

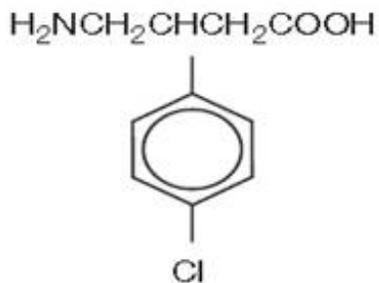
BACLOFEN- baclofen tablet
Asclemed USA, Inc.

BACLOFEN TABLETS, USP
Rx only

DESCRIPTION

Baclofen, USP is a muscle relaxant and antispastic.

Its chemical name is 4-amino-3-(4-chlorophenyl)-butanoic acid. The structural formula is:



$\text{C}_{10}\text{H}_{12}\text{ClNO}_2$ M.W. 213.66

Baclofen, USP is a white to off-white odorless or practically odorless crystalline powder. It is slightly soluble in water, very slightly soluble in methanol and insoluble in chloroform.

Each tablet, for oral administration, contains 5 mg, 10 mg, 15 mg or 20 mg baclofen, USP. In addition, each tablet contains the following inactive ingredients: Microcrystalline Cellulose, Pregelatinized Starch, Sodium Starch Glycolate, Colloidal Silicon dioxide and Magnesium Stearate.

CLINICAL PHARMACOLOGY

The precise mechanism of action of baclofen is not fully known. Baclofen 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. Although baclofen is an analog of the putative inhibitory neurotransmitter gamma-aminobutyric acid (GABA), there is no conclusive evidence that actions on GABA systems are involved in the production of its clinical effects. In studies with animals baclofen has been shown to have general CNS depressant properties as indicated by the production of sedation with tolerance, somnolence, ataxia, and respiratory and cardiovascular depression. Baclofen is rapidly and extensively absorbed and eliminated. Absorption may be dose-dependent, being reduced with increasing doses. Baclofen is excreted primarily by the kidney in unchanged form and there is relatively large intersubject variation in absorption and/or elimination.

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.

CONTRAINDICATIONS

Hypersensitivity to baclofen.

WARNINGS

a. Neonatal Withdrawal Symptoms: Withdrawal symptoms have been reported starting hours to days after delivery in neonates whose mothers were treated with oral baclofen throughout pregnancy. The symptoms of withdrawal in these infants have included increased muscle tone, tremor, jitteriness, and seizure. If the potential benefit justifies the potential risk to the fetus and oral baclofen is continued during pregnancy, gradually reduce the dose and discontinue baclofen before delivery. If slow withdrawal is not feasible, advise the parents or caregivers of the potential for neonatal withdrawal.

b. Abrupt Drug Withdrawal: Hallucinations and seizures have occurred on abrupt withdrawal of baclofen. Therefore, except for serious adverse reactions, the dose should be reduced slowly when the drug is discontinued.

c. Impaired Renal Function: Because baclofen is primarily excreted unchanged through the kidneys, it should be given with caution, and it may be necessary to reduce the dosage.

d. Stroke: Baclofen has not significantly benefited patients with stroke. These patients have also shown poor tolerability to the drug.

e. Pregnancy: Baclofen has been shown to increase the incidence of omphaloceles (ventral hernias) in fetuses of rats given approximately 13 times the maximum dose recommended for human use, at a dose which caused significant reductions in food intake and weight gain in dams. This abnormality was not seen in mice or rabbits.

There was also an increased incidence of incomplete sternebral ossification in fetuses of rats given approximately 13 times the maximum recommended human dose, and an increased incidence of unossified phalangeal nuclei of forelimbs and hindlimbs in fetuses of rabbits given approximately 7 times the maximum recommended human dose. In mice, no teratogenic effects were observed, although reductions in mean fetal weight with consequent delays in skeletal ossification were present when dams were given 17 and 34 times the human daily dose. There are no studies in pregnant women. Baclofen

should be used during pregnancy only if the benefit clearly justifies the potential risk to the fetus.

PRECAUTIONS

Because of the possibility of sedation, patients should be cautioned regarding the operation of automobiles or other dangerous machinery, and activities made hazardous by decreased alertness. Patients should also be cautioned that the central nervous system effects of baclofen may be additive to those of alcohol and other CNS depressants.

Baclofen should be used with caution where spasticity is utilized to sustain upright posture and balance in locomotion or whenever spasticity is utilized to obtain increased function.

In patients with epilepsy, the clinical state and electroencephalogram should be monitored at regular intervals, since deterioration in seizure control and EEG have been reported occasionally in patients taking baclofen.

It is not known whether this drug is excreted in human milk. As a general rule, nursing should not be undertaken while a patient is on a drug since many drugs are excreted in human milk.

A dose-related increase in incidence of ovarian cysts and a less marked increase in enlarged and/or hemorrhagic adrenal glands was observed in female rats treated chronically with baclofen.

Ovarian cysts have been found by palpation in about 4% of the multiple sclerosis patients that were treated with baclofen for up to one year. In most cases these cysts disappeared spontaneously while patients continued to receive the drug. Ovarian cysts are estimated to occur spontaneously in approximately 1% to 5% of the normal female population.

Pediatric Use

Safety and effectiveness in pediatric patients below the age of 12 years have not been established.

ADVERSE REACTIONS

The most common is transient drowsiness (10 to 63%). In one controlled study of 175 patients, transient drowsiness was observed in 63% of those receiving baclofen compared to 36% of those in the placebo group. Other common adverse reactions are dizziness (5 to 15%), weakness (5 to 15%) and fatigue (2 to 4%).

Others reported:

Neuropsychiatric: Confusion (1 to 11%), headache (4 to 8%), insomnia (2 to 7%); and, rarely, euphoria, excitement, depression, hallucinations, paresthesia, muscle pain, tinnitus, slurred speech, coordination disorder, tremor, rigidity, dystonia, ataxia, blurred vision, nystagmus, strabismus, miosis, mydriasis, diplopia, dysarthria, epileptic seizure.

Cardiovascular: Hypotension (0 to 9%). Rare instances of dyspnea, palpitation, chest pain, syncope.

Gastrointestinal:Nausea (4 to 12%), constipation (2 to 6%); and rarely, dry mouth, anorexia, taste disorder, abdominal pain, vomiting, diarrhea, and positive test for occult blood in stool.

Genitourinary:Urinary frequency (2 to 6%); and rarely, enuresis, urinary retention, dysuria, impotence, inability to ejaculate, nocturia, hematuria.

Other:Instances of rash, pruritus, ankle edema, excessive perspiration, weight gain, nasal congestion.

Some of the CNS and genitourinary symptoms may be related to the underlying disease rather than to drug therapy. The following laboratory tests have been found to be abnormal in a few patients receiving baclofen: increased SGOT, elevated alkaline phosphatase, and elevation of blood sugar.

OVERDOSAGE

Signs and Symptoms:Vomiting, muscular hypotonia, drowsiness, accommodation disorders, coma, respiratory depression and seizures.

Treatment:In the alert patient, empty the stomach promptly by induced emesis followed by lavage. In the obtunded patient, secure the airway with a cuffed endotracheal tube before beginning lavage (do not induce emesis). Maintain adequate respiratory exchange, do not use respiratory stimulants.

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 40-80 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).

HOW SUPPLIED

Baclofen Tablets, USP 5 mg are available as a White to off white, round flat-faced, beveled edge tablets debossed with "023" on one side and plain on other side, containing 5 mg baclofen USP packaged in bottles of 100 tablets.

NDC 76420-356-30 30s count (repackaged from NDC 52817-319-XX)

NDC 76420-356-60 60s count (repackaged from NDC 52817-319-XX)

NDC 76420-356-90 90s count (repackaged from NDC 52817-319-XX)

NDC 76420-356-01 100s count (repackaged from NDC 52817-319-10)

Baclofen Tablets, USP 10 mg are available as a White to off white, round flat-faced, beveled edge tablets debossed with "024" on one side and score on other side, containing 10 mg baclofen USP packaged in bottles of 100, 500 and 1000 tablets.

NDC 76420-357-30 30s count (repackaged from NDC 52817-320-XX)

NDC 76420-357-60 60s count (repackaged from NDC 52817-320-XX)

NDC 76420-357-90 90s count (repackaged from NDC 52817-320-XX)

NDC 76420-357-01 100s count (repackaged from NDC 52817-320-10)

NDC 76420-357-12 120s count (repackaged from NDC 52817-320-XX)

NDC 76420-357-05 500s count (repackaged from NDC 52817-320-50)

NDC 76420-357-00 1000s count (repackaged from NDC 52817-320-00)

Baclofen Tablets, USP 15 mg are available as a White to off white, round flat-faced, beveled edges tablets debossed with "AB1" on one side and plain on the other side, containing 15 mg baclofen USP packaged in bottles of 100 tablets.

NDC 76420-358-30 30s count (repackaged from NDC 52817-318-XX)

NDC 76420-358-60 60s count (repackaged from NDC 52817-318-XX)

NDC 76420-358-90 90s count (repackaged from NDC 52817-318-XX)

NDC 76420-358-01 100s count (repackaged from NDC 52817-318-10)

Baclofen Tablets, USP 20 mg are available as a White to off white, round flat-faced, beveled edge tablets debossed with "025" on one side and score on other side, containing 20 mg baclofen USP packaged in bottles of 100, 500 and 1000 tablets.

NDC 76420-359-30 30s count (repackaged from NDC 52817-321-XX)

NDC 76420-359-60 60s count (repackaged from NDC 52817-321-XX)

NDC 76420-359-90 90s count (repackaged from NDC 52817-321-XX)

NDC 76420-359-01 100s count (repackaged from NDC 52817-321-10)

NDC 76420-359-05 500s count (repackaged from NDC 52817-321-50)

NDC 76420-359-00 1000s count (repackaged from NDC 52817-321-00)

PHARMACIST: Dispense in a well closed container as defined in the USP, with a child-resistant closure (as required).

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

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Relabeled and Repackaged by:

Enovachem PHARMACEUTICALS

Torrance, CA 90501

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL-5 mg

Packaged By:
Enovachem PHARMACEUTICALS
379 Van Ness Ave.
Suite 1403-1406
Torrance, CA 90501
Baclofen Tablets, USP 5 mg
NDC: 76420-356-30
Qty: 30
Distributed By: TruPharma, LLC
Source NDC: 52817-319-XX
Description: white to off white/round,flat faced,beveled-edge,oboessead.023
Lot #: 00000000 Exp: 5/21/2025
Batch #: 00000000
Drug Status: RX
CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35630 1
(17) 250521
(10) 00000000
(21) 167845

Baclofen Tablets, USP 5 mg
NDC: 76420-356-30
S/N: 167845
Qty: 30

Baclofen Tablets, USP 5 mg
NDC: 76420-356-30
S/N: 167845
Qty: 30

Baclofen Tablets, USP 5 mg
NDC: 76420-356-30
S/N: 167845
Qty: 30

Relabeled By:
Enovachem PHARMACEUTICALS
379 Van Ness Ave.
Suite 1403-1406
Torrance, CA 90501
Baclofen Tablets, USP 5 mg
NDC: 76420-356-01
Qty: 100
Distributed By: TruPharma, LLC
Source NDC: 52817-319-10
Description: white to off white/round,flat faced,beveled-edge,oboessead.023
Lot #: 00000000 Exp:
Batch #: 00000000
Drug Status: RX
CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35601 1
(17)
(10) 00000000
(21)

Baclofen Tablets, USP 5 mg
NDC: 76420-356-01
S/N:
Qty: 100

Baclofen Tablets, USP 5 mg
NDC: 76420-356-01
S/N:
Qty: 100

Baclofen Tablets, USP 5 mg
NDC: 76420-356-01
S/N:
Qty: 100

Packaged By:
Enovachem PHARMACEUTICALS
379 Van Ness Ave.
Suite 1403-1406
Torrance, CA 90501
Baclofen Tablets, USP 5 mg
NDC: 76420-356-60
Qty: 60
Distributed By: TruPharma, LLC
Source NDC: 52817-319-XX
Description: white to off white/round,flat faced,beveled-edge,oboessead.023
Lot #: 00000000 Exp: 5/21/2025
Batch #: 00000000
Drug Status: RX
CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35660 8
(17) 250521
(10) 00000000
(21) 167846

Baclofen Tablets, USP 5 mg
NDC: 76420-356-60
S/N: 167846
Qty: 60

Baclofen Tablets, USP 5 mg
NDC: 76420-356-60
S/N: 167846
Qty: 60

Baclofen Tablets, USP 5 mg
NDC: 76420-356-60
S/N: 167846
Qty: 60

Packaged By:
Enovachem PHARMACEUTICALS
379 Van Ness Ave.
Suite 1403-1406
Torrance, CA 90501
Baclofen Tablets, USP 5 mg
NDC: 76420-356-90
Qty: 90
Distributed By: TruPharma, LLC
Source NDC: 52817-319-XX
Description: white to off white/round,flat faced,beveled-edge,oboessead.023
Lot #: 00000000 Exp: 5/21/2025
Batch #: 00000000
Drug Status: RX
CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35690 5
(17) 250521
(10) 00000000
(21) 167847

Baclofen Tablets, USP 5 mg
NDC: 76420-356-90
S/N: 167847
Qty: 90

Baclofen Tablets, USP 5 mg
NDC: 76420-356-90
S/N: 167847
Qty: 90

Baclofen Tablets, USP 5 mg
NDC: 76420-356-90
S/N: 167847
Qty: 90

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL-10 mg

Packaged By:

Enovachem
 PHARMACEUTICALS
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-30

Qty: 30

Distributed By: TruPharma, LLC
 Source NDC: 52817-320-XX
 Description: white to off white/round/flat faced/beveled-edge/debossed.024
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT. KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35730 8
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-30
 S/N:
 Qty: 30

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-30
 S/N:
 Qty: 30

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-30
 S/N:
 Qty: 30

Relabeled By:

Enovachem
 PHARMACEUTICALS
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-01

Qty: 100

Distributed By: TruPharma, LLC
 Source NDC: 52817-320-10
 Description: white to off white/round/flat faced/beveled-edge/debossed.024
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT. KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35701 8
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-01
 S/N:
 Qty: 100

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-01
 S/N:
 Qty: 100

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-01
 S/N:
 Qty: 100

Packaged By:

Enovachem
 PHARMACEUTICALS
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-60

Qty: 60

Distributed By: TruPharma, LLC
 Source NDC: 52817-320-XX
 Description: white to off white/round/flat faced/beveled-edge/debossed.024
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT. KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35760 5
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-60
 S/N:
 Qty: 60

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-60
 S/N:
 Qty: 60

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-60
 S/N:
 Qty: 60

Relabeled By:

Enovachem
 PHARMACEUTICALS
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-05

Qty: 500

Distributed By: TruPharma, LLC
 Source NDC: 52817-320-50
 Description: white to off white/round/flat faced/beveled-edge/debossed.024
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT. KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35705 6
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-05
 S/N:
 Qty: 500

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-05
 S/N:
 Qty: 500

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-05
 S/N:
 Qty: 500

Packaged By:

Enovachem
 PHARMACEUTICALS
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-90

Qty: 90

Distributed By: TruPharma, LLC
 Source NDC: 52817-320-XX
 Description: white to off white/round/flat faced/beveled-edge/debossed.024
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT. KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35790 2
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-90
 S/N:
 Qty: 90

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-90
 S/N:
 Qty: 90

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-90
 S/N:
 Qty: 90

Relabeled By:

Enovachem
 PHARMACEUTICALS
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-00

Qty: 1000

Distributed By: TruPharma, LLC
 Source NDC: 52817-320-00
 Description: white to off white/round/flat faced/beveled-edge/debossed.024
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT. KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35700 1
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-00
 S/N:
 Qty: 1000

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-00
 S/N:
 Qty: 1000

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-00
 S/N:
 Qty: 1000

Packaged By:

Enovachem
 PHARMACEUTICALS
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-12

Qty: 120

Distributed By: TruPharma, LLC
 Source NDC: 52817-320-XX
 Description: white to off white/round/flat faced/beveled-edge/debossed.024
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT. KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35712 4
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-12
 S/N:
 Qty: 120

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-12
 S/N:
 Qty: 120

Baclofen Tablets, USP 10 mg
 NDC: 76420-357-12
 S/N:
 Qty: 120

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL-15 mg

Packaged By:
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501
Baclofen Tablets, USP 15 mg
 NDC: 76420-358-30
 Qty: 30
 Distributed By: TruPharma, LLC
 Source NDC: 52817-318-XX
 Description: white to off white/round,flat faced,beveled-edge/obossed,018
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35830 5
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 15 mg
 NDC: 76420-358-30
 S/N:
 Qty: 30
 Baclofen Tablets, USP 15 mg
 NDC: 76420-358-30
 S/N:
 Qty: 30
 Baclofen Tablets, USP 15 mg
 NDC: 76420-358-30
 S/N:
 Qty: 30

Relabeled By:
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501
Baclofen Tablets, USP 15 mg
 NDC: 76420-358-01
 Qty: 100
 Distributed By: TruPharma, LLC
 Source NDC: 52817-318-10
 Description: white to off white/round,flat faced,beveled-edge/obossed,018
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35801 5
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 15 mg
 NDC: 76420-358-01
 S/N:
 Qty: 100
 Baclofen Tablets, USP 15 mg
 NDC: 76420-358-01
 S/N:
 Qty: 100
 Baclofen Tablets, USP 15 mg
 NDC: 76420-358-01
 S/N:
 Qty: 100

Packaged By:
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501
Baclofen Tablets, USP 15 mg
 NDC: 76420-358-60
 Qty: 60
 Distributed By: TruPharma, LLC
 Source NDC: 52817-318-XX
 Description: white to off white/round,flat faced,beveled-edge/obossed,018
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35860 2
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 15 mg
 NDC: 76420-358-60
 S/N:
 Qty: 60
 Baclofen Tablets, USP 15 mg
 NDC: 76420-358-60
 S/N:
 Qty: 60
 Baclofen Tablets, USP 15 mg
 NDC: 76420-358-60
 S/N:
 Qty: 60

Packaged By:
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501
Baclofen Tablets, USP 15 mg
 NDC: 76420-358-90
 Qty: 90
 Distributed By: TruPharma, LLC
 Source NDC: 52817-318-XX
 Description: white to off white/round,flat faced,beveled-edge/obossed,018
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35890 9
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 15 mg
 NDC: 76420-358-90
 S/N:
 Qty: 90
 Baclofen Tablets, USP 15 mg
 NDC: 76420-358-90
 S/N:
 Qty: 90
 Baclofen Tablets, USP 15 mg
 NDC: 76420-358-90
 S/N:
 Qty: 90

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL-20 mg

Packaged By:
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501
Baclofen Tablets, USP 20 mg
 NDC: 76420-359-30
 Qty: 30
 Distributed By: TruPharma, LLC
 Source NDC: 52817-321-XX
 Description: white to off white/round,flat faced,beveled-edge/obossed,028
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35930 2
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 20 mg
 NDC: 76420-359-30
 S/N:
 Qty: 30
 Baclofen Tablets, USP 20 mg
 NDC: 76420-359-30
 S/N:
 Qty: 30
 Baclofen Tablets, USP 20 mg
 NDC: 76420-359-30
 S/N:
 Qty: 30

Relabeled By:
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501
Baclofen Tablets, USP 20 mg
 NDC: 76420-359-01
 Qty: 100
 Distributed By: TruPharma, LLC
 Source NDC: 52817-321-10
 Description: white to off white/round,flat faced,beveled-edge/obossed,028
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35901 2
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 20 mg
 NDC: 76420-359-01
 S/N:
 Qty: 100
 Baclofen Tablets, USP 20 mg
 NDC: 76420-359-01
 S/N:
 Qty: 100
 Baclofen Tablets, USP 20 mg
 NDC: 76420-359-01
 S/N:
 Qty: 100

Packaged By:
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501
Baclofen Tablets, USP 20 mg
 NDC: 76420-359-60
 Qty: 60
 Distributed By: TruPharma, LLC
 Source NDC: 52817-321-XX
 Description: white to off white/round,flat faced,beveled-edge/obossed,028
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35960 9
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 20 mg
 NDC: 76420-359-60
 S/N:
 Qty: 60
 Baclofen Tablets, USP 20 mg
 NDC: 76420-359-60
 S/N:
 Qty: 60
 Baclofen Tablets, USP 20 mg
 NDC: 76420-359-60
 S/N:
 Qty: 60

Relabeled By:
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501
Baclofen Tablets, USP 20 mg
 NDC: 76420-359-05
 Qty: 500
 Distributed By: TruPharma, LLC
 Source NDC: 52817-321-50
 Description: white to off white/round,flat faced,beveled-edge/obossed,028
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35905 0
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 20 mg
 NDC: 76420-359-05
 S/N:
 Qty: 500
 Baclofen Tablets, USP 20 mg
 NDC: 76420-359-05
 S/N:
 Qty: 500
 Baclofen Tablets, USP 20 mg
 NDC: 76420-359-05
 S/N:
 Qty: 500

Packaged By:
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501
Baclofen Tablets, USP 20 mg
 NDC: 76420-359-90
 Qty: 90
 Distributed By: TruPharma, LLC
 Source NDC: 52817-321-XX
 Description: white to off white/round,flat faced,beveled-edge/obossed,028
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35990 6
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 20 mg
 NDC: 76420-359-90
 S/N:
 Qty: 90
 Baclofen Tablets, USP 20 mg
 NDC: 76420-359-90
 S/N:
 Qty: 90
 Baclofen Tablets, USP 20 mg
 NDC: 76420-359-90
 S/N:
 Qty: 90

Relabeled By:
 379 Van Ness Ave.
 Suite 1403-1406
 Torrance, CA 90501
Baclofen Tablets, USP 20 mg
 NDC: 76420-359-00
 Qty: 1000
 Distributed By: TruPharma, LLC
 Source NDC: 52817-321-00
 Description: white to off white/round,flat faced,beveled-edge/obossed,028
 Lot #: 00000000 Exp:
 Batch #: 00000000
 Drug Status: RX
 CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.
 KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].



(01) 0 0376420 35900 5
 (17)
 (10) 00000000
 (21)

Baclofen Tablets, USP 20 mg
 NDC: 76420-359-00
 S/N:
 Qty: 1000
 Baclofen Tablets, USP 20 mg
 NDC: 76420-359-00
 S/N:
 Qty: 1000
 Baclofen Tablets, USP 20 mg
 NDC: 76420-359-00
 S/N:
 Qty: 1000

BACLOFEN

baclofen tablet

Product Information

Product Type	HUMAN PRESCRIPTION	Item Code	NDC:76420-356(NDC:52817-
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Product Type	DRUG	(Source)	319)	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	BACLOFEN (UNII: H789N3FKE8) (BACLOFEN - UNII:H789N3FKE8)	BACLOFEN	5 mg	
Inactive Ingredients				
	Ingredient Name		Strength	
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)			
	MAGNESIUM STEARATE (UNII: 70097M6I30)			
	CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)			
	STARCH, CORN (UNII: O8232NY3SJ)			
	SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)			
Product Characteristics				
Color	white (White to off white)	Score	no score	
Shape	ROUND	Size	5mm	
Flavor		Imprint Code	023	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-356-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
2	NDC:76420-356-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
3	NDC:76420-356-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
4	NDC:76420-356-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA209102	04/01/2018		

BACLOFEN

baclofen tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:76420-357(NDC:52817-320)	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
BACLOFEN (UNII: H789N3FKE8) (BACLOFEN - UNII:H789N3FKE8)		BACLOFEN	10 mg	
Inactive Ingredients				
Ingredient Name			Strength	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)				
STARCH, CORN (UNII: O8232NY3SJ)				
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)				
Product Characteristics				
Color	white (White to off white)	Score	2 pieces	
Shape	ROUND	Size	7mm	
Flavor		Imprint Code	024	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-357-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
2	NDC:76420-357-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
3	NDC:76420-357-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
4	NDC:76420-357-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
5	NDC:76420-357-12	120 in 1 BOTTLE; Type 0: Not a Combination Product	08/13/2025	
6	NDC:76420-357-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
7	NDC:76420-357-00	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
ANDA	ANDA209102	04/01/2018		

BACLOFEN

baclofen tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:76420-358(NDC:52817-318)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACLOFEN (UNII: H789N3FKE8) (BACLOFEN - UNII:H789N3FKE8)	BACLOFEN	15 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	white (White to off white)	Score	no score
Shape	ROUND	Size	8mm
Flavor		Imprint Code	UpArrowheadB1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-358-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
2	NDC:76420-358-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
3	NDC:76420-358-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
4	NDC:76420-358-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209102	02/05/2024	

BACLOFEN

baclofen tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:76420-359(NDC:52817-321)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	white (White to off white)	Score	2 pieces
Shape	ROUND	Size	9mm
Flavor		Imprint Code	025
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76420-359-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
2	NDC:76420-359-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
3	NDC:76420-359-90	90 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
4	NDC:76420-359-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
5	NDC:76420-359-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	
6	NDC:76420-359-00	1000 in 1 BOTTLE; Type 0: Not a Combination Product	05/22/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209102	04/01/2018	

Labeler - Asclemed USA, Inc. (059888437)

Establishment

Name	Address	ID/FEI	Business Operations
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-356, 76420-357, 76420-358, 76420-359) , repack(76420-356, 76420-357, 76420-358, 76420-359)

Revised: 8/2025

Asclemed USA, Inc.