

CLINDAMYCIN- clindamycin capsule
Cronus Pharma LLC

Clindamycin Hydrochloride Capsules, USP

For Use In Dogs Only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Clindamycin Hydrochloride Capsules, USP contain clindamycin hydrochloride which is the hydrated salt of clindamycin. Clindamycin is a semisynthetic antibiotic produced by a 7(S)-chlorosubstitution of the 7(R)-hydroxyl group of a naturally produced antibiotic produced by *Streptomyces lincolnensis* var. *lincolnensis*.

Clindamycin Hydrochloride Capsules, USP (For Use in Dogs Only):

25 mg Capsule, each yellow and colorless capsule contains clindamycin hydrochloride equivalent to 25 mg of clindamycin.

75 mg Capsule, each green and colorless capsule contains clindamycin hydrochloride equivalent to 75 mg of clindamycin.

150 mg Capsule, each blue and colorless capsule contains clindamycin hydrochloride equivalent to 150 mg of clindamycin.

300 mg Capsule, each turquoise and colorless capsule contains clindamycin hydrochloride equivalent to 300 mg of clindamycin.

CLINICAL PHARMACOLOGY

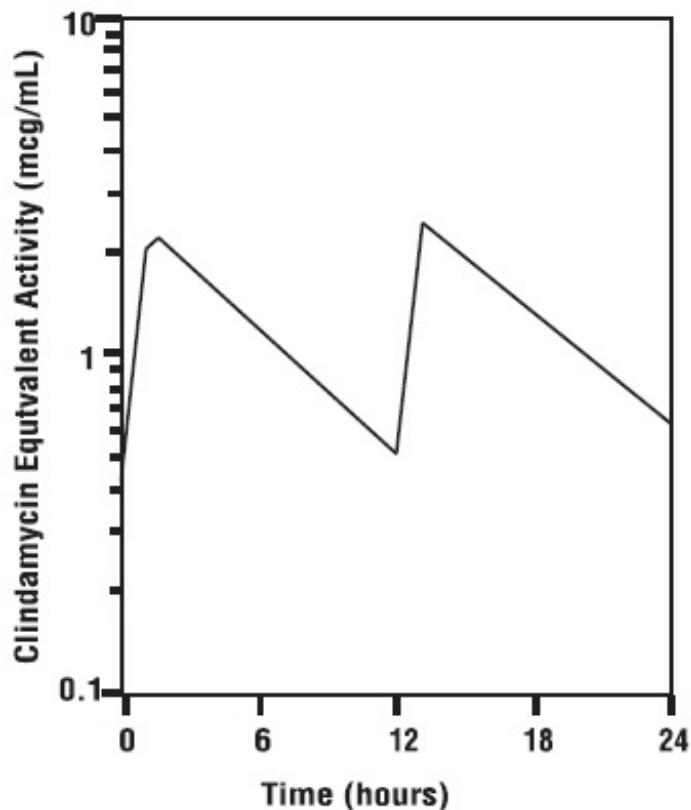
Absorption

Clindamycin hydrochloride is rapidly absorbed from the canine gastrointestinal tract.

Dog Serum Levels

Serum levels at or above 0.5 µg/mL can be maintained by oral dosing at a rate of 2.5 mg/lb of clindamycin hydrochloride every 12 hours. This same study revealed that average peak serum concentrations of clindamycin occur 1 hour and 15 minutes after oral dosing. The elimination half -life for clindamycin in dog serum was approximately 5 hours. There was no bioactivity accumulation after a regimen of multiple oral doses in healthy dogs.

Clindamycin Serum Concentrations 2.5 mg/lb (5.5 mg/kg) After B.I.D. Oral Dose of Clindamycin Hydrochloride Capsules to Dogs



Metabolism and Excretion

Extensive studies of the metabolism and excretion of clindamycin hydrochloride administered orally in animals and humans have shown that unchanged drug and bioactive and bioinactive metabolites are excreted in urine and feces. Almost all of the bioactivity detected in serum after clindamycin hydrochloride product administration is due to the parent molecule (clindamycin). Urine bioactivity, however, reflects a mixture of clindamycin and active metabolites, especially N-demethyl clindamycin and clindamycin sulfoxide.

Site and Mode of Action

Clindamycin is an inhibitor of protein synthesis in the bacterial cell. The site of binding appears to be in the 50S sub-unit of the ribosome. Binding occurs to the soluble RNA fraction of certain ribosomes, thereby inhibiting the binding of amino acids to those ribosomes. Clindamycin differs from cell wall inhibitors in that it causes irreversible modification of the protein-synthesizing subcellular elements at the ribosomal level.

Microbiology

Clindamycin is a lincosaminide antimicrobial agent with activity against a wide variety of aerobic and anaerobic bacterial pathogens. Clindamycin is a bacteriostatic compound that inhibits bacterial protein synthesis by binding to the 50S ribosomal sub-unit. The minimum inhibitory concentrations (MICs) of Gram-positive and obligate anaerobic pathogens isolated from dogs in the United States are presented in Table 1. Bacteria were isolated in 1998-1999. All MICs were performed in accordance with the Clinical and Laboratory Standards Institute (CLSI).

Table 1. Clindamycin MIC Values ($\mu\text{g/mL}$) from Diagnostic Laboratory Survey Data Evaluating Canine Pathogens in the U.S. during 1998-99¹

Organism	Number of Isolates	MIC ₅₀	MIC ₈₅	MIC ₉₀	Range
Soft Tissue/Wound²					
Staphylococcus aureus	17	0.5	0.5	≥ 4.0	0.25- ≥ 4.0
Staphylococcus intermedius	28	0.25	0.5	≥ 4.0	0.125- ≥ 4.0
Staphylococcus spp	18	0.5	0.5	≥ 4.0	0.25- ≥ 4.0
Beta-hemolytic streptococci	46	0.5	0.5	≥ 4.0	0.25- ≥ 4.0
Streptococcus spp	11	0.5	≥ 4.0	≥ 4.0	0.25- ≥ 4.0
Osteomyelitis/Bone³					
Staphylococcus aureus	20	0.5	0.5	0.5	0.5 ⁴
Staphylococcus intermedius	15	0.5	≥ 4.0	≥ 4.0	0.25- ≥ 4.0
Staphylococcus spp	18	0.5	≥ 4.0	≥ 4.0	0.25- ≥ 4.0
Beta-hemolytic streptococci	21	0.5	2.0	2.0	0.25- ≥ 4.0
Streptococcus spp	21	≥ 4.0	≥ 4.0	≥ 4.0	0.25- ≥ 4.0
Dermal/Skin⁵					
Staphylococcus aureus	25	0.5	≥ 4.0	≥ 4.0	0.25- ≥ 4.0
Staphylococcus intermedius	48	0.5	≥ 4.0	≥ 4.0	0.125- ≥ 4.0
Staphylococcus spp	32	0.5	≥ 4.0	≥ 4.0	0.25- ≥ 4.0
Beta-hemolytic streptococci	17	0.5	0.5	0.5	0.25-0.5

1 The correlation between the in vitro susceptibility data and clinical response has not been determined.

2 Soft Tissue/Wound: includes samples labeled wound, abscess, aspirate, exudates, draining tract, lesion, and mass.

3 Osteomyelitis/Bone: includes samples labeled bone, fracture, joint, tendon

4 No range, all isolates yielded the same value

5 Dermal/Skin: includes labeled skin, skin swab, biopsy, incision, lip

INDICATIONS

Clindamycin Hydrochloride Capsules, USP (for use in dogs only) are indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below:

Dogs: Skin infections (wounds and abscesses) due to coagulase positive staphylococci (*Staphylococcus aureus* or *Staphylococcus intermedius*). **Deep wounds and abscesses** due to *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.

Dental infections due to *Staphylococcus aureus*, *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.

Osteomyelitis due to *Staphylococcus aureus*, *Bacteroides fragilis*, *Prevotella melaninogenicus*, *Fusobacterium necrophorum* and *Clostridium perfringens*.

CONTRAINDICATIONS

Clindamycin Hydrochloride Capsules, USP are contraindicated in animals with a history of

hypersensitivity to preparations containing clindamycin or lincomycin.

Because of potential adverse gastrointestinal effects, do not administer to rabbits, hamsters, guinea pigs, horses, chinchillas or ruminating animals.

WARNINGS

Keep out of reach of children. Not for human use.

PRECAUTIONS

During prolonged therapy of one month or greater, periodic liver and kidney function tests and blood counts should be performed.

The use of Clindamycin Hydrochloride Capsules, USP occasionally results in overgrowth of non-susceptible organisms such as clostridia and yeasts. Therefore, the administration of Clindamycin Hydrochloride Capsules should be avoided in those species sensitive to the gastrointestinal effects of clindamycin (see **CONTRAINDICATIONS**). Should superinfections occur, appropriate measures should be taken as indicated by the clinical situation.

Patients with very severe renal disease and/or very severe hepatic disease accompanied by severe metabolic aberrations should be dosed with caution, and serum clindamycin levels monitored during high-dose therapy.

Clindamycin hydrochloride has been shown to have neuromuscular blocking properties that may enhance the action of other neuromuscular blocking agents. Therefore, Clindamycin Hydrochloride Capsules, USP should be used with caution in animals receiving such agents.

Safety in gestating bitches and queens or breeding male dogs has not been established.

ADVERSE REACTIONS

Side effects occasionally observed in either clinical trials or during clinical use were vomiting and diarrhea.

To report a suspected adverse reaction call 1-844-227-6687 (1-844-2-CRONUS)

DOSAGE AND ADMINISTRATION

Dogs: Infected Wounds, Abscesses, and Dental Infections

Oral: 2.5-15.0 mg/lb body weight every 12 hours.

Duration: Treatment with Clindamycin Hydrochloride capsules, USP may be continued up to a maximum of 28 days if clinical judgment indicates. Treatment of acute infections should not be continued for more than three or four days if no response to therapy is

seen.

Dosage Schedule

Capsules

Clindamycin Hydrochloride Capsules, USP 25 mg, administer 1-6 capsules every 12 hours for each 10 pounds of body weight.

Clindamycin Hydrochloride Capsules, USP 75 mg, administer 1 -6 capsules every 12 hours for each 30 pounds of body weight.

Clindamycin Hydrochloride Capsules, USP 150 mg, administer 1-6 capsules every 12 hours for each 60 pounds of body weight.

Clindamycin Hydrochloride Capsules, USP 300 mg, administer 1-6 capsules every 12 hours for each 120 pounds of body weight.

Dogs: Osteomyelitis

Oral: 5.0-15.0 mg/lb body weight every 12 hours.

Duration: Treatment with Clindamycin Hydrochloride Capsules is recommended for a minimum of 28 days. Treatment should not be continued for longer than 28 days if no response to therapy is seen.

Dosage Schedule:

Capsules

Clindamycin Hydrochloride Capsules, USP 25 mg, administer 2-6 capsules every 12 hours for each 10 pounds of body weight.

Clindamycin Hydrochloride Capsules, USP 75 mg, administer 2 -6 capsules every 12 hours for each 30 pounds of body weight.

Clindamycin Hydrochloride Capsules, USP 150 mg, administer 2-6 capsules every 12 hours for each 60 pounds of body weight.

Clindamycin Hydrochloride Capsules, USP 300 mg, administer 2-6 capsules every 12 hours for each 120 pounds of body weight

ANIMAL SAFETY SUMMARY

Rat and Dog Data: One year oral toxicity studies in rats and dogs at doses of 30, 100 and 300 mg/kg/day (13.6, 45.5 and 136.4 mg/lb/day) have shown clindamycin hydrochloride capsules to be well tolerated. Differences did not occur in the parameters evaluated to assess toxicity when comparing groups of treated animals with contemporary controls. Rats administered clindamycin hydrochloride at 600 mg/kg/day (272.7 mg/lb/day) for six months tolerated the drug well; however, dogs orally dosed at 600 mg/kg/day (272.7 mg/lb/day) vomited, had anorexia, and subsequently lost weight. At necropsy these dogs had erosive gastritis and focal areas of necrosis of the mucosa of the gallbladder.

Safety in gestating bitches or breeding males has not been established.

STORAGE

Store at controlled room temperature 68° to 77°F (20° to 25°C).

How Supplied

Clindamycin Hydrochloride Capsules are available as:

25 mg - bottles of 200

75 mg - bottles of 200

150 mg - bottles of 100 and 500

300 mg - bottles of 100

To report suspected adverse drug events, for technical assistance or to obtain a copy of the safety data sheet (SDS), contact Cronus Pharma LLC at 1-844-227-6687 or 1-844-2-CRONUS.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at <https://www.fda.gov/animal-veterinary/safety-health>.

Approved by FDA under ANADA # 200-298

Manufactured for:

Cronus Pharma LLC,

East Brunswick, NJ 08816.

Contact No: 1-844-227-6687

(1-844-2-CRONUS)

Made in India

Distributed by:

Cronus Pharma LLC

2 Tower Center Boulevard, Suite 1101A,

East Brunswick, NJ 08816

Contact No: 1-844-227-6687 (1-844-2-CRONUS)

e-Fax No: 732-647-1272

Email: contact@cronuspharma.com

Issued: 08/2019

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 69043-013-20

Clindamycin Hydrochloride Capsules, USP

25 mg

Equivalent to 25 mg clindamycin

Approved by FDA under ANADA # 200-298

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

200 Capsules

For Use in Dogs Only

NDC 69043-013-20

Clindamycin Hydrochloride Capsules, USP

25 mg

Equivalent to 25 mg clindamycin
 Approved by FDA under ANADA # 200-298
CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

200 Capsules For Use in Dogs Only

Cronus Pharma

Approved for use in dogs.
Recommended dosage:
 For therapy of wounds, abscesses and dental infections:
 1-6 capsules for each 10 pounds body weight every 12 hours.
 For therapy of osteomyelitis, 2-6 capsules for each 10 pounds of body weight every 12 hours.
 See package insert for complete product information.
Warning: Keep out of reach of children. Not for human use.
 Keep container tightly closed.
 Store at controlled room temperature 68° to 77°F (20° to 25°C).
Each capsule contains:
 Clindamycin hydrochloride equivalent to clindamycin, 25 mg.
 Code No.: TN/Drugs/TN00002327
 Issued: 08/2019
 LC01320-02

Manufactured for:
Cronus Pharma LLC,
 East Brunswick, NJ 08816.
 Contact No: 1-844-227-6687
 (1-844-2-CRONUS)
 Made in India

N 3 6 9 0 4 3 0 1 3 2 0 1

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 69043-014-20

Clindamycin Hydrochloride Capsules, USP

75 mg

Equivalent to 75 mg clindamycin

Approved by FDA under ANADA # 200-298

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

200 Capsules

For Use in Dogs Only

NDC 69043-014-20

Clindamycin Hydrochloride Capsules, USP

75 mg

200 Capsules

Equivalent to 75 mg clindamycin
 Approved by FDA under ANADA # 200-298
CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

For Use in Dogs Only

Cronus Pharma

Approved for use in dogs.
Recommended dosage:
 For therapy of wounds, abscesses and dental infections:
 1-6 capsules for each 30 pounds body weight every 12 hours.
 For therapy of osteomyelitis, 2-6 capsules for each 30 pounds of body weight every 12 hours.
 See package insert for complete product information.
Warning: Keep out of reach of children. Not for human use. Keep container tightly closed.
 Store at controlled room temperature 68° to 77°F (20° to 25°C).
Each capsule contains:
 Clindamycin hydrochloride equivalent to clindamycin, 75 mg.

Manufactured for:
Cronus Pharma LLC,
 East Brunswick, NJ 08816.
 Contact No: 1-844-227-6687
 (1-844-2-CRONUS)
 Code No.: TN/Drugs/TN00002327
 Issued: 08/2019
 LC01420-02
 Made in India

N 3 6 9 0 4 3 0 1 4 2 0 8

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 69043-015-01

Clindamycin Hydrochloride Capsules, USP

150 mg

Equivalent to 150 mg clindamycin

Approved by FDA under ANADA # 200-298

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

100 Capsules

For Use in Dogs Only

NDC 69043-015-01

Clindamycin Hydrochloride Capsules, USP

150 mg

100 Capsules

Equivalent to 150 mg clindamycin
Approved by FDA under ANADA # 200-298

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

For Use in Dogs Only

Cronus Pharma

Approved for use in dogs.
Recommended dosage:
For therapy of wounds, abscesses and dental infections:
1-6 capsules for each 60 pounds body weight every 12 hours.
For therapy of osteomyelitis, 2-6 capsules for each 60 pounds of body weight every 12 hours.
See package insert for complete product information.
Warning: Keep out of reach of children. Not for human use. Keep container tightly closed.
Store at controlled room temperature 68° to 77°F (20° to 25°C).

Each capsule contains:
Clindamycin hydrochloride equivalent to clindamycin, 150 mg. *

Manufactured for:
Cronus Pharma LLC,
East Brunswick, NJ 08816.
Contact No: 1-844-227-6687
(1-844-2-CRONUS)

Code No.: TN/Drugs/TN00002327
Issued: 08/2019
LC01501-02
Made in India

N 369043015014

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 69043-015-05

Clindamycin Hydrochloride Capsules, USP

150 mg

Equivalent to 150 mg clindamycin

Approved by FDA under ANADA # 200-298

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

500 Capsules

For Use in Dogs Only

NDC 69043-015-05

**Clindamycin Hydrochloride
Capsules, USP**

150 mg

500 Capsules

Equivalent to 150 mg clindamycin
Approved by FDA under ANADA # 200-298

CAUTION: Federal law restricts this drug to
use by or on the order of a licensed veterinarian.

For Use in Dogs Only

Cronus
Pharma

Approved for use in dogs.

Recommended dosage:

For therapy of wounds, abscesses and dental
infections: 1-6 capsules for each 60 pounds
body weight every 12 hours.

For therapy of osteomyelitis, 2-6 capsules for
each 60 pounds of body weight every 12 hours.
See package insert for complete product
information.

Warning: Keep out of reach of children. Not for
human use.

Keep container tightly closed.
Store at controlled room temperature 68° to
77°F (20° to 25°C).

Each capsule contains:

Clindamycin hydrochloride equivalent to
clindamycin, 150 mg.

Manufactured for:

Cronus Pharma LLC,
East Brunswick, NJ 08816.
Contact No: 1-844-227-6687
(1-844-2-CRONUS)

Made in India

Code No.: TN/Drugs/TN00002327

LC01505-02

Issued: 08/2019



PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 69043-016-01

Clindamycin Hydrochloride Capsules, USP

300 mg

Equivalent to 300 mg clindamycin

Approved by FDA under ANADA # 200-298

CAUTION: Federal law restricts this drug to use by or on the order of a licensed
veterinarian.

100 Capsules

For Use in Dogs Only

NDC 69043-016-01


Clindamycin Hydrochloride Capsules, USP

300 mg

100 Capsules

Equivalent to 300 mg clindamycin
Approved by FDA under ANADA # 200-298
CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

For Use in Dogs Only



Approved for use in dogs.
Recommended dosage:
For therapy of wounds, abscesses and dental infections: 1-6 capsules for each 120 pounds body weight every 12 hours.

For therapy of osteomyelitis, 2-6 capsules for each 120 pounds of body weight every 12 hours.
See package insert for complete product information.

Warning: Keep out of reach of children. Not for human use.

Keep container tightly closed.
Store at controlled room temperature
68° to 77°F (20° to 25°C).

Each capsule contains:
Clindamycin hydrochloride equivalent to clindamycin, 300 mg.

Code No.: TN/Drugs/TN00002327
LC01601-02
Issued: 08/2019

Manufactured for:
Cronus Pharma LLC,
East Brunswick, NJ 08816.
Contact No: 1-844-227-6687
(1-844-2-CRONUS)

Made in India

N 369043016011

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CLINDAMYCIN				
clindamycin capsule				
Product Information				
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:69043-013	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
CLINDAMYCIN HYDROCHLORIDE (UNII: T20OQ1YN1W) (CLINDAMYCIN - UNII:3U02EL437C)		CLINDAMYCIN	25 mg	
Product Characteristics				
Color	YELLOW (YELLOW-WHITE)	Score	no score	
Shape	CAPSULE	Size	16mm	
Flavor		Imprint Code	CRONUS;CLIN25	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69043-013-20	200 in 1 BOTTLE		
Marketing Information				

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200298	10/04/2019	

CLINDAMYCIN

clindamycin capsule

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:69043-014
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN HYDROCHLORIDE (UNII: T20OQ1YN1W) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	75 mg

Product Characteristics

Color	GREEN (GREEN-WHITE)	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	CRONUS;CLIN75
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69043-014-20	200 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200298	10/04/2019	

CLINDAMYCIN

clindamycin capsule

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:69043-015
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN HYDROCHLORIDE (UNII: T200Q1YN1W) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	150 mg

Product Characteristics

Color	BLUE (BLUE-WHITE)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	CRONUS;CLIN150
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69043-015-01	100 in 1 BOTTLE		
2	NDC:69043-015-05	500 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200298	10/04/2019	

CLINDAMYCIN

clindamycin capsule

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:69043-016
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CLINDAMYCIN HYDROCHLORIDE (UNII: T200Q1YN1W) (CLINDAMYCIN - UNII:3U02EL437C)	CLINDAMYCIN	300 mg

Product Characteristics

Color	TURQUOISE (TURQUOISE-WHITE)	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	CRONUS;CLIN300
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69043-016-01	100 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200298	10/04/2019	

Labeler - Cronus Pharma LLC (079421067)

Revised: 10/2021

Cronus Pharma LLC