

# 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

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:66277-339
<b>Route of Administration</b>	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

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

### 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

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

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ISOTRETINOIN</b> (UNII: EH28UP18IF) (ISOTRETINOIN - UNII:EH28UP18IF)	ISOTRETINOIN	40 mg

### Inactive Ingredients

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

### Product Characteristics

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

## 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: 1/2022

Galephar Pharmaceutical Research Inc.