Tolperisone (450mg) + Diclofenac (100mg)

# **Tolprist DSR Tablet**

Tolperisone (450 mg) + Diclofenac (100 mg) Tablet

### **Description:**

Tolperisone (450 mg) + Diclofenac (100 mg) tablet is a combination therapy that combines a muscle relaxant and a nonsteroidal anti-inflammatory drug (NSAID) to provide effective relief from pain and muscle spasms. This tablet is specifically designed for patients experiencing significant musculoskeletal pain, muscle spasms, and inflammation due to conditions such as acute back pain, cervical spondylosis, and soft tissue injuries.

### **Composition:**

### **Each tablet contains:**

Tolperisone: 450 mgDiclofenac: 100 mg

### **Indications:**

Tolperisone 450 mg + Diclofenac 100 mg tablet is indicated for the treatment of:

- 1. Acute and chronic musculoskeletal pain associated with:
  - o Muscle spasms
  - Soft tissue injuries (e.g., sprains, strains)
  - Cervical spondylosis and lumbar spondylosis
- 2. Inflammatory conditions such as:
  - Osteoarthritis
  - o Rheumatoid arthritis
  - Ankylosing spondylitis

- 3. Acute low back pain or back muscle strain
- **4.** Post-operative pain (following surgery or injury)
- 5. Fibromyalgia and other conditions involving muscle tension and spasm

### **Mechanism of Action:**

• Tolperisone:

Tolperisone is a central muscle relaxant. It works by acting on the central nervous system (CNS) to reduce muscle tone and decrease the intensity of muscle spasms. It targets spinal reflexes, which helps relax the muscles without causing significant sedation, allowing the patient to remain alert.

Diclofenac:
 Diclofenac is an NSAID that works by inhibiting the cyclooxygenase (COX) enzymes, which are responsible for the production of prostaglandins—chemicals that cause inflammation, pain, and fever.

# **Dosage and Administration:**

- For Adult Patients:
  - The typical dose is one tablet of Tolperisone (450 mg) + Diclofenac (100 mg) once or twice a day, as prescribed by a healthcare provider.
  - The dosage may be adjusted based on the severity of symptoms or the response to treatment.
- For Elderly Patients:
   Older adults may be more sensitive to
   the effects of Diclofenac and Tolperisone,

especially in terms of gastrointestinal and renal side effects.

- Administration:
  - Take the tablet orally, with a glass of water, after meals to minimize the risk of gastrointestinal upset.
  - Do not crush or chew the tablet; swallow it whole.

#### **Side Effects:**

# Common side effects may include:

- 1. Tolperisone-related side effects:
  - o Dizziness, drowsiness, or headache
  - Fatigue or tiredness
  - Nausea or stomach discomfort
  - Skin rash or itching
- 2. Diclofenac-related side effects:
  - Gastrointestinal symptoms such as nausea, vomiting, gastritis, indigestion, and abdominal pain
  - o Diarrhea or constipation
  - Headache, dizziness
  - Elevated blood pressure
  - Fluid retention or edema
- 3. Serious side effects (rare but possible):
  - Gastrointestinal bleeding, ulcers, or perforation, especially in longterm use
  - Severe allergic reactions (rash, swelling, difficulty breathing)
  - Liver damage (yellowing of skin or eyes, dark urine)
  - Kidney problems (reduced urine output, swelling)

#### **Precautions:**

Gastrointestinal Risk:
Both Tolperisone and Diclofenac may cause gastric irritation. Diclofenac, in particular, can increase the risk of gastric ulcers, bleeding, and perforation. Consideration for co-administration with gastroprotective agents (like proton

pump inhibitors) is advised in patients with a history of gastrointestinal issues.

- Pregnancy and Breastfeeding:
  - Pregnancy Category C: Diclofenac should be avoided during the third trimester of pregnancy, as it may harm the fetus. Use during pregnancy should be done only when clearly needed and after a risk-benefit assessment.
  - It is unknown if Tolperisone or Diclofenac are excreted in breast milk. Use with caution in breastfeeding mothers, and consult a healthcare provider.
- Elderly Patients:
   Older adults may be more vulnerable to
   the side effects of NSAIDs and muscle
   relaxants.

## **Storage:**

- Store at room temperature (15°C to 30°C), in a dry place.
- Protect from moisture and light.
- Keep out of reach of children.

Note: Tolperisone 450 mg + Diclofenac 100 mg tablet should be used as part of a comprehensive treatment plan, including appropriate rest, physical therapy, and lifestyle changes. Always follow the prescribed dosage and consult a healthcare provider for any adjustments to treatment.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd.
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