Global Labeling

Voltaren Emulgel

Gel

Diclofenac diethylamine 2.32%

Summary of Product Characteristics

Document status:	FINAL
Release date:	13 Apr 2020
Number of pages:	8

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1 NAME OF THE MEDICINAL PRODUCT

Voltaren Emulgel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of Voltaren Emulgel contains 23.2 mg of diclofenac diethylamine, which corresponds to 20 mg of diclofenac sodium.

3 PHARMACEUTICAL FORM

Gel for external use 2 %.

Soft, homogeneous, cream-like gel, from white to yellowish colour.

4 CLINICAL PARTICULARS

4.1 Pharmacotherapeutic group

Drugs for external use for joint and muscle pain. Non-steroidal anti-inflammatory drug for external use.

ATX Code: M02AA15

Voltaren Emulgel contains the active ingredient diclofenac, which belongs to the group of non-steroidal anti-inflammatory drugs (NSAIDs). The drug is specially designed for rubbing into the skin, and it better penetrates into the skin. The active substance acts on deep tissue inflammation.

The drug is used to relieve pain and reduce inflammation and swelling in number of painful conditions affecting the joints and muscles. The drug can be used to treat:

• muscle and joint injuries (for example: dislocations, torn ligaments, bruises, sprains and pains after sports or as a result of accident injuries). It quickly relieves pain, including moderate to severe pain, improves motor activity of patients and helps to normalize functions;

• tendinitis (for example: "tennis elbow"), swelling around the elbow or knee;

• arthrosis of knee joints and finger joints of mild degree.

The drug can be used for adults and children over 12 years.

4.2 Posology and method of administration

Adults and adolescents aged 12 years and over.

Voltaren Emulgel should be applied over the affected area 2 times daily and rubbed gently into the skin. The amount needed depends on the size of the painful area: 2 g to 4 g Voltaren

Emulgel (a quantity ranging in size from a cherry to a walnut) is sufficient to treat an area of about 400-800 cm². After application, the hands should be washed, unless they are the site being treated.

Do not use the drug longer than 14 days.

Longer use may be recommended by a doctor.

After 7 days of using the drug, if there is no improvement in pain or swelling, you should consult the doctor.

It's not recommended for children under 12 years of age.

4.3 Contraindications

- Allergy (hypersensitivity) to diclofenac or to any of the excipients contained in the gel (see 6.1, List of excipients) or other non-steroidal anti-inflammatory drugs, such as ibuprofen or acetylsalicylic acid (which is used to prevent blood coagulation). If you are not sure, consult a doctor or pharmacist.

  Symptoms of an allergic reaction to this drug may include: wheezing or shortness of breath (asthma); skin rashes with blisters or hives; swelling of the face or tongue; runny nose.
- During the last trimester of pregnancy.

4.4 Special warnings and precautions for use

- Do not use if there are: cuts, open wounds, rashes or a specimen. It is necessary to stop treatment if skin rashes occur after application of the drug.
- Avoid using the drug on large areas of the skin, or longer than approved for use, except when recommended by a doctor.
- The drug must be used only externally. Do not take internally. Do not swallow the drug. Wash hands after use. Beware of getting into the eyes. If this happened, wash your eyes thoroughly with clean water. Consult your doctor or pharmacist if there is a feeling of discomfort.
- Patient can use bandages or dressings, which are usually used for injuries, such as dislocations. Do not use airtight (plastic) dressings.

Important information about the individual components of the drug

The drug contains:

- **propylene glycol**, which can cause mild skin irritation at the site of application of the drug in some patients.

- **butylhydroxytoluene**, which can cause local skin reactions (e.g. contact dermatitis) or irritation of the eyes and mucous membranes.

4.5 Interaction with other medicinal products and other forms of interaction

Since systemic absorption of diclofenac from topical application is very low, interactions are unlikely.

4.6 Pregnancy and lactation

Consultation with a doctor or pharmacist before taking the medicine during pregnancy, planned or probable pregnancy and lactation should be advised.

- It is not recommended for use if pregnant, especially during the last trimester, as this can harm the baby or cause complications during childbirth.
- It is not recommended for use within breast-feeding.

4.7 Effects on ability to drive and use machines

Topical application of diclofenac has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Like all medicines, Voltaren Emulgel can cause undesirable effects, but not in all patients.

Some adverse reactions that occur rarely or very rarely can be severe.

If any of the following symptoms occur, which may be a sign of an allergic reaction, STOP taking the drug and immediately consult a doctor or pharmacist:

- skin rashes with blisters; hives. *(Can be observed in 1 to 10 per 10,000 people).*
- wheezing, difficulty breathing, or a feeling of chest tightness (asthma). *(Can be observed in less than 1 in 10,000 people).*
- swelling of the face, lips, tongue, or throat. *(Can be observed in less than 1 in 10,000 people).*

Other adverse reactions that may occur are usually passing and not severe *(but, if you are concerned, contact your doctor or pharmacist).*

Frequently occurring adverse reactions *(can be observed in 1 to 10 in 100 people).*

- skin rashes, itching, redness or soreness of the skin.

Very rare adverse reactions *(can be observed in less than 1 in 10,000 people).*

- skin may be more sensitive to the sun. Possible signs of sunburn include: itching, swelling and the appearance of blisters.

4.9 Overdose

The low systemic absorption of topical diclofenac renders overdose unlikely.

5 PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:

Drugs for external use for joint and muscle pain. Non-steroidal anti-inflammatory drug for external use.

ATC Code: M02A A15

5.1 Pharmacodynamic properties

Mechanism of action and pharmacodynamic effects:
Diclofenac is a potent non-steroidal anti-inflammatory drug (NSAID) with effective analgesic, anti-inflammatory and antipyretic properties. Diclofenac exerts its therapeutic effects primarily through inhibition of prostaglandin synthesis by cyclo-oxygenase 2 (COX-2).

Voltaren Emulgel is an anti-inflammatory and analgesic preparation designed for topical application.

In inflammation and pain of traumatic or rheumatic origin, Voltaren Emulgel relieves pain, decreases swelling.

5.2 Pharmacokinetic properties

Absorption
The quantity of diclofenac absorbed through the skin is proportional to the size of the treated area, and depends on both the total dose applied and the degree of skin hydration.

After topical application of Voltaren Emulgel 2.32% (2 applications/day) to approximately 400 cm2 of skin, the extent of systemic exposure as determined by plasma concentration of diclofenac was equivalent to diclofenac diethylamine 1.16% gel (4 applications/day). The relative bioavailability of diclofenac (AUC ratio) for Voltaren Emulgel 2.32% versus 50 mg diclofenac sodium tablet was 4.5% on day 7 (for equivalent diclofenac sodium dose). Absorption was not modified by a moisture and vapour permeable bandage.

Voltaren Emulgel 2.32% formulation contains a permeation enhancer (0.75% oleyl alcohol). In an in vitro skin barrier penetration study, this formulation was compared to Voltaren Emulgel 1.16%, both applied at 20mg/cm2 in a single dose. The findings demonstrated approximately three times higher cumulative diclofenac skin permeation for Voltaren Emulgel

2.32% (6.11 ± 1.27 μg/cm2) compared to Voltaren Emulgel 1.16% (2.07±0.38 μg/cm2) after 24 hours. These results were reproduced in another study.

Distribution

9.7% of diclofenac is bound to serum proteins, mainly albumin (99.4%).

Diclofenac concentrations have been measured from plasma, synovial tissue and synovial fluid after topical administration of a diclofenac diethylamine gel to hand and knee joints. Maximum plasma concentrations are approximately 100 times lower than after oral administration of the same quantity of diclofenac.

Diclofenac accumulates in the skin which acts as reservoir from where there is a sustained release of drug into underlying tissues. From the skin and underlying tissue, diclofenac preferentially distributes and persists in deep inflamed tissues (such as the joint), rather than in the bloodstream. Diclofenac is found in tissues at concentrations up to 20 times higher than in plasma.

Metabolism

The biotransformation of diclofenac involves single and multiple hydroxylation steps followed by glucuronidation, and glucuronidation of the intact molecule.

Elimination

Diclofenac and its metabolites are excreted mainly in the urine.

The total systemic clearance of diclofenac from plasma is 263 ± 56 ml/min. The terminal plasma half-life is 1-2 hours. Four of the metabolites, including the two active ones, also have short plasma half-lives of 1-3 hours. One metabolite, 3'-hydroxy-4'-methoxy-diclofenac, has a longer half-life but is virtually inactive.

5.3 Preclinical safety data

Non-clinical data from acute and repeated dose toxicity studies, as well as from genotoxicity, and carcinogenicity studies with diclofenac revealed no specific hazard forhumans at the intended therapeutic doses. Topical diclofenac was well tolerated in a variety of studies. There was no potential for phototoxicity and diclofenac-containing gel caused no skin sensitisation.

Reproductive Toxicology

Diclofenac demonstrated no evidence of impairment on the fertility of male or female rats. There was no evidence that diclofenac had a teratogenic potential in mice, rats or rabbits. The prenatal, perinatal and postnatal development of the offspring was not affected.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

For Emulgel

Carbomers
Macrogol cetostearyl ether
Cocoyl caprylocaprate
Diethylamine
Isopropyl alcohol
Propylene glycol
Paraffin, liquid
Oleyl alcohol
Perfume eucalyptus sting
Butylhydroxytoluene
Water, purified

Information might differ in some countries.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months. Do not use after the date indicated on the package.

6.4 Special precautions for storage

Store below 30°C. Keep out of the sight and reach of children.

6.5 Nature and contents of container

50 g or 100 g in a laminated tube with a protective membrane and a screw cap of white colour. The tube together with the instruction for use is packed in a cardboard box.

7 MANUFACTURING SITE

GSK Consumer Healthcare S.A., Switzerland

Address: Route de l'Etraz, 1260 Nyon, Switzerland

8 MARKETING AUTHORISATION HOLDER

GSK Consumer Healthcare S.A., Switzerland

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9. DATE OF REVISION OF THE TEXT

13.04.2020