

**LOPERAMIDE HCL AND SIMETHICONE- loperamide hcl and simethicone tablet**  
**Ohm Laboratories Inc.**

-----  
**Drug Facts**

***Active ingredients (in each caplet)***

Loperamide HCl USP, 2 mg

Simethicone USP, 125 mg

***Purposes***

Anti-diarrheal

Anti-gas

***Uses***

relieves symptoms of diarrhea plus bloating, pressure and cramps, commonly referred to as gas

***Warnings***

**Allergy alert:**

Do not use if you have ever had a rash or other allergic reaction to loperamide HCl

**Heart Alert:** Taking more than directed can cause serious heart problems or death

**Do not use**

- if you have bloody or black stool
- if you have difficulty swallowing

**Ask a doctor before use if you have**

- fever
- mucus in the stool
- a history of liver disease
- a history of abnormal heart rhythm

**Ask a doctor or pharmacist before use if you are**

taking a prescription drug. Loperamide may interact with certain prescription drugs.

**When using this product**

tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.

## Stop use and ask a doctor if

- symptoms get worse
- diarrhea lasts for more than 2 days
- you get abdominal swelling or bulging. These may be signs of a serious condition.
- you have difficulty swallowing the caplet

## If pregnant or breast-feeding,

ask a health professional before use.

## Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1800-222-1222).

## Directions

- **drink plenty of clear fluids to help prevent dehydration caused by diarrhea**
- take only on an empty stomach (1 hour before or 2 hours after a meal)
- take with a full (8 oz.) glass of water
- find right dose on chart below. If possible, use weight to dose; otherwise, use age.

adults and children 12 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
children 9-11 years (60-95 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
children 6-8 years (48-59 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours
children 2-5 years (34 to 47 lbs)	ask a doctor
children under 2 years (upto 33 lbs)	do not use

## Other information

- **calcium:** contains 142 mg/caplet
- store between 20-25° C (68-77° F). Protect from light.
- **TAMPER EVIDENT: THIS PRODUCT PROTECTED WITH SEALED BLISTER UNITS. DO NOT USE IF ANY ARE TORN OR BROKEN.**

## Inactive ingredients

calcium silicate, colloidal silicon dioxide, dibasic calcium phosphate, microcrystalline cellulose, sodium starch glycolate, stearic acid

**Questions?**

call **1-800-406-7984**

Manufactured by:  
Sun Pharmaceutical  
Industries Limited,  
MOHALI, INDIA

Distributed by:  
Ohm Laboratories Inc.,  
New Brunswick,  
NJ 08901

**PRINCIPAL DISPLAY PANEL - 6 Capsule Blister Pack Carton**

†Compare To  
the active ingredients of  
Imodium®  
Multi-Symptom Relief

NDC 51660-069-06

ohm®

Loperamide HCl and  
Simethicone Tablets,  
2 mg/125 mg

Anti-Diarrheal/Anti-Gas  
Multi-Symptom Relief

Relieves symptoms of diarrhea plus

- Cramps & Pressure
- Bloating
- Gas

6 CAPLETS\*

(\*capsule-shaped tablets)

NWZ

5233191

**Drug Facts (continued)**

Do not use if you have bloody or black stool  
 if you have difficulty swallowing  
 Ask a doctor before use if you have fever  
 Ask a doctor before use if you have a history of liver disease  
 a history of abnormal heart rhythm  
 mucus in the stool  
 Ask a doctor or pharmacist before use if you are taking a prescription drug. Loperamide may interact with certain prescription drugs.  
 When using this product, tiredness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.  
 Stop use and ask a doctor if symptoms get worse  
 diarrhea lasts for more than 2 days  
 you get abdominal swelling or bloating. These may be signs of a serious condition.  
 you have difficulty swallowing the caplet  
 If pregnant or breast-feeding, ask a health professional before use.  
 Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

**Drug Facts (continued)**

Find right dose on chart below. If possible, use weight to dose; otherwise, use age.

adults and children 12 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; in 4 hours
children 9-11 years (60-95 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
children 6-8 years (48-59 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours
children 2-5 years (34 to 47 lbs)	ask a doctor
children under 2 years (up to 33 lbs)	do not use

**Other information**

each caplet contains: calcium 142 mg  
 store between 20 - 25°C (68 - 77°F). Protect from light.  
 Tamper evident: Do Not use if carton is open or if blister unit is open or torn

**Drug Facts**

**Active ingredients (in each caplet)**

Loperamide HCl USP, 2 mg.....Anti-diarrheal  
 Simethicone USP, 125 mg.....Anti-gas

**Uses** relieves symptoms of diarrhea plus bloating, pressure and cramps, commonly referred to as gas

**Warnings**

Allergy alert: Do not use if you have ever had a rash or other allergic reaction to loperamide HCl  
 Heart alert: Taking more than directed can cause serious heart problems or death

NDC 51690-060-06

Compare To the active ingredients of **Imodium® Multi-Symptom Relief**

ohm®

# Loperamide HCl and Simethicone Tablets, 2 mg/125 mg

Anti-Diarrheal/Anti-Gas  
 Multi-Symptom Relief

Relieves symptoms of diarrhea **plus**

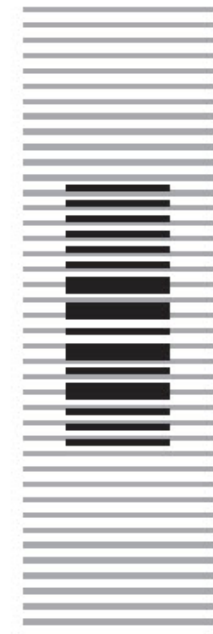
- Cramps & Pressure
- Bloating
- Gas



6 CAPLETS\* (\*capsule-shaped tablets)



Questions? call 1-800-406-7984



Manufactured by:  
 Sun Pharmaceutical  
 Industries Limited,  
 MOHALI, IN DIA  
 Distributed by:  
 Orlin Laboratories Inc.,  
 New Brunswick,  
 NJ 08901  
 0722



## PRINCIPAL DISPLAY PANEL - 12 Caplet Blister Pack Carton

†Compare To  
the active ingredients of  
Imodium®

Multi-Symptom Relief

NDC 51660-069-12

ohm®

Loperamide HCl and  
Simethicone Tablets,  
2 mg/125 mg

Anti-Diarrheal/Anti-Gas  
Multi-Symptom Relief

Relieves symptoms of diarrhea plus

- Cramps & Pressure
- Bloating
- Gas

12 CAPLETS\*

(\*capsule-shaped tablets)

NWZ

5233192

**Drug Facts (continued)**

**Do not use** ■ If you have bloody or black stool ■ If you have difficulty swallowing ■ If you have a history of abnormal heart rhythm ■ A history of stomach or liver disease ■ Mucus in the stool ■ A history of liver disease ■ Ask a doctor before use if you have ■ Fever ■ Nausea ■ Vomiting ■ Stomach pain ■ Ask a doctor or pharmacist before use if you are taking a prescription drug. Loperamide may interact with certain prescription drugs.

When using this product, dizziness, drowsiness or dizziness may occur. Be careful when driving or operating machinery.

Stop use and ask a doctor if ■ Symptoms get worse ■ Diarrhea lasts for more than 2 days ■ You get abdominal swelling or bloating. These may be signs of a serious condition.

If pregnant or breastfeeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1800-222-1222).

**Directions**

■ Drink plenty of clear fluids to help prevent dehydration caused by diarrhea. ■ Take only on an empty stomach (1 hour before or 2 hours after a meal). ■ Take with a full (8 oz) glass of water.

**Other Information**

■ Each caplet contains calcium 142 mg ■ Store between 20 - 25°C (68 - 77°F). Protect from light. ■ Tamper evident Do Not use if contents open or if blister units are open or torn.

**Drug Facts (continued)**

■ Find right dose on chart below. If possible, use weight to dose; otherwise, use age.

Adults and children 12 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; but no more than 4 caplets in 24 hours
Children 9-11 years (60-95 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 3 caplets in 24 hours
Children 6-8 years (48-59 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; but no more than 2 caplets in 24 hours
Children 2-5 years (34 to 47 lbs)	ask a doctor
Children under 2 years (up to 33 lbs)	do not use

**Drug Facts**

**Active ingredients (in each caplet)**

Loperamide HCl USP, 2 mg; Simethicone USP, 125 mg.

**Purposes**

Anti-diarrheal  
Anti-gas

**Uses** relieves symptoms of diarrhea plus bloating, pressure and cramps, commonly referred to as gas.

**Warnings**

**Allergy alert:** Do not use if you have ever had a rash or other allergic reaction to loperamide HCl.

**Heart alert:** Taking more than directed can cause serious heart problems or death.

NDC 51660-069-72

Compare To the active ingredients of **Imodium®** Multi-Symptom Relief

**ohm®**

**Loperamide HCl and Simethicone Tablets, 2 mg/125 mg**

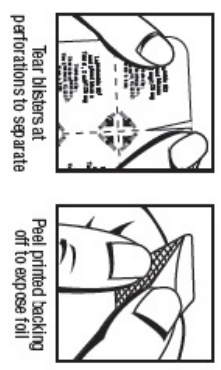
**Anti-Diarrheal/Anti-Gas Multi-Symptom Relief**

Relieves symptoms of diarrhea **plus**

- Cramps & Pressure
- Bloating
- Gas

069

**12 CAPLETS\*** (\*capsule-shaped tablets)



Manufactured by:  
Sun Pharmaceutical Industries Limited,  
MOHALI, INDIA

Distributed by:  
Ohm Laboratories Inc.,  
New Brunswick,  
NJ 08901

0722

Questions? call 1-800-406-7984

starch glycolate, stearic acid



Keep the carton.  
It contains important information.  
†Ohm is a registered trademark of  
Sun Pharmaceutical Industries, Inc.  
All other trademarks are property  
of their respective owners.

**Drug Facts (continued)**

**Inactive ingredients**  
calcium silicate, colloidal silicon dioxide, dibasic  
calcium phosphate, microcrystalline cellulose, sodium

## PRINCIPAL DISPLAY PANEL - 18 Caplet Blister Pack Carton

†Compare To  
the active ingredients of  
Imodium®  
Multi-Symptom Relief

NDC 51660-069-18

ohm®

Loperamide HCl and  
Simethicone Tablets,  
2 mg/125 mg

Anti-Diarrheal/Anti-Gas  
Multi-Symptom Relief

Relieves symptoms of diarrhea plus

- Cramps & Pressure
- Bloating
- Gas

18 CAPLETS\*

(\*capsule-shaped tablets)



NWZ



**Drug Facts (continued)**

Do not use if you have bloody or black stool  
 if you have difficulty swallowing  
 Ask a doctor before you use if you have  
 ■ fever  
 ■ history of abnormal heart rhythm  
 ■ a recent history of liver disease  
 ■ a recent history of alcoholism  
 Ask a doctor or pharmacist before use if you are taking  
 a prescription drug. Loperamide may interact with  
 certain prescription drugs.  
 When using this product, dizziness, drowsiness or  
 dizziness may occur. Be careful when driving or  
 operating machinery.  
 Stop use and ask a doctor if  
 ■ symptoms get worse  
 ■ diarrhea lasts for more than 2 days  
 ■ you get abdominal swelling or bloating. These may  
 be signs of a serious condition.  
 If pregnant or breast-feeding, ask a health  
 professional before use.  
 Keep out of reach of children.  
 In case of overdose, get medical help or contact a  
 Poison Control Center right away (1-800-222-1222).

**Drug Facts (continued)**

Find right dose on chart below. If possible, use  
 weight to dose; otherwise, use age.

adults and children 12 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool; in 24 hours
children 9-11 years (60-95 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; in 24 hours
children 6-8 years (48-59 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool; in 24 hours
children 2-5 years (34 to 47 lbs) ask a doctor	ask a doctor

children under 2 years  
(up to 33 lbs)  
do not use

**Other information**

■ each caplet contains: calcium 142 mg  
 ■ store between 20° - 25°C (68° - 77°F). Protect  
 from light  
 ■ Tamper evident: Do not use if caplet is open or if  
 blister unit is open or torn

**Drug Facts**

**Active ingredients (in each caplet)**

Loperamide HCl USP, 2 mg.....Anti-diarrheal  
 Simethicone USP, 125 mg.....Anti-gas

Uses relieves symptoms of diarrhea plus bloating, pressure and cramps, commonly referred to as gas

**Warnings**

**Alert:** Do not use if you have ever had a rash or other allergic reaction to loperamide HCl  
**Heart alert:** Taking more than directed can cause serious heart problems or death

5233193

NDC 51660-069-18

ohm<sup>®</sup>

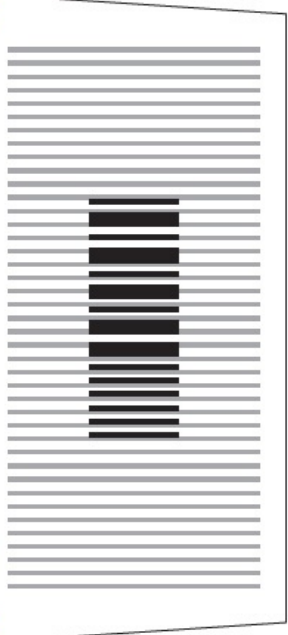
**Loperamide HCl and  
 Simethicone Tablets,  
 2 mg/125 mg**

**Anti-Diarrheal/Anti-Gas  
 Multi-Symptom Relief**

Relieves symptoms of diarrhea **plus**

- Cramps & Pressure
- Bloating
- Gas

18 CAPLETS\* (\*capsule-shaped tablets)



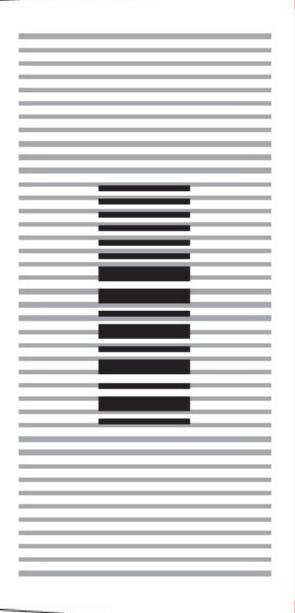
**Drug Facts (continued)**

**Active ingredients**

calcium silicate, colloidal silicon dioxide, docusate  
 calcium phosphate, microcrystalline cellulose, sodium  
 starch glycolate, sodium carboxymethylcellulose, sodium  
 croscarmellose, croscarmellose sodium, croscarmellose  
 potassium, croscarmellose sodium, croscarmellose sodium

**Questions?** call 1-800-406-7984

3 N  
 51660 06918 1



ohm is a registered trademark of Sun Pharmaceutical Industries, Inc.  
 All other trademarks are property of their respective owners.

Manufactured by:  
 Sun Pharmaceutical  
 Industries Limited,  
 MOHALL, INDIA

Distributed by:  
 Ohm Laboratories Inc.,  
 New Brunswick,  
 NJ 08901

0722

Tear blisters at  
 perforations to separate

Peel printed backing  
 off to expose foil



## **PRINCIPAL DISPLAY PANEL - 24 Caplet Blister Pack Carton**

†Compare To  
the active ingredients of  
Imodium®  
Multi-Symptom Relief

NDC 51660-069-24

ohm®

Loperamide HCl and  
Simethicone Tablets,  
2 mg/125 mg

Anti-Diarrheal/Anti-Gas  
Multi-Symptom Relief

Relieves symptoms of diarrhea plus

- Cramps & Pressure
- Bloating
- Gas

24 CAPLETS\*  
(\*capsule-shaped tablets)

**Directions**

- Drink plenty of clear fluids to help prevent dehydration caused by diarrhea
- Take only on an empty stomach (1 hour before or 2 hours after a meal)
- Take with a full (8 oz.) glass of water

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away (1 800-222-1222).

**If pregnant or breast-feeding, ask a health professional before use.**

- You have difficulty swallowing the caplet
- Signs of a serious condition:
- You get abdominal swelling or bugging. These may damage a fetus for more than 2 days
- Symptoms get worse
- Stop, use an ask a doctor if operating machinery.

**When using this product (dizziness, drowsiness or certain prescription drugs):**

- As a doctor or pharmacist before use if you are taking
- Ask a doctor or pharmacist before use if you are taking
- History of abnormal heart rhythm
- Use in the stool
- History of liver disease
- History of abnormal heart rhythm
- Ask a doctor or pharmacist before use if you have:
- Use if you have difficulty swallowing
- Do not use if you have bloody or black stool

**Other Information**

- Each caplet contains: calcium 142 mg
- Store between 20 - 25°C (68 - 77°F). Protect from light
- Use if tamper evident Do Not use if carbon is open or if blister unit is open or torn

Drug Facts (continued)	
adults and children 12 years and over	2 caplets after the first loose stool; 1 caplet after each subsequent loose stool.
children 9-11 years (60-95 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool.
children 6-8 years (48-59 lbs)	1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool.
children 2-5 years (15 to 47 lbs)	1/2 caplet after the first loose stool; 1/4 caplet after each subsequent loose stool.
children under 2 years (up to 33 lbs)	do not use

**Drug Facts (continued)**

- Find the dose on each half bowl. If possible, use weight to dose; otherwise, use age.
- 12 years and over: 2 caplets after the first loose stool; 1 caplet after each subsequent loose stool.
- children 9-11 years: 1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool.
- children 6-8 years: 1 caplet after the first loose stool; 1/2 caplet after each subsequent loose stool.
- children 2-5 years: 1/2 caplet after the first loose stool; 1/4 caplet after each subsequent loose stool.

NWZ

**Drug Facts**

**Active Ingredients (in each caplet)**

- Loperamide HCl USP, 2 mg
- Simethicone USP, 125 mg

Anti-diarrheal  
Anti-gas

**Uses**

relieves symptoms of diarrhea plus bloating, pressure and cramps, commonly referred to as gas

**Warnings**

**Heart alert:** Taking more than directed can cause a serious heart problem or death

**Allergy alert:** Do not use if you have ever had a rash or other allergic reaction to loperamide HCl

5233 194

NDC 51660-06-24

**ohm<sup>®</sup>**

**Loperamide HCl and Simethicone Tablets, 2 mg/125 mg**

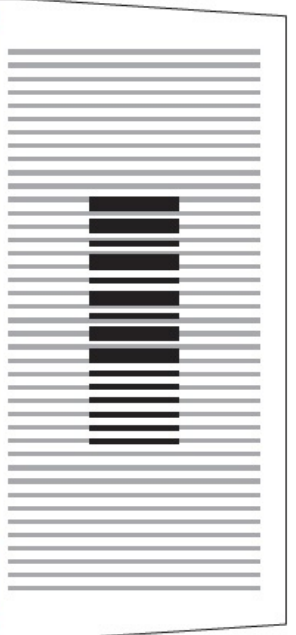
**Anti-Diarrheal/Anti-Gas Multi-Symptom Relief**

Relieves symptoms of diarrhea plus

- Cramps & Pressure
- Bloating
- Gas

**24 CAPLETS\* (capsule-shaped tablets)**

**Compare To**  
the active ingredients of  
**Imodium<sup>®</sup>**  
**Multi-Symptom Relief**



**Drug Facts (continued)**

**Inactive ingredients**

calcium silicate, colloidal silicon dioxide, dibasic calcium phosphate, microcrystalline cellulose, sodium starch glycolate, sodium croscarmellose, sodium lauryl sulfate

**Questions?** call 1-800-406-7984

**Other Information**

- Each caplet contains: calcium 142 mg
- Store between 20 - 25°C (68 - 77°F). Protect from light
- Use if tamper evident Do Not use if carbon is open or if blister unit is open or torn

**Warnings**

**Heart alert:** Taking more than directed can cause a serious heart problem or death

**Allergy alert:** Do not use if you have ever had a rash or other allergic reaction to loperamide HCl

**ohm** is a registered trademark of Sun Pharmaceutical Industries, Inc. All other trademarks are property of their respective owners.

Manufactured by:  
Sun Pharmaceutical Industries, Limited, MUMBAI, INDIA

Distributed by:  
Ohm Laboratories Inc., New Brunswick, NJ 08901 0722

**Peel printed backing off to expose foil**

**Tear blisters at perforations to separate**

**Drug Facts (continued)**

**Inactive ingredients**

calcium silicate, colloidal silicon dioxide, dibasic calcium phosphate, microcrystalline cellulose, sodium starch glycolate, sodium croscarmellose, sodium lauryl sulfate

**Questions?** call 1-800-406-7984

**LOPERAMIDE HCL AND SIMETHICONE**

loperamide hcl and simethicone tablet

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:51660-069
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>LOPERAMIDE HYDROCHLORIDE</b> (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg
<b>DIMETHICONE</b> (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	125 mg

**Inactive Ingredients**

Ingredient Name	Strength
<b>CALCIUM SILICATE</b> (UNII: S4255P4G5M)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>ANHYDROUS DIBASIC CALCIUM PHOSPHATE</b> (UNII: L11K75P92J)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	

**Product Characteristics**

<b>Color</b>	WHITE (white to off-white)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	16mm
<b>Flavor</b>		<b>Imprint Code</b>	NA
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51660-069-06	6 in 1 BLISTER PACK; Type 0: Not a Combination Product	01/13/2022	
2	NDC:51660-069-12	2 in 1 CARTON	01/13/2022	
2		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:51660-069-18	3 in 1 CARTON	01/13/2022	
3		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		

4	NDC:51660-069-24	4 in 1 CARTON	01/13/2022	
4		6 in 1 BLISTER PACK; Type 0: Not a Combination Product		
<b>Marketing Information</b>				
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>		<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA077500		01/13/2022	

**Labeler** - Ohm Laboratories Inc. (184769029)

**Registrant** - Sun Pharmaceutical Industries, Inc. (146974886)

<b>Establishment</b>			
<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Sun Pharmaceutical Industries Limited		650456002	MANUFACTURE(51660-069)

Revised: 8/2022

Ohm Laboratories Inc.