

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Mobigel Spray 4% cutaneous spray, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1g of solution contains 40mg of diclofenac sodium.

For excipients see 6.1.

3 PHARMACEUTICAL FORM

Cutaneous spray, 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

For cutaneous use only. Not to be administered orally.

Adults

Sufficient solution should be sprayed onto the skin to ensure a generous covering of Mobigel® Spray 4% cutaneous spray, solution over the affected site. Normally, 4-5 pump strokes (0.8-1.0 g of spray containing 32-40 mg of diclofenac sodium) would be required. The treatment should be repeated 3 times a day at regular intervals. The maximum daily dose is 15 pump strokes (3.0 g of spray containing 120 mg of diclofenac sodium).

Mobigel® Spray 4% cutaneous spray, solution 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.

Elderly

The posology is the same as for adults.

Children and adolescents:

There are insufficient data on efficacy and safety available for the children and adolescents below 14 years of age (see also contraindications section 4.3).

In children aged 14 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 insufficiency

For the use of Mobigel® Spray 4% cutaneous spray, solution in patients with hepatic or renal insufficiency see section 4.4.

4.3 Contraindications

Hypersensitivity to diclofenac, acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs) or any excipients of the finished medicinal product.

Patients with or without asthma in whom attacks of asthma, urticaria or acute rhinitis are precipitated by aspirin or other non-steroidal anti-inflammatory agents.

In the last trimester of pregnancy.

Children and adolescents: the use in children and adolescents aged less than 14 years is not recommended

4.4 Special warnings and precautions for use

Patients should be warned against excessive exposure to sunlight in order to reduce the incidence of photosensitivity. Discontinue if any rash develops. Not for use with occlusive dressings.

Mobigel Spray 4% cutaneous spray, solution should only be administered onto intact skin, not on open wounds or diseased skin areas. Contact with eyes and mucous membranes as well as oral use should be avoided.

The concomitant use of Mobigel Spray 4% cutaneous spray, solution with oral NSAIDs should be cautioned as the incidence of systemic side effects may increase (see interactions).

Where Mobigel Spray 4% cutaneous spray, solution is applied to a relatively large area of skin (i.e. more than 600 square centimetres of the body surface) and over a prolonged period (i.e. more than 4 weeks), the possibility of systemic side-effects cannot be completely excluded. If such usage is envisaged, the data sheet on diclofenac oral dosage forms should be consulted (for example, there is the potential for hypersensitivity, asthmatic and renal adverse reactions).

Bronchospasm may be precipitated in patients suffering from or with previous history of bronchial asthma or allergenic disease.

Mobigel Spray 4% cutaneous spray, solution should only be used with caution in patients with a history of peptic ulcer, hepatic or renal insufficiency, or bleeding diathesis, or inflammatory bowel disease, as isolated cases with topical diclofenac have been reported.

Mobigel Spray 4% cutaneous spray, solution contains propylene glycol which may cause skin irritation.

Mobigel Spray 4% cutaneous spray, solution contains peppermint oil which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

The systemic availability of diclofenac from this pharmaceutical presentation is very low. Hence the risk of interactions with other medicinal products is small. Concurrent aspirin or other NSAIDs may result in an increased incidence of adverse reactions.

4.6 Pregnancy and lactation

There is insufficient experience for the use during pregnancy and lactation. Therefore the use is not recommended.

Use in pregnancy: No evidence of a malformative effect was observed with diclofenac. However, additional epidemiological data is necessary to assess safety. During the last trimester of pregnancy, the use of prostaglandin synthetase inhibitors may result in:

- pulmonary and cardiac toxicity in the foetus (pulmonary hypertension with preterm closing of the ductus arteriosus)
- renal insufficiency in the foetus with oligohydramnios
- and increased possibility of bleeding in the mother and child.

Therefore, Mobigel Spray 4% cutaneous spray, solution should be used with caution and only if clearly necessary during the first six months of pregnancy and must not be applied to a large area of the skin (i.e. more than 600 square centimetres of the body surface). It must not be used for long-term treatment (> three weeks). Treatment with Mobigel Spray 4% cutaneous spray, solution is contraindicated during the last trimester of pregnancy.

Use during lactation: It is not expected that any measurable amount of diclofenac will occur in breast milk following topical application. However, NSAIDs are excreted in human milk. Therefore Mobigel Spray 4% cutaneous spray, solution is not recommended for use in nursing mothers. An application to the breast area of nursing mothers is contraindicated.

In preclinical studies of toxicity to reproduction, diclofenac showed adverse effects (see section 5.3).

4.7 Effects on ability to drive and use machines

Patients who experience dizziness or other central nervous disturbances while taking NSAIDs should refrain from driving or operating machinery, but this would be very unlikely using topical preparations.

4.8 Undesirable effects

Skin disorders are commonly reported.

Skin: Application site reactions, rashes, pruritus and urticaria, drying, reddening, burning sensations, contact dermatitis.

In a clinical trial 236 patients with ankle distortions were treated with 4-5 pump strokes of Mobigel Spray 4% cutaneous spray, solution t.i.d. (120 patients) or placebo (116 patients) for 14 days. The following adverse drug reactions were reported for Mobigel Spray 4% cutaneous spray, solution:

Organ system	Very common (> 1/10)	Common (> 1/100, <1/10)	Uncommon (>1/1000, <1/100)	Rare (>1/10000, <1/1000)
Skin and subcutaneous disorders				
Pruritus			0.9 %	

Undesirable effects may be reduced by using the minimum effective dose for the shortest possible duration. The total single dose of product should not exceed 1.0 g of spray.

Nevertheless during long term treatment (> three weeks) and/or when treating large areas (i.e. more than 600 square centimetres of the body surface) there is a possibility of systemic adverse reactions. Reactions like abdominal pain, dyspepsia, gastric and renal disorders may occur.

In patients using topical NSAID preparations asthma has been reported rarely. In isolated cases generalised skin rash, hypersensitivity reactions such as angioedema and photosensitivity reactions have been reported.

4.9 Overdose

During recommended use there is practically no risk due to overdosage. If accidentally Mobigel Spray 4% cutaneous spray, solution has been administered orally symptomatic treatment is recommended.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

ATC code: M02AA 15

Sodium diclofenac is a non-steroidal anti-inflammatory drug (NSAID) which has also analgesic properties. The inhibition of prostaglandin synthesis is considered to be an essential part of its mode of action.

5.2 Pharmacokinetic properties

After cutaneous application of 1.5 g Mobigel Spray 4% cutaneous spray, solution 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 Mobigel Spray 4% cutaneous spray, solution.

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

5.3 Preclinical safety data

In rabbit skin, Mobigel Spray 4% cutaneous spray, solution is classified as non-irritant.

Preclinical data based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and carcinogenic potential of diclofenac reveal no special hazard for humans other than already mentioned in earlier sections of this SPC.

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

Isopropyl alcohol

Soy bean lecithin

Ethanol

Disodium phosphate dodecahydrate

Sodium dihydrogen phosphate dihydrate
Disodium edetate
Propylene glycol
Peppermint oil
Ascorbyl palmitate
Hydrochloric acid 10% (w/w)
Sodium hydroxide 10% (w/w)
Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened bottle (30 ml and 15 ml): 3 years

Unopened bottles (10 ml): 2 years

In-use: 6 months

6.4 Special precautions for storage

Store in the original package.

6.5 Nature and contents of container

Glass bottle with metering pump/nozzle/spray valve and cap, 7.5 g, 12.5 g and 25 g solution.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

**7 MARKETING AUTHORISATION HOLDER
GOLDSHIELD PHARMACEUTICALS LIMITED**

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CROYDON

SURREY

CR0 0XT

UNITED KINGDOM

8 MARKETING AUTHORISATION NUMBER(S)

PL 12762/0402

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE
AUTHORISATION**

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Date of latest renewal: 13/05/2007

10 DATE OF REVISION OF THE TEXT

21/03/2011

11 DOSIMETRY (IF APPLICABLE)

**12 INSTRUCTIONS FOR PREPARATION OF
RADIOPHARMACEUTICALS (IF APPLICABLE)**