

HYDROCODONE BITARTRATE AND ACETAMINOPHEN- hydrocodone bitartrate and acetaminophen tablet
Northwind Pharmaceuticals

Boxed Warning Section

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Package Label.Principal Display Panel

NDC: 51655-804-27

HYDROCODONE BIT & ACETAMINOPHEN 7.5MG/325MG CII

12 Tablets

Rx Only

Lot:

Exp:

Store at 20C to 25C (68-77F)

Keep out of reach of children.

Dosage: See package insert.

Manufactured By: Aurolife Pharma LLC

Manufacture Address: Dayton, NJ 08810

Manufacture NDC: 13107-020-05

Mfg Lot: 020150016B

Distributed by: Northwind Pharmaceuticals Indianapolis, IN 46256

Rx#:



HYDROCODONE BITARTRATE AND ACETAMINOPHEN

hydrocodone bitartrate and acetaminophen tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:51655-804(NDC:13107-020)
Route of Administration	ORAL	DEA Schedule	CII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCODONE BITARTRATE (UNII: NO70W886KK) (HYDROCODONE - UNII:6YKS4Y3WQ7)	HYDROCODONE BITARTRATE	7.5 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
POVIDONE K30 (UNII: U725QWY32X)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSPVIDONE (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white (White to Off-White)	Score	no score
Shape	CAPSULE	Size	14mm
Flavor		Imprint Code	U02
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51655-804-27	12 in 1 BOTTLE; Type 0: Not a Combination Product	07/31/2015	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA201013	07/31/2015	

Labeler - Northwind Pharmaceuticals (036986393)

Registrant - Northwind Pharmaceuticals (036986393)

Establishment

Name	Address	ID/FEI	Business Operations
EPM Packaging		079124340	repack(51655-804)

Revised: 7/2015

Northwind Pharmaceuticals