

## JOINTY PLUS GEL

Linseed Oil, Diclofenac Diethylamine,  
Methyl Salicylate and Menthol Gel

### COMPOSITION:

Diclofenac Diethylamine	BP	1.16% w/w
Eq. to Diclofenac Sodium		1.00% w/w
Linseed Oil (Oleum Lini)	BP	3.00% w/w
Methyl Salicylate	BP	10.00% w/w
Menthol	BP	5.00% w/w
Benzyl Alcohol (As Preservative)	BP	1.00% w/w
Gel Base		q.s.

### DESCRIPTION:

JOINTY PLUS GEL is semi-solid preparation which contains Linseed Oil, Diclofenac Diethylamine, Methyl Salicylate and Menthol. Linseed oil is  $\alpha$ -linolenic acid which has an anti-inflammatory action. Diclofenac Diethylamine and Methyl Salicylate are Non-steroidal anti-inflammatory drugs. Menthol has a local distracting and mild analgesic action, besides inducing a cooling sensation. Benzyl Alcohol is used as preservative.

### PHARMACODYNAMICS:

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

ATC code: M02AA15

The pharmacological action of the formulation is based on the ingredients. It has a local analgesic, anti-inflammatory and anti-oedematous action. Diclofenac sodium and methyl salicylate are non-steroidal anti-inflammatory 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  $\alpha$ -linolenic 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:

- ∇ Diseases of the locomotor system: rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis, osteoarthritis of peripheral joints and spinal column, osteochondrosis with radicular syndrome, sciatica);
- ∇ Rheumatic damage to soft tissues (tenosynovitis, bursitis);
- ∇ Muscular pain of rheumatic or non-rheumatic origin;
- ∇ Traumatic damage to soft tissues (due to sprains, bruises).

### DOSAGE AND ADMINISTRATION: FOR EXTERNAL USE ONLY.

*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).

*Children from 6 to 12 years old* to apply no more than 2 times a day, a single dose of 2 grams. 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.

### CONTRAINDICATION:

Hypersensitivity to diclofenac, methyl salicylate or other components of the formulation, acetylsalicylic acid or other NSAIDs, aspirin "asthma", pregnancy (third trimester), lactation period, children below 6 years, broken skin.

### SPECIAL WARNING AND PRECAUTION FOR USE:

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.

### INTERACTION WITH OTHER MEDICINE AND CONCOMITANT USE:

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

### PREGNANCY AND LACTATION:

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 drug 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

### UNDESIRABLE EFFECT:

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%).

### INCOMPATIBILITY:

Not applicable.

### SHELF LIFE:

36 Months

### PACKAGING:

30 gm tube is packed in a printed carton along with pack insert

### STORAGE CONDITION:

Store in a cool, dry place below 30°C. Protect from light. Keep out of reach of children.

### DISTRIBUTED BY:

Relief Pharma Ltd.  
5th Street of Taimany, Kabul  
Afghanistan.

### MANUFACTURED BY:

Cian Healthcare Ltd.  
(An ISO 9001 : 2015 & WHO GMP Certified Co.)  
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