BACLOREN™

Baclofen 10 mg Tablets & 20 mg Extended Release Tablets

Description

BACLOREN contains baclofen 10 mg uncoated tablets and BACLOREN 20 mg extended release tablets. Baclofen is a gamma-amino-butyric acid (GABA) derivative used as a skeletal muscle relaxant. Baclofen stimulates GABA-B receptors leading to decreased frequency and amplitude of muscle spasms. It is especially useful in treating muscle spasticity associated with spinal cord injury.

Mechanism of Action:

Baclofen is a direct agonist at GABAB receptors. The precise mechanism of action of Baclofen is not fully known. It is capable of inhibiting both monosynaptic and polysynaptic reflexes at the spinal level, possibly by hyperpolarization of afferent terminals, although actions at supraspinal sites may also occur and contribute to its clinical effect.

Indication:

It is prescribed for Muscle Spasms and as Muscle Relaxants.

Dosage:

Baclofen:
Initial:

5 mg t.i.d. for 3 days

10 mg t.i.d. for 3 days

15 mg t.i.d. for 3 days

20 mg t.i.d. for 3 days

Thereafter additional increases may be necessary but the total daily dose should not exceed a maximum of 80 mg daily (20 mg q.i.d.).

Administration:

It comes as a tablet and to be taken by mouth.

Presentation:

Bacloren is available as strip of 10 Tablets.

Storage:

Store below 30^{o}C. Keep in cool and dry place. Protect from light and moisture.

La Renon Healthcare Pvt Ltd.
207-208 Iscon Elegance, Circle P, Prahlad Nagar Cross Roads,
S.G. Highway, Ahmedabad-380015, Gujarat, India.
Phone: + 91-79-3046-1000 (30 lines)
Fax: +91-79-3046-1001
E-mail: info@larenon.com | Web: www.larenon.com

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La Renon®

Relax into the Flow of Life

BACLOREN™

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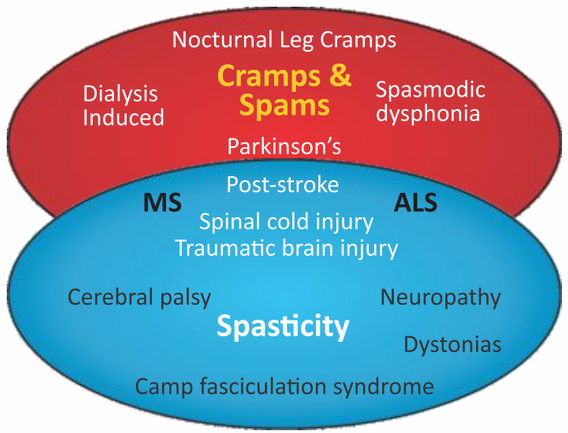
Background:

Muscle relaxants make up a heterogeneous group of drugs that mainly exert their pharmacologic effect centrally at the level of the spinal cord, the brainstem, or the cerebrum, and that have an insignificant, if any effect, at the muscle fiber level. Their centrally mediated mechanism of action can exert a clinically significant peripheral therapeutic effect[1].

- Spasticity is defined as a motor disorder characterized by velocity dependent increase in tonic stretch reflexes (muscle tone) with exaggerated tendon jerks[2].
- Spasticity is usually accompanied by permanent or at least intermittent voluntary muscle activation, resulting in weakness and clumsiness of voluntary movements[3].
- Spasticity can prevent or hamper function, cause pain, disturb sleep, cause unnecessary complications and present major difficulties for care workers[3].



- Skeletal muscle relaxant compounds classified into two main categories: antispasticity and antispasmodic medications.
- Antispasticity agents work on the spinal cord or directly on the skeletal muscles to improve muscle hypertonicity and involuntary spasms.
- Antispasmodics decrease muscle spasms through alterations of CNS conduction. These are divided into benzodiazepines, which inhibit transmission on the postsynaptic γ-aminobutyric acid (GABA) neurons, and nonbenzodiazepine agents, which act at the brain stem and spinal cord.

Prevalence:

- Pain of muscle origin or myogenic pain is commonly observed among patients experiencing chronic pain[1].
- The incidence of spasticity-related muscle pain in patients with stroke, multiple sclerosis, or after spinal cord injury can reach as high as 65%, 74%, and 67%, respectively[1].
- Studies show that spasticity occurs in 20% - 30% of all stroke victims and in less than half of those with pareses[4].
- 1 in 10 people (9.4 per cent) worldwide suffers from low back pain[5].

Reference:

1. Physical Medicine & Rehabilitation Clinics of North America
2. Lance JW, Feldman RG, Young RR, Koeller C. Spasticity: disordered motor control. Chicago, EL: Yearbook Medical, 1980
3. Age and Ageing 1998
4. American Journal of Phys Med Rehabil. 2012
5. International Journal of Basic and Applied Medical Sciences; 5 (1): 166-179; 2015

Clinical Effectiveness:

1. Postgraduate Medical Journal; 1975

"Evaluation of Baclofen for Spasticity in Multiple Sclerosis"

Thirty-six patients with MS having disability due to spasticity in the presence of reasonable voluntary muscle power or spasticity/muscle spasms causing difficulty in day-to-day care selected for the study.

Result:

PROGRESS OF THIRTY-FIVE PATIENTS ON BACLOFEN:

	Ambulant	Wheelchair	Muscle Spasms*
Improvement			
Considerable	4	4	9
Slight	5	3	4
No Benefit			
Considerable	4	4	9
Slight	5	3	4
Total	21	14	21

Includes patients in ambulant and wheelchair groups.

Conclusion:

Baclofen provide relief in spasticity or muscle spasms in about 50% of the patients with MS.

2. The American Journal of Medicine; 2006

"Baclofen in the Treatment of Alcohol Withdrawal Syndrome: A Comparative Study V/s Diazepam"

- Study on 37 patients with alcohol withdrawal syndrome (AWS) enrolled in the study and randomly divided into 2 groups.
- Baclofen orally administered to 18 patients and Diazepam orally administered to 19 patients.
- The Clinical Institute Withdrawal Assessment (CIWA-Ar) used to evaluate physical symptoms of AWS.

Results & conclusion:

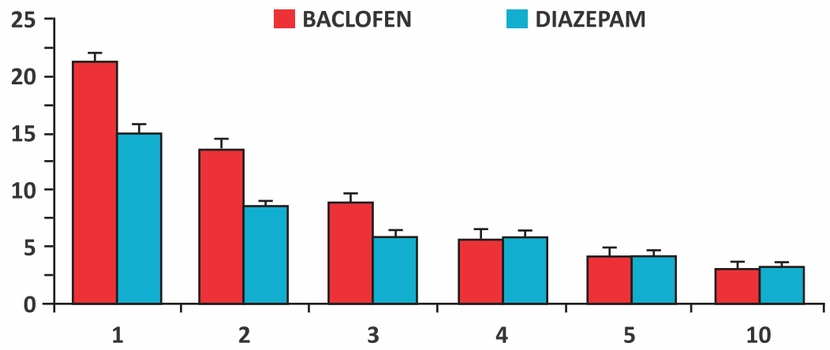


Figure 1: Score of Clinical Institute Withdrawal Assessment for Alcohol-revised (CIWA-Ar) Scale in patients treated for 10 consecutive days with baclofen (30 mg /day, per os; n=18) and diazepam (0.5-0.75 mg /kg/day on days 1-6, tapering the dose by 25% daily from day 7 to day 10; n=19). CIWA-Ar administration occurred once a day, on days 1, 2, 3, 4, 5 and 10, immediately before the first daily administration of drugs (scoring of day 1 acting as baseline).

- Both baclofen and diazepam significantly decreased CIWA-Ar score, without significant differences between the two treatments.
- The efficacy of baclofen in treatment of uncomplicated AWS is comparable to that of the "gold standard" diazepam. These results suggest that baclofen is alternative drug for treatment of uncomplicated AWS