been reported at a frequency of 0.9% in a clinical trial, 236 patients with ankle distortions were treated with 4–5 pump strokes of Swiss relief Spray Gel t.i.d. (120 patients) or placebo (116 patients) for 14 days.

When Swiss relief Spray Gel is applied on large areas of skin and over a prolonged period, the occurrence of systemic undesirable effects cannot be excluded.

Reactions such as abdominal pain, dyspepsia, gastric, hepatic or renal disorders and systemic hypersensitivity reactions may occur.

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.

Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form <http://sideeffects.health.gov.il>

In addition, you can report to Perrigo via the following address: www.perrigo-pharma.co.il

4.9 Overdose

The low systemic absorption of topical diclofenac renders overdose very unlikely.

However undesirable effects similar to those observed following an overdose of diclofenac tablets can be expected if Swiss relief Spray Gel is inadvertently ingested (i.e. a 15 ml spray bottle containing 500 mg of diclofenac sodium).

In the event of accidental ingestion resulting in significant systemic adverse effects, general therapeutic measures normally adopted to treat poisoning with non-steroidal anti-inflammatory medicines should be used. Gastric decontamination and the use of activated charcoal should be considered, especially within a short time of ingestion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti-inflammatory preparations, non-steroids for topical use.

ATC code: M02AA 15

Diclofenac is a non-steroidal anti-inflammatory-/analgesic active substance which, via inhibition of prostaglandin synthesis, has been shown to be effective in standard animal models of inflammation. In humans, diclofenac reduces inflammation-related pain and swelling.

5.2 Pharmacokinetic properties

After cutaneous application of 1.5 g Swiss relief Spray Gel a rapid onset of diclofenac absorption can be observed leading to measurable plasma levels of about 1 ng/ml as early as 30 minutes and to maximum levels of about 3 ng/ml at about 24 hours after application.

The achieved systemic concentrations of diclofenac are about 50 times lower than those achieved following oral administration of equivalent amounts of diclofenac. Systemic plasma levels are not supposed to contribute to the efficacy of Swiss relief Spray Gel.

Diclofenac is extensively bound to plasma proteins (about 99 %).

5.3 Preclinical safety data

In rabbit skin, Swiss relief Spray Gel is classified as non-irritant.

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential of diclofenac.

In rats and rabbits oral doses of diclofenac were not teratogenic but caused embryotoxicity at maternally toxic doses.

Diclofenac did not affect fertility in rats but inhibited ovulation in rabbits and reduced implantation in rats.

In rats, diclofenac resulted in dose-dependent constriction of the fetal ductus arteriosus, dystocia and delayed parturition.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water.

Propylene glycol

Isopropyl alcohol

Soy bean lecithin 76%

Ethanol, anhydrous

Disodium phosphate dodecahydrate

Peppermint oil

Sodium dihydrogen phosphate dihydrate

Disodium edetate

Ascorbyl palmitate

Hydrochloric acid concentrated- for pH-adjustment

Sodium hydroxide - for pH-adjustment

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials

In-use: 6 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Glass bottle with plastic closure.

Pack sizes of 12.5 g (15 ml bottle) and 25 g (30 ml bottle) solution.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

Perrigo Israel Agencies Ltd., 1 Rakefet St., Shoham, Israel

8 MANUFACTURER

Mika Pharma, Auestrasse 39, D - 67346 Speyer, Germany

9 REGISTRATION NUMBER

138-39-31668-00

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