



EASE THE UNEASED

TOLMOVE

Tolperisone Tablets 150 mg & 450 mg Sustained Release Tablets

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Background:

- Spasms may affect many different types of muscles in the body, leading to many different symptoms.
- Lower back pain can be caused by a variety of problems with any parts of the complex, interconnected network of spinal muscles, nerves, bones, discs or tendons in the lumbar spine.

Prevalence of Low Back Pain :

- 1 in 10 people (9.4 per cent) worldwide suffers from low back pain¹
- Out of all 291 conditions studied, low back pain came top of the league table in terms of years lost to disability, and sixth in terms of DALYs¹
- The prevalence of back pain in 6.2% (in general population) to 92% (in construction workers): depending upon the population under study²

Prevalence of low back pain in India :

Authors	Study Population	LBP Definition for The Study	Population size (n)	Prevalence
Mahajan et al., (2003)	General population in Jammu	Not defined	1014	34.7%
Sharma et al., (2003)	Workage adults of rural North India	Not defined	11234	23.09%
Haldiya et al., (2010)	General population in Jodhpur district	Not defined	10015	6.2%
Bihari et al., (2011)	Residents of national capital region	Not defined	2086	More than 50%
Banerjee et al., (2012)	General population in Pimpri, Pune	History of long standing pain in lumbosacral region with no history of trauma	2633	34.21%
Dutta et al., (2013)	General population in eastern part of India	Not defined	476	32.98%
Sharma and Mahajan (2013)	Zari workers of urban slum of Mumbai	Not defined	800	76.3%
Kumar et al., (2013)	Dental professionals in India	Not defined	646	72.01%
Hameed (2013)	Information technology professionals of Tamilnadu	Symptoms such as ache, pain, and discomfort in the low back region which arise mainly due to work activities	400	51%

Clinical Effectiveness:

1. "A Post-Marketing Surveillance Study of Tolperisone : It's Use in the General Clinical Practice in India"

According to *Journal of Clinical and Diagnostic Research*; 2011

Study on 165 patients at the mean age of $43.88 \pm (SD) 11.27$ years with in the dose range of 150–900 mg/day suggest that:

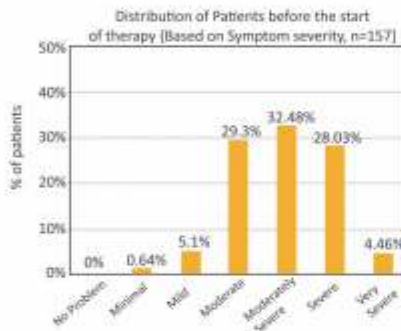


Fig: Distribution of patients based on symptom severity before Therapy

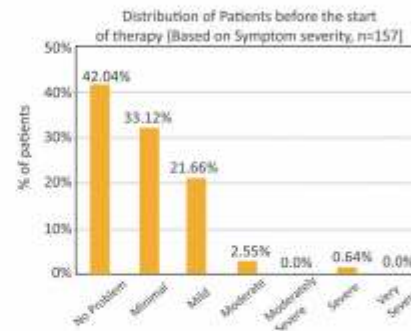


Fig: Distribution of patients based on symptom severity after therapy with tolperisone

Result and Conclusion:

- The treatment with tolperisone is effective and it improves the patient's ability to perform routine activities.
 - In the total study population, 92% of the patients did not report any adverse event following the treatment with tolperisone.
 - Tolperisone is safe in a wide range of patients, including the elderly and patients with co-morbid diseases.
 - The recommended dosage of tolperisone is 150 mg, three times daily (450 mg/day).
- 2. "Clinical Comparative Study: Efficacy and Tolerability of Tolperisone and Thiocolchicoside in Acute Low Back Pain and Spinal Muscle Spasticity"**

According to *Asian Spine Journal*; 2011

A multicentric, randomized, comparative clinical trial on 250 patients at 150 mg of tolperisone thrice daily or 8 mg of Thiocolchicoside twice daily for 7 days.

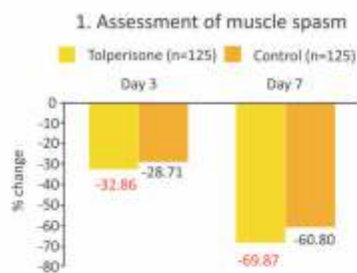


Fig 1: Percentage change in finger-to-floor distance (cm) with Tolperisone and Thiocolchicoside.



Fig 2: Change in mean Laseague's manoeuvre score with Tolperisone and Thiocolchicoside

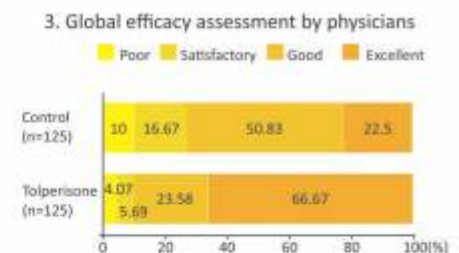


Fig 3: Global efficacy assessment by physician (% of patients) with Tolperisone and thiocolchicoside.

Results:

- Finger to floor distance (FFD): Both the medications demonstrates a significant effect on the FFD.
- The muscle relaxant effect of Tolperisone and TC as assessed by Laseague's manoeuvre score(LMS) suggest that the percentage change in LMS with Tolperisone is 36.74% and Thiocochochicoside is 26.43% on day 3 and 67.24% and 53.38% respectively on day 7.
- Global efficacy assessment by physicians suggest that Tolperisone produced good to excellent efficacy in 90% of patients where as thiocolchicoside produced good to excellent efficacy in 73% of patients.

Conclusion:

- Tolperisone is an effective skeletal muscle relaxant agent with efficacy similar to thiocolchicoside
- Relatively better tolerated option for treatment of patients with low back pain associated with muscle spasm.

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Description:

TOLMOVE contains Tolperisone Tablets in the strength of 150 mg Film coated and 450 mg sustained release film coated tablet. Tolperisone, has been widely used as spasmolytics of choice. It has higher muscle relaxant activity than the dextrorotatory enantiomer. It exhibits membrane stabilizing potency, which is characteristic of anti arrhythmic and local anesthetic agents.

Mechanism of Action:

- Centrally acting muscle relaxant, tolperisone acts at the level of spinal cord by blocking sodium channels and calcium channels. Tolperisone exerts its spinal reflex inhibitory action predominantly via a pre synaptic inhibition of the transmitter release from the primary afferent endings via a combined action on voltage-gated sodium and calcium channels.
- Tolperisone increases the blood supply to skeletal muscles; this action is noteworthy since a muscle contracture may compress the small blood vessels and induce an ischemia leading to release of pain stimulating compounds.
- Tolperisone causes preferential antinociceptive activity against thermal stimulation that is likely to be attributed to its local anesthetic action.
- Tolperisone causes muscle relaxation by its action on central nervous system. It also leads to membrane stabilization & has analgesic activity. The muscle relaxation is dose dependent.

Indication:

- Low back pain syndrome
- Painful reflex muscle spasm
- Post-cerebral stroke spasticity
- Neurolathyrism
- Trapezitis
- Rehabilitation programmes
- Periarthritis

Dosage:

Tablets

- The usually recommended dose of Tolperisone hydrochloride in adults is 150 mg/day, three times daily (450 mg/day), that can be increased to a maximum daily dose of 600 mg if required.

Administration:

- It comes as Film Coated tablets and to be taken by mouth with or without food.

Storage:

- Store at a temperature not exceeding 30°C, protected from light and moisture.

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