

1. NAME OF THE MEDICINAL PRODUCT

ACECLOFENAC, LINSEED OIL, METHYL SALICYLATE, CAPSAICIN, BENZYL ALCOHOL GEL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 30gm contains:

Aceclofenac BP	1.5 % w/w
Linseed Oil BP	3.0 % w/w
Methyl Salicylate BP	10.0 % w/w
Capsaicin USP	0.01% w/w
Benzyl alcohol BP (As Preservative)	1.0 % w/w
Gel Base	Q.S.

3. PHARMACEUTICAL FORM

Gel

4. Clinical particulars

4.1 Therapeutic indications

Local treatment of inflammatory and degenerative forms of diseases of musculoskeletal system, which are accompanied by pain and swelling such as:

Rheumatoid arthritis, Ankylosing spondylitis (Bechterew's disease)

Acute podagric (related to gout), inflammation, psoriatic and post-traumatic arthritis

Rheumatic damage of soft tissues (tenonitis bursitis, myositis)

Degeneration diseases of joints (arthrosis of large and small joints)

Osteochondritis of spinal column

Myalgia, neuralgia, lumbosacral radiculitis

Trauma pain, ligamentous laxity, sprain of ligaments, muscles, tendons

Pain in muscles and joints, induced by hard physical activity

4.2 Posology and method of administration

Treatment of essential hypertension:

Route of Administration: Topical

In depending on area of painfulness 2-4 g of gel (strip is 4 to 8 cm) is applied on skin is rubbed lightly 2-3 times per day. Average daily dose compound 10 g of gel, equivalent to 100 mg of Diclofenac. The drug should not be applied on damaged skin. One should be careful to avoid accidental contact with the eyes and on mucous tunic. It shouldn't apply the gel on open wound

The drug is prescribed carefully for patients with hypersensitivity to local usage of acetylsalicylic acid, different salicylates and other NSAID (bronchial asthma attacks, skin reactions and acute rhinitis). It is necessary to weigh all factors of usefulness and risk.

Gel is used carefully in patients with ulcer of the stomach or intestines, disorders of the liver and kidney, haematological disorders, relapse of nasal polyposis. It is necessary to wash hands after usage of medicine to avoid the accidental entry of drug in eyes and mucous tunics

4.3 Contraindications

Aceclofenac should not be prescribed during pregnancy, especially during the last trimester of pregnancy, in women attempting to conceive and lactation unless there are compelling reasons for doing so. The lowest effective dosage should be used; Aspirin induced bronchial asthma; Break in the skin or open wound in area should be avoided, Children below 12 years of age (because there is no data about external usage this medicine in this age group)., The last trimester of

pregnancy, Unclear Disorders of hematosi s, Exacerbation of stomach and duodenal ulcer.

4.4 Special warnings and precautions for use

The drug is prescribed carefully for patients with hypersensitivity to local usage of acetylsalicylic acid, different salicylates and other NSAID (bronchial asthma attacks, skin reactions and acute rhinitis). It is necessary to weigh all factors of usefulness and risk.

Gel is used carefully in patients with ulcer of the stomach or intestines, disorders of the liver and kidney, haematological disorders, relapse of nasal polyposis. It is necessary to wash hands after usage of medicine to avoid the accidental entry of drug in eyes and mucous tunics

4.5 Interaction with other medicinal products and other forms of interaction

Gel can be used along with other medicines, because the components of this drug do not interact systemically with other medicines, including use of Aceclofenac sodium by oral route. But in cases of long usage of Gel in large dosage it is necessary to know that Aceclofenac can increase effect of anticoagulants, GCS, Lithium and it can decrease action of furosemide, thiazide diuretics. It can increase concentration of digoxin in plasma and decrease tolerance of other NSAID, increasing their ulcerogenic action on mucous coat of GIT. The concurrent s local usage some medicines, containing NAAA, can irritate the skin locally in the form of urticaria, reddening, desquamation.

4.6 Pregnancy and Lactation

It is not allowed to apply gel on big areas of body or to use for a long time during pregnancy and lactation period, because data about safety of the drug on foetus and neonates is not available.

4.7 Effects on ability to drive and use machines

None mentioned

4.8 Undesirable effects

Generally, the preparation is tolerated well. The small part of drug (about 5 %) is absorbed into the bloodstream when used locally. It more or less eliminates possibility of side effects associated with NSAID Sometimes skin irritation such as, skin rash, oedema, appearance of wheals, papules, scutes, reddening, burning, prickling, skin itch occur at the site of application.

4.9 Overdose

The overdose is not possible as a result of local application of Gel.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Aceclofenac

1. It inhibits cyclooxygenase (COX) activity and to suppress the PGE2 production by inflammatory cells, by inhibiting IL-Beta & TNF in the inflammatory cells (Intracellular Action).
2. It blocks degeneration and stimulates synthesis of extra cellular matrix of cartilages by inhibiting the action of different cytokines.
3. Drug and its metabolites inhibit IL-6 production by human chondrocytes. This leads to inhibition of increase of inflammatory cells in synovial tissue, inhibition of IL-1 amplification, inhibition of increased MMP synthesis and thus ensuring proteoglycan production.
4. It inhibits IL-1 and TNF production by human chondrocytes, inflammatory cells and synovial cells and therefore blocks suppression of GAG and collagen synthesis and stimulates growth factors mediated synthesis of GAG and collagen.

Capsaicin

Although the precise mechanism of action of capsaicin is not fully understood, current evidence

suggests that capsaicin renders skin insensitive to pain by depleting and preventing re-accumulation of substance P in peripheral sensory neurons. Substance P is thought to be the principal chemo-mediator of pain impulses from the periphery to the Central Nervous System.

Linseed oil is Alfa linoleic acid, which has anti-inflammatory, antioxidant actions, improves blood circulation at place of application.

The action of medicine begins within few minutes after application on skin. During 20-30 min it achieves maximum activity level. It provides relief from the symptoms from day one of beginning of treatment.

5.2 Pharmacokinetic properties

When Gel is applied locally, the active substance is absorbed through the skin. In healthy volunteers approximately 6% of the dose applied is absorbed, as determined by urinary excretion of diclofenac and its hydroxylated metabolites. Findings in patients confirm that diclofenac penetrates inflamed areas following local application of Gel.

After topical administration of Gel to hand and knee joints diclofenac can be measured in plasma, synovial tissue and synovial fluid. Maximum plasma concentrations of diclofenac are about 100 times lower than after oral administration of Gel.

5 Preclinical safety data

None known

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carbomer-940 USP NF
Hydrogenated Castor Oil BP
Propylene Glycol BP
Butylated Hydroxytoluene BP
Citric acid BP
Di. Sodium Edetate BP
Diethylamine IH
Purified Water BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 Months

6.4 Nature and contents of container<and special equipment for use, administration or implantation>

Packing: 30 gm Tube packed in carton.

6.5 Special precautions for disposal <and other handling>

No special requirements

7 <APPLICANT/MANUFACTURER>

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