

EPURIS- isotretinoin capsule Galephar Pharmaceutical Research Inc.

Epuris 10 mg Box of 3 blister cards



Epuris 20 mg Box of 3 blister cards



Epuris 30 mg Box of 3 blister cards



Epuris 40 mg Box of 3 blister cards



EPURIS

isotretinoin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66277-339
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOTRETINOIN (UNII: EH28UP181F) (ISOTRETINOIN - UNII:EH28UP181F)	ISOTRETINOIN	30 mg

Inactive Ingredients

Ingredient Name	Strength
PROPYL GALLATE (UNII: 8D4SNN7V92)	
SOYBEAN OIL (UNII: 241ATL177A)	
PEG-32 HYDROGENATED PALM GLYCERIDES (UNII: G6EP177239)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	

Product Characteristics

Color	brown	Score	no score
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Shape	CAPSULE	Size	23mm
Flavor		Imprint Code	G242;30
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66277-339-30	3 in 1 BOX	05/07/2013	
1	NDC:66277-339-10	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		05/07/2013	

EPURIS

isotretinoin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66277-340
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOTRETINOIN (UNII: EH28UP18IF) (ISOTRETINOIN - UNII:EH28UP18IF)	ISOTRETINOIN	40 mg

Inactive Ingredients

Ingredient Name	Strength
PROPYL GALLATE (UNII: 8D4SNN7V92)	
SOYBEAN OIL (UNII: 241ATL177A)	
PEG-32 HYDROGENATED PALM GLYCERIDES (UNII: G6EP177239)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	

Product Characteristics

Color	brown, red	Score	no score
Shape	CAPSULE	Size	26mm
Flavor		Imprint Code	G325;40
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66277-340-30	3 in 1 BOX	05/07/2013	
1	NDC:66277-340-10	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		05/07/2013	

EPURIS

isotretinoin capsule

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66277-338
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ISOTRETINOIN (UNII: EH28UP18IF) (ISOTRETINOIN - UNII:EH28UP18IF)	ISOTRETINOIN	20 mg

Inactive Ingredients

Ingredient Name	Strength
PROPYL GALLATE (UNII: 8D4SNN7V92)	
SOYBEAN OIL (UNII: 241ATL177A)	
PEG-32 HYDROGENATED PALM GLYCERIDES (UNII: G6EP177239)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	

Product Characteristics

Color	red	Score	no score
Shape	CAPSULE	Size	22mm
Flavor		Imprint Code	G241;20
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66277-	3 in 1 BOX	05/07/2013	

1	338-30	3 in 1 BOX	05/07/2013	
1	NDC:66277-338-10	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		05/07/2013	

EPURIS				
isotretinoin capsule				
Product Information				
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66277-337	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	Ingredient Name	Basis of Strength	Strength	
	ISOTRETINOIN (UNII: EH28UP18IF) (ISOTRETINOIN - UNII:EH28UP18IF)	ISOTRETINOIN	10 mg	
Inactive Ingredients				
	Ingredient Name	Strength		
	PROPYL GALLATE (UNII: 8D4SNN7V92)			
	SOYBEAN OIL (UNII: 241ATL177A)			
	PEG-32 HYDROGENATED PALM GLYCERIDES (UNII: G6EP177239)			
	SORBITAN MONOOLEATE (UNII: 06XEA2VD56)			
Product Characteristics				
Color	yellow	Score	no score	
Shape	CAPSULE	Size	18mm	
Flavor		Imprint Code	G240;10	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66277-337-30	3 in 1 BOX	05/07/2013	
1	NDC:66277-337-10	10 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Export only		05/07/2013	

Labeler - Galephar Pharmaceutical Research Inc. (003551624)

Registrant - Galephar Pharmaceutical Research Inc. (968996160)

Establishment

Name	Address	ID/FEI	Business Operations
Galephar Pharmaceutical Research Inc		968996160	analysis(66277-337, 66277-338, 66277-339, 66277-340) , manufacture(66277-337, 66277-338, 66277-339, 66277-340) , pack(66277-337, 66277-338, 66277-339, 66277-340)

Revised: 12/2024

Galephar Pharmaceutical Research Inc.