



Module-1 Administrative Information and Product Information

1.4.1.1 Name of the Medicinal Product

Chlorzoxazone, Diclofenac Sodium and Paracetamol Tablets

1.4.1.1.1 Strength

(250 mg + 50 mg + 325 mg) /Tablet

1.4.1.1.2 Pharmaceutical Form

Solid oral dosage form

1.4.1.2 Qualitative and Quantitative declaration

1.4.1.2.1 Qualitative declaration

Chlorzoxazone USP

Diclofenac Sodium BP

Paracetamol BP

1.4.1.2.2 Quantitative declaration

Sr. No.	Ingredients	Specification	Std Qty/ Tablet (mg)	Reason for Inclusion
MIXING				
1	Chlorzoxazone (A)	USP	250.0	Skeletal Muscle Relaxant
2	Paracetamol (A)	BP	325.0	Analgesic, Antipyretic
3	Diclofenac Sodium (A)	BP	50.00	Non-Steroidal Anti-Inflammatory
4	Croscarmellose Sodium	USP(NF)	30.00	Disintegrant
5	Povidone (P.V.P.K.-30)	BP	3.000	Binder
6	Microcrystalline Cellulose (Avicel)	BP	57.29	Diluent
BINDING				
7.	Sodium Lauryl Sulfate	BP	5.000	Surfactant



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8	Maize Starch	BP	32.26	Diluent
9	Povidone (P.V.P.K.-30)	BP	3.000	Binder
10	Propylene Glycol	BP	3.000	Binding Agent
11	Purified Water (#)	BP	Q.S.	vehicle
LUBRICATION				
12	Sodium Starch Glycolate (Type A)	BP	50.00	Disintegrant
13	Croscarmellose Sodium	USP(NF)	40.00	Disintegrant
14	Microcrystalline Cellulose (Avicel)	BP	44.79	Lubricant
15	Colloidal Anhydrous Silica (Aerosil)	BP	9.000	Disintegrant
16	Magnesium Stearate	BP	4.000	Lubricant
Theoretical Avg. Weight (Core)			900.0	
COATING				
17	Colour sunset yellow SC-SP-2029	In House	25.00	Colouring agent
18	Isopropyl Alcohol (#)	BP	200.0	solvent
19	Dichloro methane (#)	BP	300.0	solvent
Theoretical Avg. Weight (Coated)			925.0	

1.4.1.3 Pharmaceutical Form

Solid Oral Dosage Form, Tablets

Orange colored, capsule shaped, film coated tablets plain on both sides.

1.4.1.4 Clinical Particulars

1.4.1.4.1 Therapeutic Indications

It is indicated for:

- The treatment of osteoarthritis, acute rheumatoid arthritis inflammation, soft tissues and muscular inflammations.



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- Treatment of ankylosing spondylitis, cervical spondylitis, intervertebral disc syndrome, painful muscle spasms associated with degenerative vertebral disorders such as low back pain.
- Relief in conditions of sprains and sports injuries.

1.4.1.4.2 Posology and Method of Administration

Adults: 1-2 tablets/day after meal or as directed by the physician.

Children: Not recommended for children below 12 years.

1.4.1.4.3 Contraindications

Hypersensitivity to Paracetamol, Diclofenac, Chlorzoxazone or other NSAIDs.

- Severe hepatic dysfunction
- Peptic ulcer
- Renal failure or impairment
- Last trimester of pregnancy
- Breast feeding

1.4.1.4.4 Special Warnings and Special Precautions for Use

Not Applicable

1.4.1.4.5 Interaction with other medicinal products and other forms of interaction

Not Applicable

1.4.1.4.6 Fertility, Pregnancy and Lactation

Pregnancy: The drug is not recommended in pregnant women.

Lactation: The drug is not recommended in breast-feeding women.

1.4.1.4.7 Effects on ability To Drive and use Machines

Not Applicable

1.4.1.4.8 Undesirable Effects



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- Generally gastrointestinal disturbances such as nausea, vomiting, abdominal discomfort and pain
- Hypersensitivity reactions
- Rash, eruptions, pruritus
- Respiratory disorders: acute asthma attack specially in case of subjects allergic to aspirin and other NSAIDs.

1.4.1.4.9 Overdose

Not Applicable

1.4.1.5 Pharmacological Properties

1.4.1.5.1 Pharmacodynamics Properties

Diclofenac: an NSAID is responsible of anti-inflammatory and analgesic activity. The mechanism of action (like all NSAIDs) is not completely understood but may result in the inhibition of prostaglandin synthesis. The presence of diclofenac enhances analgesic action and antipyretic paracetamol.

Paracetamol: has a peripheral analgesic action, is by raising the pain threshold. It is antipyretic and acts on the hypothalamic temperature control at the central level.

Chlorzoxazone: Action has a muscle relaxant with sedative average property. The experimental data in the animal and in man indicate that chlorzoxazone is first in the spinal cord of the subcortical region of the brain where it inhibits the multi-synaptic reflex involved in the appearing and maintains skeletal muscle spasms of varied etiology.

1.4.1.5.2 Pharmacokinetic Properties

Diclofenac: The peak plasma concentration is reached 2 hours after administration.

Paracetamol: Its onset of action is rapid. Well absorbed in the digestive tract. Peak plasma concentrations 30 min – 2 hr after ingestion.

Chlorzoxazone: Serum detected as early as 30 minutes and peak 1-2 hours after administration. It is rapidly metabolized and excreted in the urine.

1.4.1.5.3 Preclinical Safety Data

Not Applicable



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1.4.1.6 Pharmaceutical Particulars

1.4.1.6.1 List of Excipients

Croscarmellose Sodium
Povidone (P.V.P.K.-30)
Microcrystalline Cellulose (Avicel)
Maize Starch
Propylene Glycol
Sodium Starch Glycolate
Croscarmellose Sodium
Colloidal Anhydrous Silica (Aerosil)
Magnesium Stearate
Colour sunset yellow SC-SP-2029

1.4.1.6.2 Incompatibilities

Not applicable.

1.4.1.6.3 Shelf Life

36 months

1.4.1.6.4 Special Precautions for Storage

Do not store above 30 °C, Protect from light.

1.4.1.6.5 Nature and Contents of Container

orange colored, capsule shaped, Film coated tablets plain on both side. Such 10 Tablets are packed in Alu-PVC blister pack. Such 10 blisters are packed in printed carton along with package insert.

1.4.1.6.6 Special precaution for disposal and other handling

Any unused product or waste material should be disposed of in accordance with local requirements.

1.4.1.7 Marketing Authorization Holder and Manufacturing Site Addresses



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1.4.1.7.1 Name and Address of Marketing Authorization Holder

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
E-mail: hiren@lincolnpharma.com;
Web site: www.lincolnpharma.com

1.4.1.7.2 Name and Address of manufacturing site(s)

Lincoln Pharmaceuticals Limited
Trimul Estate, Khatraj, Taluka: Kalol,
District: Gandhinagar Gujarat, India.
Telephone no.: +91-79-41078096
Fax: +91-79-41078062
E-mail: hiren@lincolnpharma.com;
Web site: www.lincolnpharma.com

1.4.1.8 Marketing Authorization Number

1.4.1.9 Date of First <Registration> / Renewal of The <Registration>

1.4.1.10 Date of Revision of the Text

1.4.1.11 Dosimetry (If Applicable)

Not Applicable

1.4.1.12 Instructions for preparation of radiopharmaceuticals (if Applicable)

Not Applicable