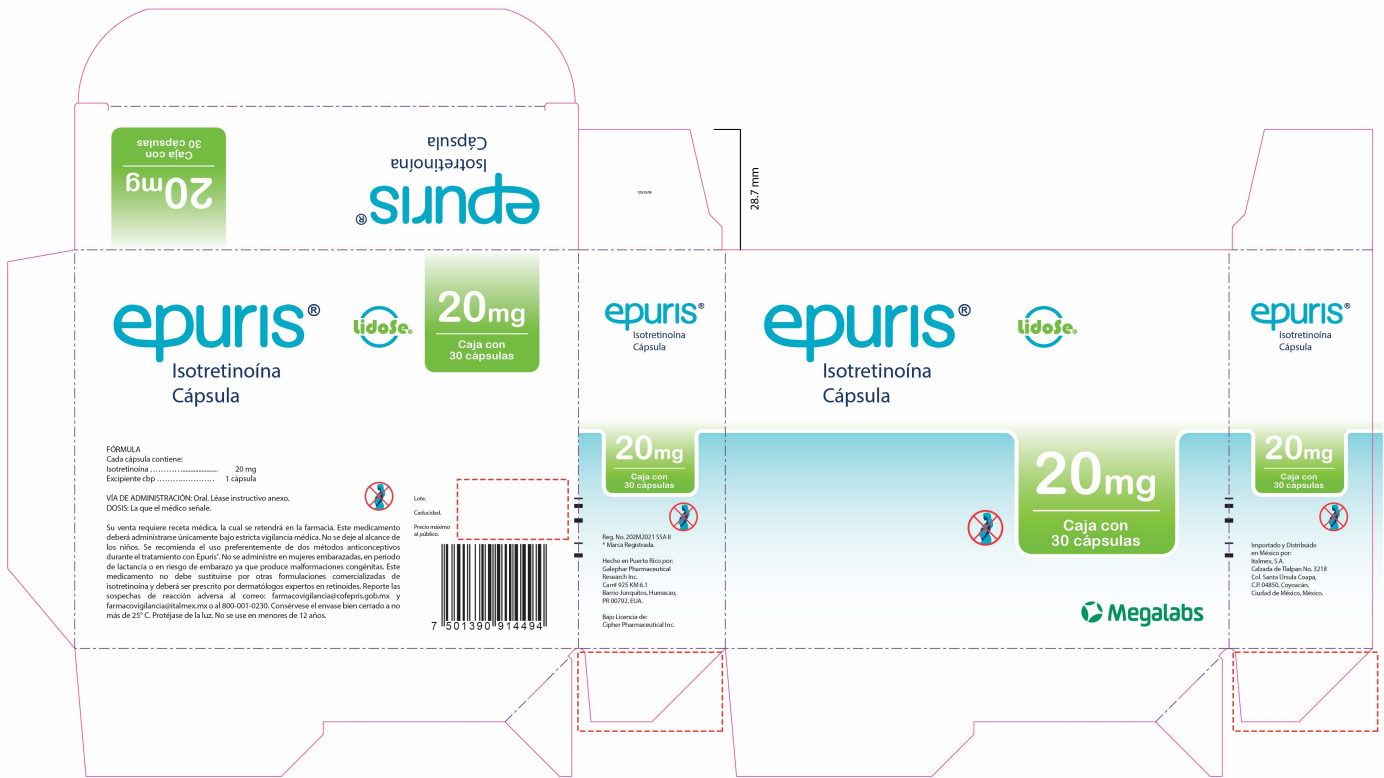


# EPURIS- isotretinoin capsule Galephar Pharmaceutical Research Inc.

## Epuris 10 mg Box of 3 blister cards



## Epuris 20 mg Box of 3 blister cards



**EPURIS**  
isotretinoin capsule

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:66277-335
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
ISOTRETINOIN (UNII: EH28UP181F) (ISOTRETINOIN - UNII:EH28UP181F)	ISOTRETINOIN	20 mg

**Inactive Ingredients**

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

**Product Characteristics**

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:66277-335-30	3 in 1 BOX	10/01/2023	
1	NDC:66277-335-10	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		10/01/2023	

## EPURIS

isotretinoin capsule

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:66277-336
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	Marketing End
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#	Item Code	Package Description	Date	Date
1	NDC:66277-336-30	3 in 1 BOX	10/01/2023	
1	NDC:66277-336-10	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		10/01/2023	

**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(66277-335, 66277-336) , manufacture(66277-335, 66277-336) , pack(66277-335, 66277-336)

Revised: 10/2023

Galephar Pharmaceutical Research Inc.