BACLOFEN- baclofen tablet Kartha Pharmaceuticals, Inc.

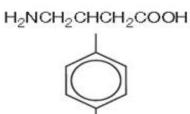
BACLOFEN TABLETS USP

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:



C10H12CINO2 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 or 20 mg baclofen, USP. In addition, each tablet contains the following inactive ingredients: microcrystalline cellulose, starch 1500 pre-gelatinized maize starch, povidone K-30, 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 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.

CONTRAINDICATIONS

Hypersensitivity to baclofen.

WARNINGS

a. <u>Neonatal Withdrawal Symptoms</u>: 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. <u>Abrupt Drug Withdrawal:</u> 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. <u>Impaired Renal Function</u>: 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. <u>Stroke</u>: Baclofen has not significantly benefited patients with stroke. These patients have also shown poor tolerability to the drug.

e. <u>Pregnancy</u>: 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, not 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:

<u>Neuropsychiatric</u>: 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.

<u>Cardiovascular</u>: Hypotension (0 to 9%). Rare instances of dyspnea, palpitation, chest

pain, syncope.

<u>Gastrointestinal</u>: 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.

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

<u>Other:</u> 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

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

<u>Treatment:</u> 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 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**, <u>Abrupt Drug Withdrawal</u>).

HOW SUPPLIED

Baclofen Tablets, USP 5 mg are available as off-white to white, round flat-faced, beveled edge tablets debossed 'KP02' on one side and '5' on other side, containing 5 mg baclofen USP packaged in bottles of 30, 100, 500 and 1,000 tablets.

NDC 73320-001-01	30s count
NDC 73320-001-02	100s count
NDC 73320-001-03	500s count
NDC 73320-001-04	1,000s count

Baclofen Tablets, USP 10 mg are available as off-white to white, round flat-faced, beveled edge tablets debossed 'KP02' on one side and '10' with functional score on the other side, containing 10 mg baclofen USP packaged in bottles of 30, 100, 500, 1,000 and 2,500 tablets.

NDC 73320-002-01	30s count
NDC 73320-002-02	100s count
NDC 73320-002-03	500s count
NDC 73320-002-04	1,000s count
NDC 73320-002-05	2,500s count

Baclofen Tablets, USP 20 mg are available as off-white to white, round flat-faced, beveled edge tablets debossed 'KP02' on one side and '20' with functional score on the other side, containing 20 mg baclofen USP packaged in bottles of 30, 100, 500 and 1,000 tablets.

NDC 73320-003-01	30s count
NDC 73320-003-02	100s count
NDC 73320-003-03	500s count
NDC 73320-003-04	1,000s count

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°F to 77°F) [see USP Controlled Room Temperature].

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

Distributed by: **Kartha Pharmaceuticals, Inc.** 1135 Four Lakes Drive, Suite F Matthews, NC 28105

MADE IN INDIA.

Revision Date: 09/2020

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 73320-001-01

Baclofen Tablets, USP

5 mg

Rx Only 30 Tablets

Kartha Pharmaceuticals, Inc.



NDC 73320-001-02

Baclofen Tablets, USP

5 mg

Rx Only 100 Tablets

Kartha Pharmaceuticals, Inc.



NDC 73320-001-03

Baclofen Tablets, USP

5 mg

Rx Only

500 Tablets

Kartha Pharmaceuticals, Inc.



NDC 73320-001-04

Baclofen Tablets, USP

5 mg

Rx Only 1000 Tablets

Kartha Pharmaceuticals, Inc.



NDC 73320-002-01

Baclofen Tablets, USP

10 mg

Rx Only 30 Tablets

Kartha Pharmaceuticals, Inc.

	Distributed Kartha Pha 1135 Four Matthews, Made In IN	Usual Do prescribing Store at 2 Controlled Dispense in USP, witha			EEP THIS AND ALL	PHARMA CODE
2	Pha our I ws, IN	I Dosage: ibing inforn at 20°C to Iled Room nse in a well vith a child r		clofen "	DRUGS/TS/23/2007	Rev. XX/20XX Artwork Code
73320100201	by: rmaceuticals, Inc Lakes Drive, Suite F NC 28105 DIA	al Dosage:See package insert for cribing information. e at 20°C to 25°C(68°F to 77°F) [see rolled Room Temperature]. ense in a well closed container as defined i with a child resistant closure (as required)	aclofen	ets, USP 0 mg	Vernie	sh free area
N 733		ge insert to 77°F) [s e]. ainer as defin ure (as requi	IISP10 Rx Only	30 Tablets	for ba will be p	atch details printed online x 20 mm
		insert for full 77° F) (see USP as defined in the as required).	Y	kartha pharmaceuticals		

NDC 73320-002-02 Baclofen Tablets, USP 10 mg Rx Only 100 Tablets Kartha Pharmaceuticals, Inc.



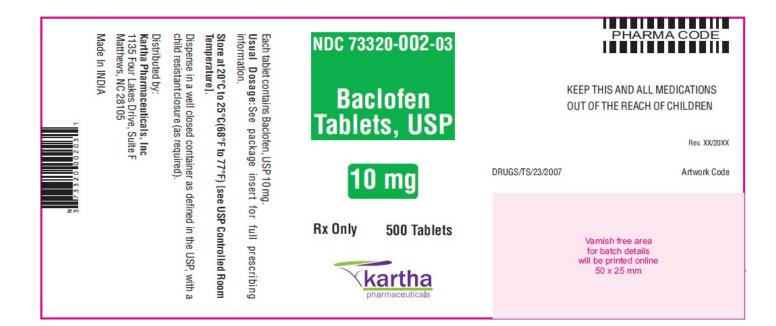
NDC 73320-002-03

Baclofen Tablets, USP

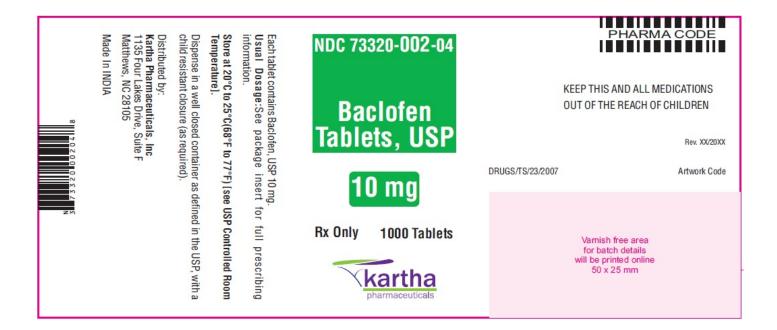
10 mg

Rx Only 500 Tablets

Kartha Pharmaceuticals, Inc.



NDC 73320-002-04 Baclofen Tablets, USP 10 mg Rx Only 1000 Tablets Kartha Pharmaceuticals, Inc.



NDC 73320-002-05

Baclofen Tablets, USP

10 mg

Rx Only 2500 Tablets

Kartha Pharmaceuticals, Inc.

	Distributed by: Kartha Pharm 1135 Four Lak Matthews, NC Made In INDIA	Dispense resistant	Each tablet con Usual Dosage: Store at 20°C Temperature].	NDC 73320-002-05	PHARMA CODE
5	rted by: Pharmaceuticals, Inc our Lakes Drive, Suite ws, NC 28105 n INDIA	Dispense in a well closed cont resistant closure (as required)	to See	Baclofen	KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN
05	cals, Inc re, Suite	sed con equired	ıs Baclofen 3 package ir 25°C(68°F	Tablets, USP	Rev. XX/20XX
0 0 0	T C).	, USP 1 nsert fo to 77°		DRUGS/TS/23/2007
3 7 3 3 2 (ts defined i	0 mg. r full presc °F) [see U:	10 mg	Artwork Code
201		n the U	ribing i SP Cor	Rx Only 2500 Tablets	
		Dispense in a well closed container as defined in the USP, with a child resistant closure (as required).	USP 10 mg. Isert for full prescribing information. to 77°F) [see USP Controlled Room	pharmaceuticals	Varnish free area for batch details will be printed online 50 x 25 mm

Rx Only

30 Tablets

Kartha Pharmaceuticals, Inc.



NDC 73320-003-02

Baclofen Tablets, USP

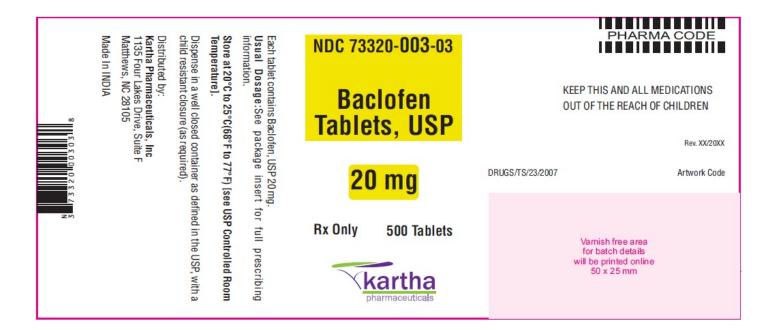
20 mg

Rx Only 100 Tablets

Kartha Pharmaceuticals, Inc.

102	Distributed by: Kartha Pharmaceuticals, Inc 1135 Four Lakes Drive, Suite F Matthews, NC 28105 Matthe In INDIA	Each tablet contains Baclofen, Usual Dosage:See packa prescribing information. Store at 20°C to 25°C(68°F Controlled Room Temperatur Dispense in a well closed cont USP, with a child resistant clos	NDC 73320-003-02 Baclofen Tablets, USP	KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILD REN DRUGS/TS/23/2007	PHARMA CODE Rev. XX/20XX Artwork Code
3 7 3 3 2 0 0 0 3 0 2	re, Suite F	contains Baclofen, USP 20 mg. sage:See package insert for full information. 0°C to 25°C(68°F to 77°F) [see USP Room Temperature]. a well closed container as defined in the child resistant closure (as required).	20 mg Rx Only 100 Tablets	f	/arnish free area for batch details I be printed online 45 x 22 mm

NDC 73320-003-03 Baclofen Tablets, USP 20 mg Rx Only 500 Tablets Kartha Pharmaceuticals, Inc.



NDC 73320-003-04

Baclofen Tablets, USP

20 mg

Rx Only 1000 Tablets

Kartha Pharmaceuticals, Inc.

					PHARMA CODE
	Distributed by: Kartha Pharmaceuti 1135 Four Lakes Dri Matthews, NC 28105 Made In INDIA	Temperature]. Dispense in a w resistant closu	Each tablet con Usual Dosage Store at 20°C	NDC 73320-003-04	
	by: rmaceutical akes Drive, NC 28105 DIA	re]. a well c osure (a	ge:See	Baclofen	KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN
3 7 3 3 2 0 0 0 3 0 4 5	by: rmaceuticals, Inc .akes Drive, Suite F NC 28105 DIA	Temperature]. Dispense in a well closed container as defined in the USP, with a child resistant closure (as required).	Each tablet contains Baclofen, USP 20 mg. Usual Dosage:See package insert for full prescribing information. Store at 20°C to 25°C(68°F to 77°F) [see USP Controlled Ro	Tablets, USP 20 mg	Rev. XX/20XX DRUGS/Ts/23/2007 Artwork Code
		the USP, with a child	ibing information. P Controlled Room	Rx Only 1000 Tablets	Varnish free area for batch details will be printed online 50 x 25 mm

BACLOFEN baclofen tablet Product Information

	oduct Type		HUMAN PRESCRIPTION DRUG	ltem	Code (Source)	ND	C:73320-001	
Ro	oute of Admini	stration	ORAL					
Ac	tive Ingredi	ent/Active	Moiety					
		Ingred	ient Name		Basis of Stre	ngth	Strengt	
BA	CLOFEN (UNII: H	1789N3FKE8) (B	ACLOFEN - UNII:H789N3FKE8)		BACLOFEN		5 mg	
In	active Ingre	dients						
		ulents	Ingredient Name				Strength	
MI	CROCRYSTALLII		(UNII: OP1R32D61U)				Strength	
	ARCH, CORN (UI							
	VIDONE K30 (U		•					
MA	GNESIUM STEA	RATE (UNII: 70	097M6I30)					
Pr	oduct Chara	acteristics						
Co	lor	white (Off wh	nite to white)	Scor	e	n	o score	
Sh	аре	ROUND (flat-	faced)	Size	Size		7mm	
Fla	vor			Impr	int Code	K	P02;5	
Co	ntains							
	ackaging							
Pa		Pac	ckage Description	Ma	rketing Start Date	Marl	keting End Date	
Pa #	ackaging Item Code		ckage Description E; Type 0: Not a Combination	Ma 07/01/	Date	Marl		
Pa # 1	item Code	30 in 1 BOTTL Product			Date /2021	Marl		
Pa # 1 2 3	Ackaging Item Code NDC:73320-001- 01 NDC:73320-001- 02 NDC:73320-001- 03	30 in 1 BOTTL Product 100 in 1 BOTT Product 500 in 1 BOTT Product	E; Type 0: Not a Combination LE; Type 0: Not a Combination LE; Type 0: Not a Combination	07/01/	Date /2021 /2021	Marl		
Pa # 1 2 3	Ackaging Item Code NDC:73320-001- 01 NDC:73320-001- 02 NDC:73320-001- 03	30 in 1 BOTTL Product 100 in 1 BOTT Product 500 in 1 BOTT Product	E; Type 0: Not a Combination LE; Type 0: Not a Combination	07/01/	Date /2021 /2021 /2021	Marl		
Pa # 1 2 3	Ackaging Item Code NDC:73320-001- 01 NDC:73320-001- 02 NDC:73320-001- 03 NDC:73320-001- 03	30 in 1 BOTTL Product 100 in 1 BOTT Product 500 in 1 BOTT Product 1000 in 1 BOT	E; Type 0: Not a Combination LE; Type 0: Not a Combination LE; Type 0: Not a Combination	07/01/ 07/01/ 07/01/	Date /2021 /2021 /2021	Marl		
Pa # 1 2 3 4	Ackaging Item Code NDC:73320-001- 01 NDC:73320-001- 02 NDC:73320-001- 03 NDC:73320-001- 03	30 in 1 BOTTLI Product 100 in 1 BOTT Product 500 in 1 BOTT Product 1000 in 1 BOT Product	E; Type 0: Not a Combination LE; Type 0: Not a Combination LE; Type 0: Not a Combination TLE; Type 0: Not a Combination	07/01/ 07/01/ 07/01/	Date /2021 /2021 /2021	Marl		
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BACLOFEN

baclofen tablet

Product Information

	oduct Type		HUMAN PRESCRIPTION DRUG	ltem	Code (Source)	NDC	:73320-002
Ro	oute of Admini	stration	ORAL				
Aq	tive Ingredi	ent/Active	Moiety				
		Ingred	ient Name		Basis of Stre	ength	Strengt
BA	CLOFEN (UNII: H	1789N3FKE8) (B	ACLOFEN - UNII:H789N3FKE8)		BACLOFEN		10 mg
In	active Ingre	diants					
	active mgre	alents	Ingredient Name			S	Strength
мі	CROCRYSTALLII	NE CELLULOSI	(UNII: OP1R32D61U)				
	ARCH, CORN (UI						
PO	VIDONE K30 (U	NII: U725QWY32	2X)				
SII	ICON DIOXIDE	(UNII: ETJ7Z6XB	U4)				
MA	GNESIUM STEA	RATE (UNII: 70	097M6I30)				
Dı	oduct Chara	octoristics					
	lor	white (Off wh	nite to white)	Scor	e	2	pieces
	ape	ROUND (flat-	·	Size	•		nm
	avor				int Code		202;10
Co	ntains						
Co	ntains						
	ackaging						
Pa		Pa	ckage Description	Мат	keting Start Date		eting End Date
Pa #	ackaging Item Code		Ckage Description E; Type 0: Not a Combination	Mai 07/01/	Date		
Pa # 1	Item Code NDC:73320-002- 01	30 in 1 BOTTL Product			Date 2021		
Pa # 1 2	Ackaging Item Code NDC:73320-002- 01 NDC:73320-002- 02	30 in 1 BOTTL Product 100 in 1 BOTT Product	E; Type 0: Not a Combination	07/01/	Date 2021 2021		
Pa # 1 2 3	Ackaging Item Code NDC:73320-002- 01 NDC:73320-002- 02 NDC:73320-002- 03	30 in 1 BOTTL Product 100 in 1 BOTT Product 500 in 1 BOTT Product	E; Type 0: Not a Combination LE; Type 0: Not a Combination	07/01/ 07/01/	Date 2021 2021 2021		
Pa # 1 2 3 4	Item Code NDC:73320-002- 01 NDC:73320-002- 02 NDC:73320-002- 02 NDC:73320-002- 03 NDC:73320-002- 03	30 in 1 BOTTLI Product 100 in 1 BOTT Product 500 in 1 BOTT Product 1000 in 1 BOT Product	E; Type 0: Not a Combination LE; Type 0: Not a Combination LE; Type 0: Not a Combination	07/01/ 07/01/ 07/01/	Date 2021 2021 2021 2021 2021 2021		
Pa # 1 2 3 4	Ackaging Item Code NDC:73320-002- 01 NDC:73320-002- 02 NDC:73320-002- 03 NDC:73320-002- 04 NDC:73320-002-	30 in 1 BOTTLI Product 100 in 1 BOTT Product 500 in 1 BOTT Product 1000 in 1 BOT Product 2500 in 1 BOT	E; Type 0: Not a Combination LE; Type 0: Not a Combination LE; Type 0: Not a Combination TLE; Type 0: Not a Combination	07/01/ 07/01/ 07/01/ 07/01/	Date 2021 2021 2021 2021 2021 2021		
Pa # 1 2 3 4 5	Ackaging Item Code NDC:73320-002- 01 NDC:73320-002- 02 NDC:73320-002- 03 NDC:73320-002- 04 NDC:73320-002-	30 in 1 BOTTLI Product 100 in 1 BOTT Product 500 in 1 BOTT Product 1000 in 1 BOT Product 2500 in 1 BOT Product	E; Type 0: Not a Combination LE; Type 0: Not a Combination LE; Type 0: Not a Combination TLE; Type 0: Not a Combination TLE; Type 0: Not a Combination	07/01/ 07/01/ 07/01/ 07/01/	Date 2021 2021 2021 2021 2021 2021		
Pa # 1 2 3 4 5	ackaging Item Code NDC:73320-002- NDC:73320-002-	30 in 1 BOTTLI Product 100 in 1 BOTT Product 500 in 1 BOTT Product 1000 in 1 BOT Product 2500 in 1 BOT Product	E; Type 0: Not a Combination LE; Type 0: Not a Combination LE; Type 0: Not a Combination TLE; Type 0: Not a Combination TLE; Type 0: Not a Combination	07/01/ 07/01/ 07/01/ 07/01/ 07/01/	Date 2021 2021 2021 2021 2021 2021		

BACLOFEN

baclofen tablet

	roduct Infor	mation					
Ρ	roduct Type		HUMAN PRESCRIPTION DRUG	ltem (Code (Source)	NDO	2:73320-003
	oute of Admini	stration	ORAL		. ,		
_							
A	ctive Ingredi		•				
		-	lient Name		Basis of Stre	ngth	Strength
B	ACLOFEN (UNII: H	1789N3FKE8) (B	ACLOFEN - UNII:H789N3FKE8)	E	BACLOFEN		20 mg
Ir	nactive Ingre	dients					
			Ingredient Name			9	Strength
м	ICROCRYSTALLI	NE CELLULOSI	E (UNII: OP1R32D61U)				
	TARCH, CORN (U		•				
	OVIDONE K30 (U	-					
	LICON DIOXIDE						
M	AGNESIUM STEA	RATE (UNII: 70	097M6I30)				
Ρ	roduct Chara	acteristics					
С	olor		hite to white)	Score		2	pieces
SI	hana						
	hape	ROUND (flat-	faced)	Size			1mm
FI	avor	ROUND (flat-	faced)		nt Code		1mm P02;20
FI		ROUND (flat-	faced)		nt Code		
FI	avor ontains	ROUND (flat-	faced)		nt Code		
FI Co	avor ontains ackaging		faced) ckage Description	Imprir	nt Code ceting Start Date	K	
FI Co	avor ontains ackaging Item Code	Pa		Imprir	eting Start Date	K	P02;20
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FI Co P # 1 2 3	avor ontains ackaging Item Code NDC:73320-003- 01 NDC:73320-003- 02 NDC:73320-003- 03 NDC:73320-003-	Pac 30 in 1 BOTTL Product 100 in 1 BOTT Product 500 in 1 BOTT Product 1000 in 1 BOTT	ckage Description E; Type 0: Not a Combination LE; Type 0: Not a Combination LE; Type 0: Not a Combination	Mark 07/01/20 07/01/20	221 021 021	K	P02;20
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