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 HCI

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

 $\text{ohm}^{\text{\circledR}}$

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

Directions

in case of overdose, get medical help or contact a professional before use. Keep out of reach of children.

Poison Control Center right away (1800-222-1222)

If pregnant or breast-feeding, ask a health

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

Stop use and ask a doctor if operating machinery.

When using this product tiredness, drowsiness or dizziness may occur. Be careful when driving or certain prescription drugs.

a prescription drug. Loperamide may interact with Ask a doctor or pharmacist before use if you are taking

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m mucus in the stool a a history of liver disease Ask a doctor before use if you have Tever

■ if you have difficulty swall owing Do not use ■ityou have bloody or black stool

Drug Facts (continued)

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adults and children weight to dose; otherwise, use age. ■ find right dose on chart below. If possible, use

Drug Facts (continued)

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

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

Loperamide HCI USP, 2 mg... Simethione USP, 125 mg... ena-gas PUTI-DISTUDES! səsodın_d Active ingredients (in each caplet)

Drug Facts

NDC 51660-069-06



Distributed by: Ohm La boratories I New Brunswick, NJ 08901 Manufactured by: Sun Pharmaceutical Industries Limited, MOHALI, IN DIA

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

ohm

Loperamide HCI and Simethicone Tablets, mg/125 mg

Anti-Diarrheal/Anti-Gas Multi-Symptom Relief

Relieves symptoms of diarrhea plus

- Cramps & Pressure
- Bloating
- Gas



6 CAPLETS*

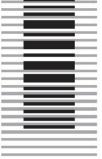
(*capsule-shaped tablets)

Questions?call 1-800-406-7984



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Inactive ingredients calcium silicate, colloidal silicon dioxide, dibasic calcium phosphate, microcryataline cellulose, sodium starch divcolate, steanc acid

Drug Facts (continued)

fOhm is a registered trademark of Sun Pharmaceuf cal Industries, Inc. All other trademarks are property of their respective owners.

Keep the carton. It contains important information.

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

■ take outh on an empty stomach (1 hour before ge juliquagou canseg più gjartijes

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Polson Control Center right away (1800-222-1222) In case of overdose, get medical help or contact a Keepoutofreach of children. pro fessional before use.

If pregnant or bre as t-fee ding, ask a health

- you have difficulty swallo wing the caplet
- you get abd ominal swelling or buiging. These may be algns of a serious condition.
 - diarrhe a lasts for more than 2 days
 - symptoms get worse
 - gob nae sug sak s goctor if

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dz zines s may occur. Be careful when difwing or When using this product tiredness, drowsiness or ceutain prescription drugs.

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- a history of abnormal heart rhy frm ■ mucus inthe stool ■ shistory of liver disease
- Ask a doctor before use If you have In fever
 - IĮ λοη μενε η ĮĮ μοτημλ εννεη ονγιμθ

Do not use if you have blood yor black stool

Urug Facts (continued)

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US 85 relieves symptoms of diarrhe a plus bloating, pressure and cramps, commornly referred to as gas

26 g-UTIA. Simethicone USP, 125 mg. Lope ramide H CI USP, 2 mg. Anti-damheal Active ingredients (in each caplet) s əsodın_d

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NDC 51660-069-12

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Distributed by: Ohm Laboratories I New Brunswick, NJ 08901 Manufactured by: Sun Pharmaceutical Industries Limited, MOHALI, INDIA

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

ohm

Loperamide HCI 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)

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Inac tive ingredients calcium alicate, coloidal silicon dioxide, dibasic calcium prospitate, microcnystalline cellulose, sodium

Drug Facts (continued)

†Ohm is a registered trademark of Sun Pharmaceulical in dustries, inc. All other trademarks are property of their respective owners.

Keep the carton. It contains important information,

PRINCIPAL DISPLAY PANEL - 18 Caplet Blister Pack Carton

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

NDC 51660-069-18

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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

Directions

In case of overdose, get medical help or contact a Poison Control Center right away (1 800-2222- 12 22) protessional before use. Keep outof reach of child ren.

If pregnant or breast-feeding, aska health

- diamhee lasts for more than 2 days
 wou get abdominal awellingor bulging. These may
 be signs of a serious condition.
 wou have difficulty a wallowing the caplet
- - symptoms get worse
 - Stop use andask adoctorif

dizziness may occur. Ве саге'ul when driving or When using this product tiredness, drowsiness or ca. gru bies cubriou qurâs

a prescription drug. Loperamide may interact with Aska dodor orpharmacist before use if you are taking

- Ask a doctor beforeuseit you have m fever m mucus in the stod m a his bry or liver disease a a history of abrormal heart rify him

Do not use ■ if you have bloody or black stod ■ if you have difficulty swallowing Drug Facts (continued)

blister unitisopen or torn ■ Tamp erevident: Do Notuse if carton is open or if thgil mo i esc h caplet contains: calcium 142 mg
 store between S - 25 °C (68 - 7 17F). Protect Other information (ed 55 of qu) esu ton do dildren under 2)ears snæy 3-2 nenblirb (sdl 74 ot 48) æka dodor sn uod 45 ni Tcaplet after the first locae abool; T/Z caplet after each subsequent locae atool; but no more than 2 caplets or A bours snsey 8-8 nenblirb (sdl 92-84) en Lod AS ni but no more than 3 caplets Tcaplet after the first loose stool; T/S caplet aftereach subsequent loose atool; easey FT-9 nenblirb (edl 39-03) in 24 hours Scaplets after the first loose stool; 1 caplet after each subsequent loose stool; adults and child ren 12 years and over weight to dose; otherwise, use age. ■ find right dose on chart below. If possible, use Unug Facts (continued)

Heart alent: Taking more than directed can cause serious heart problems or death Albergy alert: Do not use if you have ever had a rash or other all ergic reaction to loperamide HCI Marnings Uses relieves symptoms of diarrh ea plus bloating, pressure and cramps, commonly reterred to as g.a.

Simethicone USP, 125 mg..... Loperami de HCI USP, 2 mg..... AVECI-OLI SILLIJGSTI səsod.ın_d Active ingredients (in each caplet)

Unig Facts

NDC 51660-069-18

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

ohm

Loperamide HCI 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)

Questions? call 1-800-406-7 984

starch glycolate, stean cadd calcium phosphate, microcrystalline cellulose, sodium calcium silicate, colloidal silicon dioxide, dibasic sınə ibər gar əv də səni

Drug Facts (continued)



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Distributed by: Ohm Laboratories Inc., New Brunswick, NJ 08901 Manufactured by: Sun Pharmaceutical Industries Limited, MOHALI, INDIA

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

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adults and child ren 12 years and over

weight to dose; otherwise, use age. ■ find ng ht dose on chart below. If possible, use

nund Facts (continued)

■ take with a full (8 oz.) glass of water

■ take only on an empty s tomach (1 hour betne or 2 hours affera meal)

 drink plenty of clear fluids to help prevent dehydration caused by diarrhea Directions

In case of overdose, get medical help orcontact a Poison Control Center right away (1 800-222- 12 22) professional before use. Keep out of reach of children.

If pregnant or breast-feeding, aska health

Stop use and ask a doctorif орегаблу тасћіпегу.

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

a prescription drug. Loperamide may in eract with cer bin prescription drugs. Aska doctor or pharmacist before use if you are taking mit yith tread lisemonds to yoskid is

mucus in the stod 🔳 a his tony of liver disease Ask a doctor before use if you have 🔳 fever

Do not use ■ if you have bloody or black atod if you have difficulty swallowing

Drug Facts (continued)

Heart allert: Taking more than directed can cause serious heart problems or death Albergy alert: Do not use if you have ever had a rash or other all ergic reaction to loperamide HCI Marnings Uses relieves symptoms of diarrhea plus bloating, pressure and cramps, commonly referred to as g as

Simethicone USP, 125 mg..... and-imA Loperami de HCI USP, 2 mg..... Anti-diarmea səsodund

(təl qaə dərə ni) ət nə ibəngni əv itə A

Urug Facts

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

in 24 hours but no more than 4 caplets

Scaplets after the first loose stool; 1 caplet after each

anpa edn eur joose stool;

NDC 51660-069-24



Anti-Diarrheal/Anti-Gas Multi-Symptom Relief

Relieves symptoms of diarrhea plus

- Cramps & Pressure
- Bloating
- · Gas

24 CAPLETS* (*capsule-shaped tablets)

(in es tions? call 1-800-406-7984

starch glycolate, steanic acid calcium phosphate, microcrystalline cellulose, sodium calcium ali cate, colloidal ali icon dioxide, dibas ic STREET BUT STREET

Drug Facts (continued)







Manufactured by:
Sun Pharmaceutical
Industries Limited,
MOHALI, INDIA
Distributed by:
Chm Laboratories Inc.,
New Brurswick,
NJ 08901

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LOPERAMIDE HCL AND SIMETHICONE

loperamide hcl and simethicone tablet

Product Information

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

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg		
DIMETHICONE (UNII: 92RU3N3Y10) (DIMETHICONE - UNII:92RU3N3Y10)	DIMETHICONE	125 mg		

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

Product Characteristics			
Color	WHITE (white to off-white)	Score	no score
Shape	CAPSULE	Size	16mm
Flavor		Imprint Code	NA
Contains			

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		
Marketing Information				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
AN	DA	ANDA077500	01/13/2022	

Labeler - Ohm Laboratories Inc. (184769029)

Registrant - Sun Pharmaceutical Industries, Inc. (146974886)

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

Revised: 8/2022 Ohm Laboratories Inc.