

**NITRO-TIME- nitroglycerin capsule**  
**TIME CAP LABORATORIES, INC**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, [click here](#).*

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**NITROGLYCERIN 2.5 MG, 6.5 MG and 9.0 MG**

**HOW SUPPLIED:**

2.5 mg Nitroglycerin Extended-Release (Pink and Clear Capsules imprinted TCL-1221) in bottles of 60's & 100's

**HOW SUPPLIED**

6.5 mg Nitroglycerin Extended-Release Capsules Blue/Yellow imprinted TCL1222 in bottles of 60's and 100's

**HOW SUPPLIED**

9.0 mg Nitroglycerin Extended Release Capsules Green/Yellow imprinted TCL1223 in bottles of 60's and 100's

**NITROGLYCERIN 2.5 MG 100 COUNT LABEL**

 Time-Cap Labs, Inc.

NDC 49483-221-10

**Nitro-Time™**  
NITROGLYCERIN  
Extended-Release Capsules

**2.5 mg**  
Rx only  
**100 Capsules**

Each extended-release capsule contains:  
Nitroglycerin..... 2.5 mg

**USUAL DOSAGE:** See package insert for dosage, including nitrate-free interval.

**PHARMACIST** Store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F). Protect from moisture. Dispense in a tight container, as defined in the USP.

**KEEP OUT OF REACH OF CHILDREN**

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Manufactured by: Time-Cap Labs, Inc.  
Farmingdale, NY 11735  
005T R0717



3 49483-221-107

Varnish Omit  
Serialization Area

**NITROGLYCERIN 6.5 MG 100 COUNT**

 **Time-Cap Labs, Inc.**

NDC 49483-222-06

**Nitro-Time™**  
NITROGLYCERIN  
Extended-Release Capsules

**6.5 mg**  
Rx only  
**60 Capsules**

Each extended-release capsule contains:  
Nitroglycerin..... 6.5 mg

**USUAL DOSAGE:** See package insert for dosage, including nitrate-free interval.

**PHARMACIST** Store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F). Protect from moisture. Dispense in a tight container, as defined in the USP.

**KEEP OUT OF REACH OF CHILDREN**

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Manufactured by: Time-Cap Labs, Inc.  
Farmingdale, NY 11735  
006T R0717



3 49483-222-06 7

Varnish Omit  
Serialization Area

**NITROGLYCERIN 9.0 MG 100 COUNT**

 **Time-Cap Labs, Inc.**

NDC 49483-223-10

**Nitro-Time™**  
NITROGLYCERIN  
Extended-Release Capsules

**9 mg**  
Rx only  
**100 Capsules**

Each extended-release capsule contains:

Nitroglycerin.....9 mg

**USUAL DOSAGE:** See package insert for dosage, including nitrate-free interval.

**PHARMACIST** Store at 25°C (77°F) excursions permitted between 15°-30°C (59°-86°F). Protect from moisture. Dispense in a tight container, as defined in the USP.

**KEEP OUT OF REACH OF CHILDREN**

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Manufactured by: Time-Cap Labs, Inc.  
Farmingdale, NY 11735  
007T R0717



3 49483-223-10 1

Varnish Omit  
Serialization Area

nitroglycerin capsule

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:49483-221
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
NITROGLYCERIN (UNII: G59M7S0WS3) (NITROGLYCERIN - UNII:G59M7S0WS3)	NITROGLYCERIN	2.5 mg

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 28 (UNII: 767IP0Y5NH)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN (UNII: 2G86QN327L)	
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
WHITE WAX (UNII: 7G1J5DA97F)	

### Product Characteristics

<b>Color</b>	pink (pink) , white (clear)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (CAPSULE)	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	TCL;1221
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-221-06	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/09/2018	
2	NDC:49483-221-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/09/2018	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/19/2014	

## NITRO-TIME

nitroglycerin capsule

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:49483-222
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITROGLYCERIN (UNII: G59M7S0WS3) (NITROGLYCERIN - UNII:G59M7S0WS3)	NITROGLYCERIN	6.5 mg

### Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 (UNII: HBR47K3TBD)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WHITE WAX (UNII: 7G1J5DA97F)	

### Product Characteristics

Color	blue (BLUE) , yellow (YELLOW)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	8mm
Flavor		Imprint Code	TCL;1222
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
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1	NDC:49483-222-06	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/09/2018	
2	NDC:49483-222-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/09/2018	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/19/2014	

## NITRO-TIME

nitroglycerin capsule

### Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:49483-223
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
NITRO GLYCERIN (UNII: G59M7S0WS3) (NITROGLYCERIN - UNII:G59M7S0WS3)	NITROGLYCERIN	9 mg

### Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
D&C YELLOW NO. 10 (UNII: 35SW5USQ3G)	
ETHYLCELLULOSES (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
GELATIN (UNII: 2G86QN327L)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WHITE WAX (UNII: 7G1J5DA97F)	

### Product Characteristics

Color	green (GREEN) , yellow (YELLOW)	Score	no score
Shape	CAPSULE (CAPSULE)	Size	9mm

<b>Flavor</b>		<b>Imprint Code</b>	TCL;1223
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49483-223-06	60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/09/2018	
2	NDC:49483-223-10	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/09/2018	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/19/2014	

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

**Establishment**

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC		037052099	manufacture(49483-221, 49483-222, 49483-223)

Revised: 10/2018

TIME CAP LABORATORIES, INC