

**PARICALCITOL- paricalcitol capsule, liquid filled**  
**TIME CAP LABORATORIES, INC**

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**PARICALCITOL CAPSULES SOFTGELS**

**HOW SUPPLIED**

4 mcg, light yellow color oval shaped soft gelatin capsules imprinted with 17 in black ink in bottles of 30

**HOW SUPPLIED**

2 mcg, brown color, oval shaped soft gelatin capsule imprinted 12 in black ink, in bottles of 30

**HOW SUPPLIED**

1 mcg, gray color oval shaped soft gelatin capsule imprinted 12 in black ink, in bottles of 30

**PDP 4 MCG**

NDC 49483 689 03

 **Time-Cap Labs, Inc.**

**PARICALCITOL, USP  
CAPSULES**

**4 mcg**

Rx only    30 Capsules

Each capsule contains: Paricalcitol, USP 4 mcg  
See package insert for complete product information.

Store at 20° to 25°C (68° to 77°F)  
(See USP Controlled Room Temperature).  
Dispense in a tight container as defined in the USP. Do not accept if seal over bottle opening is broken or missing.

Manufactured for: **Time-Cap Labs, Inc.**  
7 Michael Avenue, Farmingdale, NY 11735, USA

Manufactured by: **Maksans Pharma Ltd.**  
Plot No. L-82, L-83, Verma Indl. Estate,  
Verma, Goa-403 722, India  
680T 0818



49483-689-037

2 mcg label

NDC 49483 688 03

 **Time-Cap Labs, Inc.**

**PARICALCITOL, USP  
CAPSULES**

**2 mcg**

Rx only    30 Capsules

Each capsule contains: Paricalcitol, USP 2 mcg.  
See package insert for complete product information.

Store at 20° to 25°C (68° to 77°F)  
(See USP Controlled Room Temperature).

Dispense in a tight container as defined in the USP. Do not accept if seal over bottle opening is broken or missing.

Manufactured for: **Time-Cap Labs, Inc.**  
7 Michael Avenue, Farmingdale, NY 11735, USA

Manufactured by: **Madsani Pharma Ltd.**  
Plot No. L-82, L-83, Verna Indl. Estate,  
Verna, Goa-403 722, India  
8801 0818



0 51 28 9 - 53 9 6 1

NDC 49483-687-03

 **Time-Cap Labs, Inc.**

**PARICALCITOL, USP  
CAPSULES  
1 mcg**

Rx only    30 Capsules


Each capsule contains: Paricalcitol, USP 1 mcg  
See package insert for complete product information.

Store at 20° to 25° C (68° to 77° F)  
(See USP Controlled Room Temperature)

Dispense in a tight container as defined in the USP. Do not accept if seal over bottle opening is broken or missing.

Manufactured for: **Time-Cap Labs, Inc.**  
7 Michael Avenue, Farmingdale, NY 11735, USA

Manufactured by: **Maksans Pharma Ltd.**  
Plot No. L-82, L-83, Varna Ind. Estate,  
Verna, Goa-403 722, India  
687T 0618



49483-687-033

**PARICALCITOL**

paricalcitol capsule, liquid filled

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:49483-689
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
PARICALCITOL (UNII: 6702D36OG5) (PARICALCITOL - UNII:6702D36OG5)	PARICALCITOL	4 ug

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	

### Product Characteristics

<b>Color</b>	white ((LIGHT YELLOW))	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	17
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-689-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2017	

### Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA204948	01/03/2017	

# PARICALCITOL

paricalcitol capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:49483-688
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
PARICALCITOL (UNII: 6702D36OG5) (PARICALCITOL - UNII:6702D36OG5)	PARICALCITOL	2 ug

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GELATIN (UNII: 2G86QN327L)	
SORBITOL (UNII: 506T60A25R)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
WATER (UNII: 059QF0KO0R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	

## Product Characteristics

<b>Color</b>	brown	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	14
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-688-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204948	12/30/2015	

# PARICALCITOL

paricalcitol capsule, liquid filled

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:49483-687
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PARICALCITOL (UNII: 6702D36OG5) (PARICALCITOL - UNII:6702D36OG5)	PARICALCITOL	1 ug

## Inactive Ingredients

Ingredient Name	Strength
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
ALCOHOL (UNII: 3K9958V90M)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
SORBITOL (UNII: 506T60A25R)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
BUTYL ALCOHOL (UNII: 8PJ61P6TS3)	
SHELLAC (UNII: 46N107B71O)	
AMMONIA (UNII: 5138Q19F1X)	

## Product Characteristics

<b>Color</b>	gray	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	9mm
<b>Flavor</b>		<b>Imprint Code</b>	12
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-687-03	30 in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2017	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA204948	01/03/2017	

**Labeler** - TIME CAP LABORATORIES, INC (037052099)

**Registrant** - TIME CAP LABORATORIES, INC (037052099)

**Establishment**

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(49483-689, 49483-688, 49483-687)

Revised: 9/2019

TIME CAP LABORATORIES, INC