The instructions on use of medicinal product
(for patients)

FLEXWELL GEL for external use only

Composition
Active substances: 1 gram of gel contains 11,61 mg diclofenac diethylamine (equivalent to diclofenac sodium 10 mg), 30 mg linseed oil, 50 mg levomenthol, 100 mg methyl salicylate.
Auxiliary substances: butylhydroxyanisole, butylhydroxytoluene, benzyl alcohol, disodium edetate, diethylamine, carbomer 980, citric acid monohydrate, macrogol glycerol hydroxystearate (cremophor RH-40), propylene glycol, purified water.

Pharmacotherapeutic group
Non-steroidal anti-inflammatory drug (NSAID)

Pharmacological properties
The pharmacological action of the formulation is based on the ingredients. It has a local analgesic, antiinflammatory and anti-oedematous action. Diclofenac sodium and methyl salicylate are non-steroidal antiinflammatory drugs with a pharmacological action based on the ability to inhibit synthesis of prostaglandins. When used locally, diclofenac and methyl salicylate are rapidly absorbed, penetrate into the subcutaneous fat, muscular tissue and joint capsule, reduce pain and inflammation in the joints, morning stiffness and swelling of joints, facilitate increase in the extent of movements. The main component of linseed oil is αlinolenic acid which has an anti-inflammatory action. Menthol induces irritation of nerve endings and has a local distracting and mild analgesic action, besides inducing a cooling sensation.

Pharmacokinetics
When applied topically, diclofenac sodium, methyl salicylate and linseed oil are absorbed and penetrate into the subcutaneous tissue, muscle tissue and joint capsule.

Indications for use
- diseases of the locomotor system (arthritis, osteoarthrosis, osteochondrosis with radicular syndrome, radiculitis);
- rheumatic damage of soft tissues (tenosynovitis, bursitis);
- muscular pain of rheumatic or non-rheumatic origin (also caused by excessive exercise); - post-traumatic inflammation of the soft tissues and joints (due to sprains, bruises and surge).

Contraindications
Hypersensitivity to diclofenac, methyl salicylate or other components of the formulation, acetylsalicylic acid or other NSAIDs, aspirin "asthma", pregnancy (third trimester), lactation period, children up to 12 years, broken skin.

Drug interaction
Diclofenac may potentiate the action of drugs which induce photo sensitisation. Clinically significant interactions with other drugs have not been reported.

Special warnings
If the drug has come into disrepair or expired - do not throw it in the waste water or on the street! Place the drug in the package and put it in the dumpster. These measures will help protect the environment!

Use during pregnancy and breast feeding
This formulation should not be used in the third trimester of pregnancy. The question of use of the drug in first and second trimesters of pregnancy is solved individually. Due to the lack of experience of using FLEXWELL GEL during lactation, its use in this period is not recommended.

Effects on ability to drive and use machines The drug does not adversely affect the ability to drive vehicles and other potentially dangerous machinery.

Method of use and dosage
Externally.
Adults and children over 12 years: apply the formulation on the skin 3-4 times in a day and rub in gently. The quantity of formulation to be used depends upon the size of the painful area. A single dose is 2-4 g (4-8 cm when the tube neck is fully open).
The duration of treatment without consulting a physician should not exceed 10 days. The possibility of a long-term use of medicine the doctor decides individually.

Precautions
For external use.
FLEXWELL GEL should be applied only on unbroken skin and not on open wounds. Occlusive dressing is not recommended after application. Care should be taken to avoid contact with the eyes and mucous membranes.
Use with caution in: severe disorders of the liver and kidney functions, bronchial asthma, pregnancy (first and second trimesters), elderly patients.

Side effects
Local reactions: eczema, photosensitisation, contact dermatitis (itching, redness, oedema of treated area of skin, papules, vesicles, peeling).
Systemic reactions: generalised skin rash, allergic reactions (urticaria, Quincke's (angioneurotic) oedema, bronchospastic reactions).

Overdose
The very low systemic absorption of the active components of the formulation when used externally makes overdose practically impossible. In case of accidental ingestion may develop systemic side effects.
Treatment for ingestion: gastric lavage, induction of emesis, activated charcoal, forced diuresis, symptomatic therapy. Dialysis is ineffective because of the high degree of binding of diclofenac to plasma proteins (approximately 99%).

Presentation 30g gel in aluminum or plastic laminated tube. One tube with instruction for use in cardboard packing.

Storage conditions Store at a temperature not exceeding 30ºC, in a place out of the reach and sight of children. Do not freeze.

Shelf life
3 years. Do not use after the expiry date.

Conditions of sale from pharmacies
Without physician’s prescription.

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