

BACLOFEN- baclofen 20mg tablet
Advanced Rx Pharmacy of Tennessee, LLC

Baclofen 20mg tablets #30

Dosage and Administration Section

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 If benefits are not evident after a reasonable trial period, patients should be slowly withdrawn from the drug (see WARNINGS, ABRUPT DRUG WITHDRAWAL).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 USP 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 USP may also be of some value in patients with spinal cord injuries and other spinal cord diseases.

Baclofen tablets USP 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

Each tablet contains:
20 mg of Baclofen, USP

NDC 0527-1337-01

USUAL DOSAGE:

See package insert for complete
prescribing information.

Dispense in a well-closed container
as defined in the USP with a
child-resistant closure.

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

**KEEP THIS AND ALL MEDICATION
OUT OF THE REACH OF CHILDREN.**

This bottle has been sealed for your
protection.

Baclofen Tablets, USP

20 mg

Distributed by:
Lannett Company, Inc.
Philadelphia, PA 19136



N 3 0527-1337-01-6

Rx Only
100 Tablets



CIB702840 Rev. 05/20

BACLOFEN

baclofen 20mg tablet

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|-------------------------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:80425-0112(NDC:0527-1337) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|-------------------|----------|
| BACLOFEN (UNII: H789N3FKE8) (BACLOFEN - UNII:H789N3FKE8) | BACLOFEN | 20 mg |

Product Characteristics

| | | | |
|-----------------|-------|---------------------|----------|
| Color | white | Score | 2 pieces |
| Shape | ROUND | Size | 10mm |
| Flavor | | Imprint Code | LCI;1337 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:80425-0112-1 | 30 in 1 BOTTLE; Type 0: Not a Combination Product | 12/20/2005 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANDA | ANDA077241 | 12/20/2005 | |

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

Establishment

| Name | Address | ID/FEI | Business Operations |
|--|---------|-----------|---------------------|
| Advanced Rx Pharmacy of Tennessee, LLC | | 117023142 | repack(80425-0 112) |

Revised: 2/2021

Advanced Rx Pharmacy of Tennessee, LLC