PRODUCT INFORMATION LEAFLET

1. Product Name

Brand Name: Iodex* UltraGel
Generic Name: Diclofenac Diethylamine Gel I.P. 1.16%w/w

2. Qualitative & Quantitative Composition

Contains:

Diclofenac Diethylamine I.P. 1.16% w/w equivalent to Diclofenac Sodium I.P. 1% w/w

3. Dosage Form

Topical Gel

4. Clinical Particulars

4.1. Uses/ Indications

- For the relief of pain, inflammation and swelling in:
  - Soft-tissue injuries: trauma of the tendons, ligaments, muscles and joints, e.g. due to sprains, strains, bruises and backache (sports injuries);
  - Localised forms of soft tissue rheumatism: tendonitis (e.g. tennis elbow), bursitis, shoulder-hand syndrome and periarthropathy;
- For the relief of pain of non-serious arthritis of the knee or fingers.

4.2. Posology and method of administration

For topical use on the skin only.

For use by adults and children aged 12 years and above.

Elderly patients (over 65 years of age): the usual adult dosage may be used.

Apply over the affected area 3 or 4 times daily and to be rubbed gently into the skin. The amount needed will vary depending upon the size of the painful or swollen area: 2 g to 4 g. Iodex UltraGel (a quantity ranging in size from a cherry to a walnut) is sufficient to treat an area of about 400-800 cm^2.

Do not use without consulting a doctor, for more than:

- 2 weeks for muscle and joint injuries (e.g., sprains, strains, bruises) or tendonitis
- 3 weeks for arthritis pain

Use no more than recommended dose for shortest period of time needed.
If the pain and/or swelling do not improve within 7 days of staring the treatment, or if it get worse, consult your doctor.

After application:

- the hands should be wiped with e.g., an absorbent paper, and then washed, unless they are the site being treated.

- Wait until Iodex UltraGel dries/absorbed before showering, bathing.

Do not throw away any medicines via wastewater (e.g. toilet or sink). Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

4.3. Contra-indications

Do not use Iodex UltraGel if you:

- are allergic to diclofenac or other non-steroidal anti-inflammatory medicines used to treat pain, fever or inflammation, such as ibuprofen or aspirin, or any of the other ingredients contained in this medicine. If you are not sure, ask your doctor

- are suffering from asthma, angioedema, urticaria, or acute rhinitis and it gets flared- up/precipitated by acetylsalicylic acid use or with other non-steroidal anti-inflammatory drugs (NSAIDs). If you are not sure, consult your doctor in case suffering from any of these conditions.

- are in the last 3 months of pregnancy.

4.4. Special Warnings and Special Precautions for use

Do not apply on skin with conditions such as cuts, open wounds, or on skin that has a rash or eczema. Discontinue the treatment if a skin rash develops after applying the product.

Do not use more product than directed or for a longer period of time than directed, unless told by your doctor.

Do not use in the mouth. Do not swallow. Wash your hands after use. Be careful not to get this medicine in your eyes. If this happens, rinse your eyes well with clean water. See your doctor if any discomfort persists.

A brace or wrap commonly used for injuries like sprains can be used but do not use under airtight (plastic) bandages.

Keep out of the sight and reach of children.

Be cautious when smoking or near naked flames due to risk of severe burns. Iodex UltraGel contains paraffin which is potentially flammable when it builds up on fabrics (clothing, bedding, dressing etc.) and may not be totally removed by laundering.

4.5. Interaction with other medicaments and other forms of interaction

Tell your doctor before use if you are taking, or have recently taken, any regular medication on prescription or over the counter products.

4.6. Pregnancy and Lactation

Seek medical advice before you use Iodex UltraGel if you are pregnant or breast-feeding or are planning to have a baby.

Not to be used in the last 3 months of pregnancy, as it could harm your unborn child or cause delivery related complications.

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 / side effects

Skin reddening, rash with or without blisters, itching, dermatitis; hives; wheezing, shortness of breath or feeling of tightness in the chest (asthma); Hypersensitivity in form of swelling of the face, lips, tongue or throat.

The skin may become more sensitive to sunlight (sun or tanning booth). Possible signs are sunburn with itching, swelling and blistering.

4.9. Overdosing

In case of overdosage, seek medical advice from a doctor immediately.

In case of overdosage, you may also contact the National Poisons Information Centre of India (24*7).

Details of the same are as below:
Department of Pharmacology
All India Institute of Medical Sciences
New Delhi-110029
Toll Free No. - 1800 116 117
Tel No.- 26589391, 26593677

5. Pharmacological Properties

5.1. Pharmacodynamic Properties & mechanism of action

Pharmacotherapeutic group: Topical non-steroidal anti-inflammatory drug (NSAID)

ATC Code: M02AA15 (Anti-inflammatory preparations, non-steroids for topical use).

Pharmacodynamics effects & Mechanism of Action:

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).

5.2. Pharmacokinetics

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. Absorption amounts to about 6 % of the applied dose of diclofenac after topical application of 2.5 g diclofenac diethylamine on 500 cm^2 skin, determined by total renal elimination, compared with diclofenac tablets.

Distribution: 99.7% 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

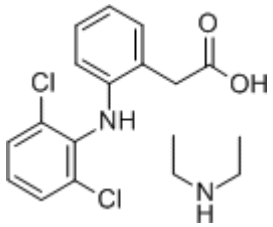
Diclofenac and its metabolites are excreted mainly in the urine.

The terminal plasma half-life is 1-2 hours.

6. Pharmaceutical Particulars

6.1. Chemical Structure

Diclofenac diethylamine:



6.2. List of Excipients

Carbomer 974P
Macrogol Cetostearyl Ether
Cocyl Caprylocaprate- Cetiol LC
Diethylamine
Isopropyl Alcohol
Liquid paraffin
Propylene Glycol
Perfume Cream 45/3
Purified Water

6.3. Incompatibilities

Not applicable

6.4. Shelf life

24 months from the date of manufacturing.

6.5. Special precautions for storage

Store in a cool, dry place, at a temperature not exceeding 30°C.
Keep out of reach and sight of children.

6.6. Nature and specification of the container

For the aluminium laminated tube:

Aluminium laminated tube fitted with HDPE shoulder, foil seal on top of the nozzle & white PP standup screw cap. Remove foil seal on top of the nozzle before first use.

For the dispenser:

Pressurised aluminium container containing a multilayer pouch (low density polyethylene layer in contact with the product) with a high density polyethylene/titanium oxide valve and polyoxymethylene actuator with protective cap.

6.7. Instructions for Use and Handling

Refer section 4. Clinical Particulars and subsections there-under.

6.8. Manufacturing License Holder

Makson Healthcare Private Limited,
Plot No. 182-183, Annaram Village, Gummadidala
Mandal, Sangareddy District-502313, Telangana
State

6.9. Marketed By

GlaxoSmithKline Asia Pvt Ltd.,
Patiala Road, Nabha- 147201
Punjab, India

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