

BACLOFEN- baclofen 10mg tablet
Advanced Rx Pharmacy of Tennessee, LLC

Baclofen 10mg tablets #90

Dosage and Administration

DOSAGE AND ADMINISTRATION

The determination of optimal dosage requires individual titration. Start therapy at a low dosage and increase gradually until optimum effect is achieved (usually between 40 to 80 mg daily).

The following dosage titration schedule is suggested:

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.).

The lowest dose compatible with an optimal response is recommended. If benefits are not evident after a reasonable trial period, patients should be slowly withdrawn from the drug (see WARNINGS, Abrupt Drug Withdrawal).

Indications and Usage Section

INDICATIONS AND USAGE

Baclofen tablets are useful for the alleviation of signs and symptoms of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity.

Patients should have reversible spasticity so that baclofen treatment will aid in restoring residual function. Baclofen tablets may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

Baclofen tablets are not indicated in the treatment of skeletal muscle spasm resulting from rheumatic disorders.

The efficacy of baclofen in stroke, cerebral palsy, and Parkinson's disease has not been established and, therefore, it is not recommended for these conditions.

Principal Display Panel

NDC 0172-4096-60

Baclofen Tablets USP 10 mg

Rx only

Each tablet contains 10 mg
baclofen, USP.

Usual Dosage: See package insert
for full prescribing information.

Store at 20° to 25°C (68° to 77°F)
[See USP Controlled Room
Temperature].

Dispense in a well-closed container
as defined in the USP, with a
child-resistant closure (as required).
**KEEP THIS AND ALL MEDICATIONS
OUT OF THE REACH OF CHILDREN.**

Manufactured In Croatia By:
PLIVA HRVATSKA d.o.o.
Zagreb, Croatia
Manufactured For:
TEVA PHARMACEUTICALS USA, INC.
North Wales, PA 19454

N
3 0172-4096-60 8



70048763

Rev. C 10/2015

100 TABLETS

TEVA

BACLOFEN

baclofen 10mg tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:80425-0080(NDC:0172-4096)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACLOFEN (UNII: H789N3FKE8) (BACLOFEN - UNII:H789N3FKE8)	BACLOFEN	10 mg

Product Characteristics

Color	white	Score	2 pieces
Shape	ROUND	Size	9mm
Flavor		Imprint Code	4096;TV
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:80425-0080-3	90 in 1 BOTTLE; Type 0: Not a Combination Product	07/21/1988	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
--------------------	------------------------------------------	----------------------	--------------------

ANDA	ANDA072234	07/21/1988	
------	------------	------------	--

Labeler - Advanced Rx Pharmacy of Tennessee, LLC (117023142)

Establishment

Name	Address	ID/FEI	Business Operations
Advanced Rx Pharmacy of Tennessee, LLC		117023142	repack(80425-0080)

Revised: 2/2021

Advanced Rx Pharmacy of Tennessee, LLC