

AMOXICILLIN- amoxicillin capsule
H.J. Harkins Company, Inc.

0011-0020

1.1 Infections of the Ear, Nose, and Throat

Amoxicillin capsules are indicated in the treatment of infections due to susceptible (ONLY β -lactamase–negative) isolates of *Streptococcus* species. (α - and β -hemolytic isolates only), *Streptococcus pneumoniae*, *Staphylococcus* spp., or *Haemophilus influenzae*.

1.2 Infections of the Genitourinary Tract

Amoxicillin capsules are indicated in the treatment of infections due to susceptible (ONLY β -lactamase–negative) isolates of *Escherichia coli*, *Proteus mirabilis*, or *Enterococcus faecalis*.

1.3 Infections of the Skin and Skin Structure

Amoxicillin capsules are indicated in the treatment of infections due to susceptible (ONLY β -lactamase–negative) isolates of *Streptococcus* spp. (α - and β -hemolytic isolates only), *Staphylococcus* spp., or *E. coli*.

1.4 Infections of the Lower Respiratory Tract

Amoxicillin capsules are indicated in the treatment of infections due to susceptible (ONLY β -lactamase–negative) isolates of *Streptococcus* spp. (α - and β -hemolytic isolates only), *S. pneumoniae*, *Staphylococcus* spp., or *H. influenzae*.

1.5 Helicobacter pylori Infection

Triple therapy for *Helicobacter pylori* with clarithromycin and lansoprazole:

Amoxicillin capsules in combination with clarithromycin plus lansoprazole as triple therapy, is indicated for the treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or 1-year history of a duodenal ulcer) to eradicate *H. pylori*. Eradication of *H. pylori* has been shown to reduce the risk of duodenal ulcer recurrence.

Dual therapy for *H. pylori* with lansoprazole: Amoxicillin capsules, in combination with lansoprazole delayed-release capsules as dual therapy, is indicated for the treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or 1-year history of a duodenal ulcer) who are either allergic or intolerant to clarithromycin or in whom resistance to clarithromycin is known or suspected. (See the clarithromycin package insert, MICROBIOLOGY.) Eradication of *H. pylori* has been shown to reduce the risk of duodenal ulcer recurrence.

1.6 Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of amoxicillin capsules and other antibacterial drugs, amoxicillin capsules should be used only to treat infections that are proven or strongly suspected to be caused by bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

2.1 Dosing for Adult and Pediatric Patients > 3 Months of Age

Treatment should be continued for a minimum of 48 to 72 hours beyond the time that the patient becomes asymptomatic or evidence of bacterial eradication has been obtained. It is recommended that there be at least 10 days' treatment for any infection caused by *Streptococcus pyogenes* to prevent the occurrence of acute rheumatic fever. In some infections, therapy may be required for several weeks. It may be

necessary to continue clinical and/or bacteriological follow-up for several months after cessation of therapy.

Table 1. Dosing Recommendations for Adult and Pediatric Patients > 3 Months of Age

Infection	Severity ^a	Usual Adult Dose	Usual Dose for Children > 3 Months ^b
Ear/Nose/Throat Skin/Skin Structure Genitourinary Tract	Mild/Moderate	500 mg every 12 hours or 250 mg every 8 hours	25 mg/kg/day in divided doses every 12 hours or 20 mg/kg/day in divided doses every 8 hours
	Severe	875 mg every 12 hours or 500 mg every 8 hours	45 mg/kg/day in divided doses every 12 hours or 40 mg/kg/day in divided doses every 8 hours
Lower Respiratory Tract	Mild/Moderate or Severe	875 mg every 12 hours or 500 mg every 8 hours	45 mg/kg/day in divided doses every 12 hours or 40 mg/kg/day in divided doses every 8 hours

^a Dosing for infections caused by bacteria that are intermediate in their susceptibility to amoxicillin should follow the recommendations for severe infections.

^b The children's dosage is intended for individuals whose weight is less than 40 kg. Children weighing 40 kg or more should be dosed according to the adult recommendations.

2.2 Dosing in Neonates and Infants Aged ≤ 12 Weeks (≤ 3 Months)

Treatment should be continued for a minimum of 48 to 72 hours beyond the time that the patient becomes asymptomatic or evidence of bacterial eradication has been obtained. It is recommended that there be at least 10 days' treatment for any infection caused by *Streptococcus pyogenes* to prevent the occurrence of acute rheumatic fever. Due to incompletely developed renal function affecting elimination of amoxicillin in this age group, the recommended upper dose of amoxicillin capsules is 30 mg/kg/day divided every 12 hours. There are currently no dosing recommendations for pediatric patients with impaired renal function.

2.3 Dosing for *H. pylori* Infection

Triple Therapy: The recommended adult oral dose is 1 gram amoxicillin, 500 mg clarithromycin, and 30 mg lansoprazole, all given twice daily (every 12 hours) for 14 days.

Dual Therapy: The recommended adult oral dose is 1 gram amoxicillin and 30 mg lansoprazole, each given three times daily (every 8 hours) for 14 days.

Please refer to clarithromycin and lansoprazole full prescribing information.

2.4 Dosing in Renal Impairment

Patients with impaired renal function do not generally require a reduction in dose unless the impairment is severe.

Severely impaired patients with a glomerular filtration rate of < 30 mL/min should not receive a 875 mg dose.

Patients with a glomerular filtration rate of 10 to 30 mL/min should receive 500 mg or 250 mg every 12 hours, depending on the severity of the infection.

Patients with a glomerular filtration rate less than 10 mL/min should receive 500 mg or 250 mg every 24 hours, depending on severity of the infection.

Hemodialysis patients should receive 500 mg or 250 mg every 24 hours, depending on severity of the infection. They should receive an additional dose both during and at the end of dialysis.

250 mg Capsule are blue/pink size “1” hard gelatin capsule filled with white to off white granular powder and imprinted with “A44” on pink body with black ink.

500 mg Capsule are blue/pink size “0EL” hard gelatin capsule filled with white to off white granular powder and imprinted with “A45” on pink body with black ink.

Amoxicillin capsules are contraindicated in patients who have experienced a serious hypersensitivity reaction (e.g., anaphylaxis or Stevens-Johnson syndrome) to amoxicillin capsules or to other β -lactam antibiotics (e.g., penicillins and cephalosporins).

5.1 Anaphylactic Reactions

Serious and occasionally fatal hypersensitivity (anaphylactic) reactions have been reported in patients on penicillin therapy including amoxicillin. Although anaphylaxis is more frequent following parenteral therapy, it has occurred in patients on oral penicillins. These reactions are more likely to occur in individuals with a history of penicillin hypersensitivity and/or a history of sensitivity to multiple allergens. There have been reports of individuals with a history of penicillin hypersensitivity who have experienced severe reactions when treated with cephalosporins. Before initiating therapy with amoxicillin, careful inquiry should be made regarding previous hypersensitivity reactions to penicillins, cephalosporins, or other allergens. If an allergic reaction occurs, amoxicillin should be discontinued and appropriate therapy instituted.

5.2 Clostridium difficile Associated Diarrhea

Clostridium difficile associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including amoxicillin, and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*.

C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin-producing strains of *C. difficile* cause increased morbidity and mortality, as these infections can be refractory to antimicrobial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial use. Careful medical history is necessary since CDAD has been reported to occur over 2 months after the administration of antibacterial agents.

If CDAD is suspected or confirmed, ongoing antibiotic use not directed against *C. difficile* may need to be discontinued. Appropriate fluid and electrolyte management, protein supplementation, antibiotic treatment of *C. difficile*, and surgical evaluation should be instituted as clinically indicated.

5.3 Development of Drug-Resistant Bacteria

Prescribing amoxicillin in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.

5.4 Use in Patients With Mononucleosis

A high percentage of patients with mononucleosis who receive amoxicillin develop an erythematous skin rash. Thus amoxicillin should not be administered to patients with mononucleosis.

The following are discussed in more detail in other sections of the labeling:

- Anaphylactic reactions [see WARNINGS AND PRECAUTIONS (5.1)]
- CDAD [see WARNINGS AND PRECAUTIONS (5.2)]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The most common adverse reactions (> 1%) observed in clinical trials of amoxicillin capsules, tablets or oral suspension were diarrhea, rash, vomiting, and nausea.

Triple Therapy: The most frequently reported adverse events for patients who received triple therapy (amoxicillin/clarithromycin/lansoprazole) were diarrhea (7%), headache (6%), and taste perversion (5%).

Dual Therapy: The most frequently reported adverse events for patients who received double therapy amoxicillin/lansoprazole were diarrhea (8%) and headache (7%). For more information on adverse reactions with clarithromycin or lansoprazole, refer to the Adverse Reactions section of their package inserts.

6.2 Postmarketing or Other Experience

In addition to adverse events reported from clinical trials, the following events have been identified during postmarketing use of penicillins. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. These events have been chosen for inclusion due to a combination of their seriousness, frequency of reporting, or potential causal connection to amoxicillin.

- **Infections and Infestations:** Mucocutaneous candidiasis.
- **Gastrointestinal:** Black hairy tongue, and hemorrhagic/pseudomembranous colitis. Onset of pseudomembranous colitis symptoms may occur during or after antibacterial treatment [see WARNINGS AND PRECAUTIONS (5.2)].
- **Hypersensitivity Reactions:** Anaphylaxis [see WARNINGS AND PRECAUTIONS (5.1)]. Serum sickness–like reactions, erythematous maculopapular rashes, erythema multiforme, Stevens-Johnson syndrome, exfoliative dermatitis, toxic epidermal necrolysis, acute generalized exanthematous pustulosis, hypersensitivity vasculitis, and urticaria have been reported.
- **Liver:** A moderate rise in AST and/or ALT has been noted, but the significance of this finding is unknown. Hepatic dysfunction including cholestatic jaundice, hepatic cholestasis and acute cytolytic hepatitis have been reported.
- **Renal:** Crystalluria has been reported [see OVERDOSAGE (10)].
- **Hemic and Lymphatic Systems:** Anemia, including hemolytic anemia, thrombocytopenia, thrombocytopenic purpura, eosinophilia, leukopenia, and agranulocytosis have been reported. These reactions are usually reversible on discontinuation of therapy and are believed to be hypersensitivity phenomena.
- **Central Nervous System:** Reversible hyperactivity, agitation, anxiety, insomnia, confusion, convulsions, behavioral changes, and/or dizziness have been reported.
- **Miscellaneous:** Tooth discoloration (brown, yellow, or gray staining) has been reported. Most reports occurred in pediatric patients. Discoloration was reduced or eliminated with brushing or dental cleaning in most cases.

7.1 Probenecid

Probenecid decreases the renal tubular secretion of amoxicillin. Concurrent use of amoxicillin and probenecid may result in increased and prolonged blood levels of amoxicillin.

7.2 Oral Anticoagulants

Abnormal prolongation of prothrombin time (increased international normalized ratio [INR]) has been reported in patients receiving amoxicillin and oral anticoagulants. Appropriate monitoring should be undertaken when anticoagulants are prescribed concurrently. Adjustments in the dose of oral

anticoagulants may be necessary to maintain the desired level of anticoagulation.

7.3 Allopurinol

The concurrent administration of allopurinol and amoxicillin increases the incidence of rashes in patients receiving both drugs as compared to patients receiving amoxicillin alone. It is not known whether this potentiation of amoxicillin rashes is due to allopurinol or the hyperuricemia present in these patients.

7.4 Oral Contraceptives

Amoxicillin may affect the gut flora, leading to lower estrogen reabsorption and reduced efficacy of combined oral estrogen/progesterone contraceptives.

7.5 Other Antibacterials

Chloramphenicol, macrolides, sulfonamides, and tetracyclines may interfere with the bactericidal effects of penicillin. This has been demonstrated in vitro; however, the clinical significance of this interaction is not well documented.

7.6 Effects on Laboratory Tests

High urine concentrations of ampicillin may result in false-positive reactions when testing for the presence of glucose in urine using CLINITEST®, Benedict's Solution, or Fehling's Solution. Since this effect may also occur with amoxicillin, it is recommended that glucose tests based on enzymatic glucose oxidase reactions (such as CLINISTIX®) be used.

Following administration of ampicillin or amoxicillin to pregnant women, a transient decrease in plasma concentration of total conjugated estriol, estriol-glucuronide, conjugated estrone, and estradiol has been noted.

8.1 Pregnancy

Teratogenic Effects: Pregnancy Category B. Reproduction studies have been performed in mice and rats at doses up to 2000 mg/kg (3 and 6 times the 3 g human dose, based on body surface area). There was no evidence of harm to the fetus due to amoxicillin. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, amoxicillin should be used during pregnancy only if clearly needed.

8.2 Labor and Delivery

Oral ampicillin is poorly absorbed during labor. It is not known whether use of amoxicillin in humans during labor or delivery has immediate or delayed adverse effects on the fetus, prolongs the duration of labor, or increases the likelihood of the necessity for an obstetrical intervention.

8.3 Nursing Mothers

Penicillins have been shown to be excreted in human milk. Amoxicillin use by nursing mothers may lead to sensitization of infants. Caution should be exercised when amoxicillin is administered to a nursing woman.

8.4 Pediatric Use

Because of incompletely developed renal function in neonates and young infants, the elimination of amoxicillin may be delayed. Dosing of amoxicillin should be modified in pediatric patients 12 weeks or younger (≤ 3 months). [See DOSAGE AND ADMINISTRATION (2.2).]

8.5 Geriatric Use

An analysis of clinical studies of amoxicillin was conducted to determine whether subjects aged 65 and over respond differently from younger subjects. These analyses have not identified differences in responses between the elderly and younger patients, but a greater sensitivity of some older individuals cannot be ruled out.

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection, and it may be useful to monitor renal function.

8.6 Dosing in Renal Impairment

Amoxicillin is primarily eliminated by the kidney and dosage adjustment is usually required in patients with severe renal impairment (GFR <30 mL/min). See DOSING IN RENAL IMPAIRMENT (2.4) for specific recommendations in patients with renal impairment.

In case of overdosage, discontinue medication, treat symptomatically, and institute supportive measures as required. A prospective study of 51 pediatric patients at a poison-control center suggested that overdosages of less than 250 mg/kg of amoxicillin are not associated with significant clinical symptoms. Interstitial nephritis resulting in oliguric renal failure has been reported in a small number of patients after overdosage with amoxicillin¹.

Crystalluria, in some cases leading to renal failure, has also been reported after amoxicillin overdosage in adult and pediatric patients. In case of overdosage, adequate fluid intake and diuresis should be maintained to reduce the risk of amoxicillin crystalluria.

Renal impairment appears to be reversible with cessation of drug administration. High blood levels may occur more readily in patients with impaired renal function because of decreased renal clearance of amoxicillin. Amoxicillin may be removed from circulation by hemodialysis.

Formulation of amoxicillin capsules, USP contains amoxicillin, a semisynthetic antibiotic, an analog of ampicillin, with a broad spectrum of bactericidal activity against many Gram-positive and Gram-negative microorganisms. Chemically, it is (2S,5R,6R)-6-[(R)-(-)-2-amino-2-(p-hydroxyphenyl)acetamido]-3,3-dimethyl-7-oxo-4-thia-1-azabicyclo[3.2.0]heptane-2-carboxylic acid trihydrate. It may be represented structurally as:

The amoxicillin molecular formula is C₁₆H₁₉N₃O₅S•3H₂O, and the molecular weight is 419.45.

Each capsule of amoxicillin with blue cap and pink body, contains 250 mg or 500 mg amoxicillin USP as the trihydrate. The body of the 250 mg capsule is imprinted with 'A44' in black ink. The body of the 500 mg capsule is imprinted with 'A45' in black ink. Inactive ingredients: D&C Red No. 28, FD&C Blue No. 1, FD&C Red No. 40, gelatin, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate, and titanium dioxide.

Meets USP Dissolution Test 2.

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic potential. Studies to detect mutagenic potential of amoxicillin alone have not been conducted; however, the following information is available from tests on a 4:1 mixture of amoxicillin and potassium clavulanate.

Amoxicillin and potassium clavulanate was non-mutagenic in the Ames bacterial mutation assay, and the yeast gene conversion assay. Amoxicillin and potassium clavulanate was weakly positive in the mouse lymphoma assay, but the trend toward increased mutation frequencies in this assay occurred at doses that were also associated with decreased cell survival. Amoxicillin and potassium clavulanate was negative

in the mouse micronucleus test and in the dominant lethal assay in mice. Potassium clavulanate alone was tested in the Ames bacterial mutation assay and in the mouse micronucleus test, and was negative in each of these assays. In a multi-generation reproduction study in rats, no impairment of fertility or other adverse reproductive effects were seen at doses up to 500 mg/kg (approximately 2 times the 3 g human dose based on body surface area).

Information for Patients

Patients should be advised that amoxicillin may be taken every 8 hours or every 12 hours, depending on the dose prescribed.

Patients should be counseled that antibacterial drugs, including amoxicillin, should only be used to treat bacterial infections. They do not treat viral infections (e.g., the common cold). When amoxicillin is prescribed to treat a bacterial infection, patients should be told that although it is common to feel better early in the course of therapy, the medication should be taken exactly as directed. Skipping doses or not completing the full course of therapy may: (1) decrease the effectiveness of the immediate treatment, and (2) increase the likelihood that bacteria will develop resistance and will not be treatable by amoxicillin or other antibacterial drugs in the future.

Patients should be counseled that diarrhea is a common problem caused by antibiotics, and it usually ends when the antibiotic is discontinued. Sometimes after starting treatment with antibiotics, patients can develop watery and bloody stools (with or without stomach cramps and fever) even as late as 2 or more months after having taken their last dose of the antibiotic. If this occurs, patients should contact their physician as soon as possible.

Patients should be aware that amoxicillin contains a penicillin class drug product that can cause allergic reactions in some individuals.

52959-011-21	RX Only: #XXXXXXXX	#XXX	<small>CAUTION: Federal law PROHIBITS the transfer of this drug to anyone other than the person to whom prescribed and prohibits dispensing without a prescription unless OTC. See outsert for add'l RX info KEEP OUT OF REACH OF CHILDREN. Store in a cool dry place 68 to 77 degrees F.</small>																																																
AMOXICILLIN 250mg CAPSULE																																																			
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Take as directed by your Doctor or See outsert for usual dosage information																																																			
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<small>Repack: HJ Harkins Co., Inc. Nipomo, CA 93444 Dispense in tight, child & light-resistant container per USP</small>																																																			

52959-020-21

RX Only: #XXXXXXXX

#XXX

CAUTION: Federal law PROHIBITS the transfer of this drug to anyone other than the person to whom prescribed and prohibits dispensing without a prescription unless OTC. See outsert for add'l RX info KEEP OUT OF REACH OF CHILDREN. Store in a cool dry place 68 to 77 degrees F.

AMOXICILLIN 500mg CAPSULE

Lot #: AM502S
Mfg: SANDOZ
Exp: 03/11
Mfg India
Loc.:

Compare to: Amoxicillin
Mfg. NDC: 65862-017-05
Pill ID: Blue and pink capsules

AMOXICILLIN 500mg CAPSULE
52959-020-21 Qty #21
03/11 Lot AM502S
Amoxicillin 65862-017-05

AMOXICILLIN 500mg CAPSULE
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AMOXICILLIN 500mg CAPSULE
52959-020-21 Qty #21
03/11 Lot AM502S
Amoxicillin 65862-017-05

Take as directed by your Doctor or
See outsert for usual dosage information

Repack: HJ Harkins Co., Inc. Nipomo., CA 93444
Dispense in tight, child & light-resistant container per USP

AMOXICILLIN

amoxicillin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52959-011
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMOXICILLIN (UNII: 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	250 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	blue, pink	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	A44
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-011-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
2	NDC:52959-011-21	21 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
3	NDC:52959-011-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
4	NDC:52959-011-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
5	NDC:52959-011-40	40 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
6	NDC:52959-011-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
7	NDC:52959-011-15	15 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065271	09/11/2005	

AMOXICILLIN

amoxicillin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:52959-020
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AMOXICILLIN (UNII: 804826J2HU) (AMOXICILLIN ANHYDROUS - UNII:9EM05410Q9)	AMOXICILLIN ANHYDROUS	500 mg

Inactive Ingredients

Ingredient Name	Strength
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	

Product Characteristics

Color	blue, pink	Score	no score
Shape	CAPSULE	Size	23mm
Flavor		Imprint Code	A45

Contains**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-020-04	4 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
2	NDC:52959-020-05	5 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
3	NDC:52959-020-06	6 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
4	NDC:52959-020-18	18 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
5	NDC:52959-020-20	20 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
6	NDC:52959-020-21	21 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
7	NDC:52959-020-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
8	NDC:52959-020-28	28 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
9	NDC:52959-020-30	30 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
10	NDC:52959-020-40	40 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
11	NDC:52959-020-42	42 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
12	NDC:52959-020-60	60 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
13	NDC:52959-020-22	22 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
14	NDC:52959-020-03	3 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
15	NDC:52959-020-17	17 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
16	NDC:52959-020-50	50 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
17	NDC:52959-020-08	8 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
18	NDC:52959-020-12	12 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
19	NDC:52959-020-02	2 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
20	NDC:52959-020-00	100 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
21	NDC:52959-020-32	32 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	
22	NDC:52959-020-15	15 in 1 BOTTLE; Type 0: Not a Combination Product	09/11/2005	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA065271	09/11/2005	

Labeler - H.J. Harkins Company, Inc. (147681894)**Establishment**

Name	Address	ID/FEI	Business Operations
H.J. Harkins Company, Inc.		147681894	manufacture(52959-011, 52959-020) , relabel(52959-011, 52959-020) , repack(52959-011, 52959-020)

Revised: 9/2018

H.J. Harkins Company, Inc.