Abcholic-300/450

Ursodeoxycholic Acid Sustained Release
300/450 mg Tablets

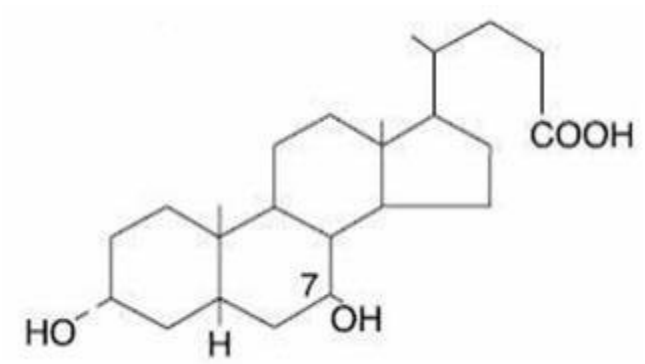
SPECIAL NOTE

Gallbladder stone dissolution with Abcholic 300 / 450 treatment requires months of therapy. Complete dissolution does not occur in all patients and recurrence of stones within 5 years has been observed in up to 50% of patients who do dissolve their stones on bile acid therapy. Patients should be carefully selected for therapy with Abcholic 300 / 450, and alternative therapies should be considered.

Abcholic 300 / 450 Capsules Description

Abcholic 300 / 450 is a bile acid available as 300 mg capsules suitable for oral administration.

Abcholic 300 / 450 (ursodeoxycholic acid) is a naturally occurring bile acid found in small quantities in normal human bile and in the biles of certain other mammals. It is a bitter-tasting, white powder freely soluble in ethanol, methanol, and glacial acetic acid; sparingly soluble in chloroform; slightly soluble in ether; and insoluble in water. The chemical name for Abcholic 300 / 450 is 3α,7β-Dihydroxy-5β-cholan-24-oic acid (C 24H 40O 4). Abcholic 300 / 450, USP has a molecular weight of 392.57. Its structure is shown below:



Inactive Ingredients: Colloidal silicon dioxide, magnesium stearate, and starch (corn). Gelatin capsules contain gelatin and titanium dioxide. The capsules are printed with edible ink containing black iron oxide.

Abcholic 300 / 450 l Capsules - Clinical Pharmacology

About 90% of a therapeutic dose of Abcholic 300 / 450 is absorbed in the small bowel after oral administration. After absorption, Abcholic 300 / 450 enters the portal vein and undergoes efficient extraction from portal blood by the liver (i.e., there is a large "first-pass" effect) where it is conjugated with either glycine or taurine and is then secreted into the hepatic bile ducts. Abcholic 300 / 450 in bile is concentrated in the gallbladder and expelled into the duodenum in gallbladder bile via the cystic and common ducts by gallbladder contractions provoked by physiologic responses to eating. Only small quantities of Abcholic 300 / 450 appear in the systemic circulation and very small amounts are excreted into urine. The sites of the drug's therapeutic actions are in the liver, bile, and gut lumen.

Beyond conjugation, Abcholic 300 / 450 is not altered or catabolized appreciably by the liver or intestinal mucosa. A small proportion of orally administered drug undergoes bacterial degradation with each cycle of enterohepatic circulation. Abcholic 300 / 450 can be both oxidized and reduced at the 7-carbon, yielding either 7-keto-lithocholic acid or lithocholic acid, respectively. Further, there is some bacterially catalyzed deconjugation of glyco- and tauro- ursodeoxycholic acid in the small bowel. Free Abcholic 300 / 450, 7-keto-lithocholic acid, and lithocholic acid are relatively insoluble in aqueous media and larger proportions of these compounds are lost from the distal gut into the feces. Reabsorbed free Abcholic 300 / 450 is reconjugated by the liver. Eighty percent of lithocholic acid formed in the small bowel is excreted in the feces, but the 20% that is absorbed is sulfated at the 3-hydroxyl group in the liver to relatively insoluble lithocholyl conjugates which are excreted into bile and lost in feces. Absorbed 7-keto-lithocholic acid is stereospecifically reduced in the liver to chenodiol.

Lithocholic acid causes cholestatic liver injury and can cause death from liver failure in certain species unable to form sulfate conjugates. Lithocholic acid is formed by 7-dehydroxylation of the dihydroxy bile acids (Abcholic 300 / 450 and chenodiol) in the gut lumen. The 7-dehydroxylation reaction appears to be alpha-specific, i.e., chenodiol is more efficiently 7-dehydroxylated than Abcholic 300 / 450 and, for equimolar doses of Abcholic 300 / 450 and chenodiol, levels of lithocholic acid appearing in bile are lower with the former. Man has the capacity to sulfate lithocholic acid. Although liver injury has not been associated with Abcholic 300 / 450 therapy, a reduced capacity to sulfate may exist in some individuals, but such a deficiency has not yet been clearly demonstrated.

Pharmacodynamics

Abcholic 300 / 450 suppresses hepatic synthesis and secretion of cholesterol, and also inhibits intestinal absorption of cholesterol. It appears to have little inhibitory effect on synthesis and secretion into bile of endogenous bile acids, and does not appear to affect secretion of phospholipids into bile.

With repeated dosing, bile ursodeoxycholic acid concentrations reach a steady-state in about 3 weeks. Although insoluble in aqueous media, cholesterol can be solubilized in at least two different ways in the presence of dihydroxy bile acids. In addition to solubilizing cholesterol in micelles, Abcholic 300 / 450 acts by an apparently unique mechanism to cause dispersion of cholesterol as liquid crystals in aqueous media. Thus, even though administration of high doses (e.g., 15 - 18 mg/kg/day) does not result in a concentration of Abcholic 300 / 450 higher than 60% of the total bile acid pool, Abcholic 300 / 450 -rich bile effectively solubilizes cholesterol. The overall effect of Abcholic 300 / 450 is to increase the concentration level at which saturation of cholesterol occurs.

The various actions of Abcholic 300 / 450 combine to change the bile of patients with gallstones from cholesterol-precipitating to cholesterol-solubilizing, thus resulting in bile conducive to cholesterol stone dissolution.

After Abcholic 300 / 450 dosing is stopped, the concentration of the bile acid in bile falls exponentially, declining to about 5% to 10% of its steady-state level in about 1 week.

Clinical Results

Gallstone Dissolution
On the basis of clinical trial results in a total of 868 patients with radiolucent gallstones treated in 8 studies (three in the U.S. involving 282 patients, one in the U.K. involving 130 patients, and four in Italy involving 456 patients) for periods ranging from 6 to 78 months with Abcholic 300 / 450 doses ranging from about 5 - 20 mg/kg/day, an Abcholic 300 / 450 dose of about 8 - 10 mg/kg/day appeared to be the best dose. With an Abcholic 300 / 450 dose of about 10 mg/kg/day, complete stone dissolution can be anticipated in about 30% of unselected patients with uncalcified gallstones < 20 mm in maximal diameter treated for up to 2 years. Patients with calcified gallstones prior to treatment, or patients who develop stone calcification or gallbladder nonvisualization on treatment, and patients with stones > 20 mm in maximal diameter rarely dissolve their stones. The chance of gallstone dissolution is increased up to 50% in patients with floating or floatable stones (i.e., those with high cholesterol content), and is inversely related to stone size for those < 20 mm in maximal diameter. Complete dissolution was observed in 81% of patients with stones up to 5 mm in diameter. Age, sex, weight, degree of obesity, and serum cholesterol level are not related to the chance of stone dissolution with Abcholic 300 / 450 .

A nonvisualizing gallbladder by oral cholecystogram prior to the initiation of therapy is not a contraindication to Abcholic 300 / 450 therapy (the group of patients with nonvisualizing gallbladders in the Abcholic 300 / 450 studies had complete stone dissolution rates similar to the group of patients with visualizing gallbladders). However, gallbladder nonvisualization developing during Abcholic 300 / 450 treatment predicts failure of complete stone dissolution and in such cases therapy should be discontinued.

Partial stone dissolution occurring within 6 months of beginning therapy with Abcholic 300 / 450 appears to be associated with a > 70% chance of eventual complete stone dissolution with further treatment; partial dissolution observed within 1 year of starting therapy indicates a 40% probability of complete dissolution.

Stone recurrence after dissolution with Abcholic 300 / 450 therapy was seen within 2 years in 8/27 (30%) of patients in the U.K. studies. Of 16 patients in the U.K. study whose stones had previously dissolved on chenodiol but later recurred, 11 had complete dissolution on Abcholic 300 / 450 . Stone recurrence has been observed in up to 50% of patients within 5 years of complete stone dissolution on Abcholic 300 / 450 therapy. Serial ultrasonographic examinations should be obtained to monitor for recurrence of stones, bearing in mind that radiolucency of the stones should be established before another course of Abcholic 300 / 450 is instituted. A prophylactic dose of Abcholic 300 / 450 has not been established.

Gallstone Prevention
Two placebo-controlled, multicenter, double-blind, randomized, parallel group trials in a total of 1,316 obese patients were undertaken to evaluate Abcholic 300 / 450 in the prevention of gallstone formation in obese patients undergoing rapid weight loss. The first trial consisted of 1,004 obese patients with a body mass index (BMI) ≥ 38 who underwent weight loss induced by means of a very low calorie diet for a period of 16 weeks. An intent-to-treat analysis of this trial showed that gallstone formation occurred in 23% of the placebo group, while those patients on 300, 600, or 1200 mg/day of Abcholic 300 / 450 experienced a 6%, 3%, and 2% incidence of gallstone formation, respectively. The mean weight loss for this 16-week trial was 47 lb for the placebo group, and 47, 48, and 50 lb for the 300, 600, and 1200 mg/day Abcholic 300 / 450 groups, respectively.

The second trial consisted of 312 obese patients (BMI ≥ 40) who underwent rapid weight loss through gastric bypass surgery. The trial drug treatment period was for 6 months following this surgery. Results of this trial showed that gallstone formation occurred in 23% of the placebo group, while those patients on 300, 600, or 1200 mg/day of Abcholic 300 / 450 experienced a 9%, 1%, and 5% incidence of gallstone formation, respectively. The mean weight loss for this 6-month trial was 64 lb for the placebo group, and 67, 74, and 72 lb for the 300, 600, and 1200 mg/day Abcholic 300 / 450 groups, respectively.

ALTERNATIVE THERAPIES

Watchful Waiting

Watchful waiting has the advantage that no therapy may ever be required. For patients with silent or minimally symptomatic stones, the rate of development of moderate-to-severe symptoms or gallstone complications is estimated to be between 2% and 6% per year, leading to a cumulative rate of 7% to 27% in 5 years. Presumably the rate is higher for patients already having symptoms.

Cholecystectomy

For patients with symptomatic gallstones, surgery offers the advantage of immediate and permanent stone removal, but carries a high risk in some patients. About 5% of cholecystectomized patients have residual symptoms or retained common duct stones. The spectrum of surgical risk varies as a function of age and the presence of disease other than cholelithiasis.

*Mortality Rates for Cholecystectomy in the U.S.(National Halothane Study, JAMA 1966; 197:775-8) 27,600 Cholecystectomies (Smoothed Rates) Deaths/1000 Operations****

	Age (Yrs)	*Cholecystectomy*	*Cholecystectomy + Common Duct Explorat*
*Low Risk Patients**			
Women	*0 - 49*	*0.54*	*2.13*
	50 - 69	*2.80*	*10.10*
Men	*0 - 49*	*1.04*	*4.12*
	50 - 69	*5.41*	*19.23*
*HighRisk Patients***			

Women	*0 - 49*	*12.66*	*47.62*
	50 - 69	*17.24*	*58.82*
Men	*0 - 49*	*24.39*	*90.91*
	50 - 69	*33.33*	*111.11*

** In good health or with moderate systemic disease.*
*** With severe or extreme systemic disease.*
**** Includes both elective and emergency surgery.*

Women in good health or who have only moderate systemic disease and are under 49 years of age have the lowest surgical mortality rate (0.054); men in all categories have a surgical mortality rate twice that of women. Common duct exploration quadruples the rates in all categories. The rates rise with each decade of life and increase tenfold or more in all categories with severe or extreme systemic disease.

Indications and Usage for Abcholic 300 / 450 Capsules

1. *Abcholic 300 / 450 is indicated for patients with radiolucent, noncalcified gallbladder stones < 20 mm in greatest diameter in whom elective cholecystectomy would be undertaken except for the presence of increased surgical risk due to systemic disease, advanced age, idiosyncratic reaction to general anesthesia, or for those patients who refuse surgery. Safety of use of Abcholic 300 / 450 beyond 24 months is not established.*
2. *Abcholic 300 / 450 is indicated for the prevention of gallstone formation in obese patients experiencing rapid weight loss.*

Contraindications

1. *Abcholic 300 / 450 will not dissolve calcified cholesterol stones, radiopaque stones, or radiolucent bile pigment stones. Hence, patients with such stones are not candidates for Abcholic 300 / 450 therapy.*
2. *Patients with compelling reasons for cholecystectomy including unremitting acute cholecystitis, cholangitis, biliary obstruction, gallstone pancreatitis, or biliary-gastrointestinal fistula are not candidates for Abcholic 300 / 450 therapy.*
3. *Allergy to bile acids.*

Precautions

Liver Tests

Abcholic 300 / 450 therapy has not been associated with liver damage. Lithocholic acid, a naturally occurring bile acid, is known to be a liver-toxic metabolite. This bile acid is formed in the gut from Abcholic 300 / 450 less efficiently and in smaller amounts than that seen from chenodiol. Lithocholic acid is detoxified in the liver by sulfation and, although man appears to be an efficient sulfater, it is possible that some patients may have a congenital or acquired deficiency in sulfation, thereby predisposing them to lithocholate-induced liver damage.

Abnormalities in liver enzymes have not been associated with Abcholic 300 / 450 therapy and, in fact, Abcholic 300 / 450 has been shown to decrease liver enzyme levels in liver disease. However, patients given Abcholic 300 / 450 should have SGOT (AST) and SGPT (ALT) measured at the initiation of therapy and thereafter as indicated by the particular clinical circumstances.

Drug Interactions

Bile acid sequestering agents such as cholestyramine and colestipol may interfere with the action of Abcholic 300 / 450 by reducing its absorption. Aluminum-based antacids have been shown to adsorb bile acids in vitroand may be expected to interfere with Abcholic 300 / 450 in the same manner as the bile acid sequestering agents. Estrogens, oral contraceptives, and clofibrate (and perhaps other lipid-lowering drugs) increase hepatic cholesterol secretion, and encourage cholesterol gallstone formation and hence may counteract the effectiveness of Abcholic 300 / 450 .

Carcinogenesis, Mutagenesis, Impairment of Fertility

Ursodeoxycholic acid was tested in 2-year oral carcinogenicity studies in CD-1 mice and Sprague-Dawley rats at daily doses of 50, 250, and 1000 mg/kg/day. It was not tumorigenic in mice. In the rat study, it produced statistically significant dose-related increased incidences of pheochromocytomas of adrenal medulla in males ($p = 0.014$, Peto trend test) and females ($p = 0.004$, Peto trend test). A 78-week rat study employing intrarectal instillation of lithocholic acid and tauro-deoxycholic acid, metabolites of Abcholic 300 / 450 and chenodiol, has been conducted. These bile acids alone did not produce any tumors. A tumor-promoting effect of both metabolites was observed when they were co-administered with a carcinogenic agent. Results of epidemiologic studies suggest that bile acids might be involved in the pathogenesis of human colon cancer in patients who had undergone a cholecystectomy, but direct evidence is lacking. Abcholic 300 / 450 is not mutagenic in the Ames test. Dietary administration of lithocholic acid to chickens is reported to cause hepatic adenomatous hyperplasia.

Pregnancy

Reproduction studies have been performed in rats and rabbits with Abcholic 300 / 450 doses up to 200-fold the therapeutic dose and have revealed no evidence of impaired fertility or harm to the fetus at doses of 20- to 100-fold the human dose in rats and at 5-fold the human dose (highest dose tested) in rabbits. Studies employing 100- to 200-fold the human dose in rats have shown some reduction in fertility rate and litter size. There have been no adequate and well-controlled studies of the use of Abcholic 300 / 450 in pregnant women, but inadvertent exposure of 4 women to therapeutic doses of the drug in the first trimester of pregnancy during the Abcholic 300 / 450 trials led to no evidence of effects on the fetus or newborn baby. Although it seems unlikely, the possibility that Abcholic 300 / 450 can cause fetal harm cannot be ruled out; hence, the drug is not recommended for use during pregnancy.

Nursing Mothers

It is not known whether Abcholic 300 / 450 is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Abcholic 300 / 450 is administered to a nursing mother.

Pediatric Use

The safety and effectiveness of Abcholic 300 / 450 in pediatric patients have not been established.

Geriatric Use

In worldwide clinical studies of Abcholic 300 / 450 , approximately 14% of subjects were over 65 years of age (approximately 3% were over 75 years old). In a subgroup analysis of existing clinical trials, patients greater than 56 years of age did not exhibit statistically significantly different complete dissolution rates from the younger population. No age-related differences in safety and effectiveness were found. Other reported clinical experience has not identified differences in response in elderly and younger patients. However, small differences in efficacy and greater sensitivity of some elderly individuals taking Abcholic 300 / 450 cannot be ruled out. Therefore, it is recommended that dosing proceed with caution in this population.

Adverse Reactions/Side Effects

The nature and frequency of adverse experiences were similar across all groups.

The following tables provide comprehensive listings of the adverse experiences reported that occurred with a 5% incidence level:

GALLSTONE DISSOLUTION

	Abcholic 300 / 450		*Placebo*
	8 - 10 mg/kg/day		
	(N = 155)		*(N = 159)*
	N	*(%)*	*N*
Body as a Whole			
Allergy	*8*	*(5.2)*	*7*
Chest Pain	*5*	*(3.2)*	*10*
Fatigue	*7*	*(4.5)*	*8*
Infection Viral	*30*	*(19.4)*	*41*
Digestive System			
Abdominal Pain	*67*	*(43.2)*	*70*
Cholecystitis	*8*	*(5.2)*	*7*
Constipation	*15*	*(9.7)*	*14*
Diarrhea	*42*	*(27.1)*	*34*
Dyspepsia	*26*	*(16.8)*	*18*
Flatulence	*12*	*(7.7)*	*12*

Gastrointestinal Disorder	*6*	*(3.9)*	*8*
Nausea	*22*	*(14.2)*	*27*
Vomiting	*15*	*(9.7)*	*11*
Musculoskeletal System			
Arthralgia	*12*	*(7.7)*	*24*
Arthritis	*9*	*(5.8)*	*4*
Back Pain	*11*	*(7.1)*	*18*
Myalgia	*9*	*(5.8)*	*9*
Nervous System			
Headache	*28*	*(18.1)*	*34*
Insomnia	*3*	*(1.9)*	*8*
Respiratory System			
Bronchitis	*10*	*(6.5)*	*6*
Coughing	*11*	*(7.1)*	*7*
Pharyngitis	*13*	*(8.4)*	*5*
Rhinitis	*8*	*(5.2)*	*11*

Sinusitis	*17*	*(11.0)*	*18*
Upper Respiratory			
Tract Infection	*24*	*(15.5)*	*21*
Urogenital System			
Urinary Tract Infection	*10*	*(6.5)*	*7*

GALLSTONE PREVENTION

	Abcholic 300 / 450		*Placebo*
	600 mg		
	(N = 322)		*(N = 325)*
	N	*(%)*	*N*
Body as a Whole			
Fatigue	*25*	*(7.8)*	*33*
Infection Viral	*29*	*(9.0)*	*29*
Influenza-like Symptoms	*21*	*(6.5)*	*19*
Digestive System			
Abdominal Pain	*20*	*(6.2)*	*39*

Constipation	*85*	*(26.4)*	*72*
Diarrhea	*81*	*(25.2)*	*68*
Flatulence	*15*	*(4.7)*	*24*
Nausea	*56*	*(17.4)*	*43*
Vomiting	*44*	*(13.7)*	*44*
Musculoskeletal System			
Back Pain	*38*	*(11.8)*	*21*
Musculoskeletal Pain	*19*	*(5.9)*	*15*
Nervous System			
Dizziness	*53*	*(16.5)*	*42*
Headache	*80*	*(24.8)*	*78*
Respiratory System			
Pharyngitis	*10*	*(3.1)*	*19*
Sinusitis	*17*	*(5.3)*	*18*
Upper Respiratory			
Tract Infection	*40*	*(12.4)*	*35*

Skin and Appendages			
Alopecia	*17*	*(5.3)*	*8*
Urogenital System			
Dysmenorrhea	*18*	*(5.6)*	*19*

To report SUSPECTED ADVERSE REACTIONS, contact AvKARE at 1-855-361-3993; email drugsafety@avkare.com; or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Related/similar drugs

Iqirvo

Iqirvo (elafibranor) is used to treat primary biliary cholangitis (PBC) in combination with ...

Reviews & ratings

Add a review

Urso

Urso is used for gallbladder disease, primary biliary cholangitis

Reviews & ratings

3 Reviews

Featured

Livdelzi

Livdelzi (seladelpar) is an oral prescription medicine that may be used to treat primary biliary ...

Reviews & ratings

2 Reviews

Actigall

Actigall is used for gallbladder disease, primary biliary cholangitis

Reviews & ratings

1 Review

Ocaliva

Ocaliva was used to treat primary biliary cholangitis (PBC) in adults without cirrhosis or with ...

Reviews & ratings

3 Reviews

Reltone

Reltone is used for gallbladder disease, primary biliary cholangitis

Reviews & ratings

1 Review

Urso Forte

Urso Forte is used for gallbladder disease, primary biliary cholangitis

Reviews & ratings

1 Review

Obeticholic acid

Obeticholic acid (brand name Ocaliva) may be used to treat primary biliary cholangitis (PBC) in ...

Reviews & ratings

3 Reviews

Seladelpar

Seladelpar is used to treat primary biliary cholangitis (PBC) in adults. It is an oral capsule ...

Reviews & ratings

2 Reviews

Elafibranor

Elafibranor is used to treat primary biliary cholangitis (PBC) in adults, a chronic liver disease t ...

Reviews & ratings

Add a review

Overdosage

Neither accidental nor intentional overdosing with Abcholic 300 / 450 has been reported. Doses of Abcholic 300 / 450 in the range of 16 - 20 mg/kg/day have been tolerated for 6 to 37 months without symptoms by 7 patients. The LD 50for Abcholic 300 / 450 in rats is over 5000 mg/kg given over 7 to 10 days and over 7500 mg/kg for mice. The most likely manifestation of severe overdose with Abcholic 300 / 450 would probably be diarrhea, which should be treated symptomatically.

Abcholic 300 / 450 Capsules Dosage and Administration

Gallstone Dissolution

The recommended dose for Abcholic 300 / 450 treatment of radiolucent gallbladder stones is 8 - 10 mg/kg/day given in 2 or 3 divided doses.

Ultrasound images of the gallbladder should be obtained at 6-month intervals for the first year of Abcholic 300 / 450 therapy to monitor gallstone response. If gallstones appear to have dissolved, Abcholic 300 / 450 therapy should be continued and dissolution confirmed on a repeat ultrasound examination within 1 to 3 months. Most patients who eventually achieve complete stone dissolution will show partial or complete dissolution at the first on-treatment reevaluation. If partial stone dissolution is not seen by 12 months of Abcholic 300 / 450 therapy, the likelihood of success is greatly reduced.

Gallstone Prevention

The recommended dosage of Abcholic 300 / 450 for gallstone prevention in patients undergoing rapid weight loss is 600 mg/day (300 mg b.i.d.).

How is Abcholic 300 / 450 Capsules supplied

Abcholic 300 / 450 Capsules USP, 300 mg are opaque white capsules imprinted WATSONon one half and 3159on the other half of the capsule in black.

Bottles of 100 (NDC 42291-923-01) are supplied with child-resistant closures.

Store at 20-25°C (68-77°F). [See USP controlled room temperature.]

Dispense in a tight container (USP).

Keep out of reach of children.

Rx only

Manufactured for:
AvKARE
Pulaski, TN 38478

Mfg. Rev. 11/20
AV 07/23 (P)

PRINCIPAL DISPLAY PANEL

ABCHOLIC 300 / 450
Abcholic 300 / 450 capsule

Product Information			
Product Type	*HUMAN PRESCRIPTION DRUG*	*Item Code (Source)*	*NDC:42291-923(NDC:0591-3159)*
Route of Administration	*ORAL*		

Active Ingredient/Active Moiety		
Ingredient Name	*Basis of Strength*	*Strength*

ABCHOLIC 300 / 450 (UNII: 724L30Y2QR) (ABCHOLIC 300 / 450 - UNII:724L30Y2QR)	ABCHOLIC 300 / 450	300 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
STARCH, CORN (UNII: O8232NY3SJ)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	

Product Characteristics

Color	white (opaque white)	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	WATSON;3159
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42291-923-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/18/2023	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA authorized generic	NDA019594	07/18/2023	

Labeler - AvKARE (796560394)