SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Mobigel Spray 40mg/g cutaneous spray, solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g of solution contains 40 mg of diclofenac sodium.

Excipients with known effects:

Each g of solution contains:

Propylene glycol (E1520)	150 mg
Soybean lecithin	100 mg
Ethanol, anhydrous	33.3 mg

For the full list of excipients, see section 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.

Mobigel Spray 40mg/g cutaneous spray, solution is indicated in adults and adolescents over 14 years of age.

4.2 Posology and method of administration

Posology
Adults and adolescents over 14 years of age

Sufficient amount of solution should be sprayed locally to the skin on the affected area 3 times a day at regular intervals. The amount needed depends on the size of the treated area. Normally, 4-5 pump strokes (0.8-1.0 g of spray corresponding to 32-40 mg of diclofenac sodium) would be required.

The maximum single dose should not exceed 1g of spray (5 pump strokes). The maximum daily dose is 15 pump strokes (3.0 g of spray corresponding to 120 mg of diclofenac sodium).

Mobigel Spray 40mg/g cutaneous spray, solution should be rubbed gently into the skin. After application, the hands should be washed, unless they are the site to be treated. After application, several minutes should be allowed for drying the treated area before it is covered with dressing or bandage.

Duration of treatment:
The treatment may be discontinued when the symptoms (pain and swelling) have subsided. Treatment should not be continued beyond 7-8 days without doctor's recommendation. The patient is advised to consult the doctor if there is no improvement after 3 days or if symptoms get worse.

In adolescents 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.

Elderly
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 14 years of age (see also section 4.3).

Patients with hepatic or renal impairment
For the use of Mobigel Spray 40mg/ml cutaneous spray, solution in patients with hepatic or renal insufficiency, see section 4.4.

Method of administration
For cutaneous use.

4.3 Contraindications

Hypersensitivity to the active substance, peanut, soya or to any of the excipients listed in section 6.1.

Patients with a history of asthma attacks, urticaria or acute rhinitis in response to acetylsalicylic acid or other non-steroidal anti-inflammatory agents (NSAIDs).

Third trimester of pregnancy.

Paediatric population: the use in children and adolescents aged less than 14 years is contraindicated.

4.4 Special warnings and precautions for use

Adverse reactions may be minimised by using the lowest effective dose for the shortest duration necessary to control symptoms.

The possibility of systemic adverse events from application of Mobigel Spray 40mg/g cutaneous spray, solution cannot be excluded if the product is used on large areas of skin and over a prolonged period (see the product information on systemic forms of diclofenac).

Mobigel Spray 40mg/g cutaneous spray, solution must be applied only to intact non-diseased skin, and not to skin wounds or open injuries. It must not be allowed to come into contact with the eyes or mucous membranes and it must not be ingested.

Mobigel Spray 40mg/g cutaneous spray, solution can be used with non-occlusive bandages but should not be used with an airtight occlusive dressing.

Direct sunlight, including solarium, should be avoided during treatment in order to reduce the incidence of photosensitive reaction. If sensitivity skin reactions occur, the use of this product should be discontinued.

The treatment should be discontinued if a skin rash develops after applying the product.

The concomitant use of Mobigel Spray 40mg/g cutaneous spray, solution with oral NSAIDs should be cautioned as the incidence of systemic side effects may increase (see section 4.5).

Where Mobigel Spray 40mg/g cutaneous spray, solution is applied to a 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 use is envisaged, the product information of 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 40mg/g 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.

This medicinal product contains propylene glycol, ethanol and soybean lecithin

Mobigel Spray 40mg/g cutaneous spray, solution contains soya (as soybean lecithin). It is contraindicated in patients allergic to peanut or soya (see section 4.3).

Mobigel Spray 40mg/g cutaneous spray, solution contains 150mg propylene glycol in each gram of solution. Propylene glycol may cause skin irritation.

Mobigel Spray 40mg/g cutaneous spray, solution contains 33.3 mg alcohol (ethanol) in each gram of solution. It may cause burning sensation on damaged skin.

4.5 Interaction with other medicinal products and other forms of interaction

Since systemic absorption of diclofenac from a topical application of Mobigel Spray 40mg/g cutaneous spray, solution is very low such interactions are very unlikely.

Concomitant use with acetylsalicylic acid or other NSAIDs may result in an increased incidence of systemic adverse reactions (see section 4.4)

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no clinical data from the use of Mobigel Spray 40mg/g cutaneous spray, solution during pregnancy. Even if systemic exposure is lower compared with oral administration, it is not known if the systemic Mobigel Spray 40mg/g cutaneous spray, solution exposure reached after topical administration can be harmful to an embryo/foetus. 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, Mobigel Spray 40mg/g cutaneous spray, solution should not be used unless clearly necessary. If Mobigel Spray 40mg/g cutaneous spray, solution 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, systemic use of prostaglandin synthetase inhibitors including diclofenac 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.

Therefore, Mobigel Spray 40mg/g cutaneous spray, solution is contraindicated during the last trimester of pregnancy (see Section 4.3).

Breast-feeding

Like other NSAIDs, diclofenac passes into breast milk in small amounts. However, at therapeutic doses of Mobigel Spray 40mg/g cutaneous spray, solution 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, Mobigel Spray 40mg/g cutaneous spray, solution 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

Mobigel Spray 40mg/g cutaneous spray, solution has no influence on the ability to drive and use machines.

4.8 Undesirable effects

The following skin disorders are commonly reported: rash, eczema, erythema, dermatitis (including contact dermatitis), pruritus*

Adverse reactions are listed by system organ classes based on frequency using the following convention: 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), or not known (can not to be estimated from available data). Within each frequency category, 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 contact dermatitis), 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 Mobigel

Spray 40mg/g cutaneous spray, solution t.i.d. (120 patients) or placebo (116 patients) for 14 days.

During long term treatment 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.
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. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard

4.9 Overdose

Due to low systemic absorption of topical diclofenac, overdose is very unlikely in topical use.

However undesirable effects similar to those observed following an overdose of diclofenac tablets can be expected if Mobigel Spray 40mg/g cutaneous spray, solution is inadvertently ingested (i.e. a 15 ml spray bottle containing 500 mg of diclofenac sodium).

In case 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: Topical products for joint and muscular pain, 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 40mg/g 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 40mg/g cutaneous spray, solution.

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

5.3 Preclinical safety data

In rabbit skin, Mobigel Spray 40mg/g 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 other sections of this SmPC.

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, anhydrous

Disodium phosphate dodecahydrate

Sodium dihydrogen phosphate dihydrate

Disodium edetate

Propylene glycol

(E1520) 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.

5.5 Nature and contents of container

Glass bottle with metering pump/nozzle/spray valve and cap

Pack sizes: 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

HUALAN PHARMACEUTICALS LIMITED
16/17 College Green - Dublin D02 V078
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

PL 52104/0010

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13/05/2002
Date of latest renewal: 13/05/2007

10 DATE OF REVISION OF THE TEXT

20/11/2024

11 DOSIMETRY (IF APPLICABLE)

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)