

## **ANTI-DIARRHEAL- loperamide hydrochloride capsule, liquid filled**

**Freds Inc**

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### **Drug Facts**

#### **Active Ingredient (in each capsule)**

Loperamide HCl 2 mg

#### **Purpose**

Anti- diarrheal

#### **Use**

controls symptoms of diarrhea, including Traveler's Diarrhea

#### **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 problem or death

#### **Do not use**

- if you have bloody or black stool
- in children under 12 years of age

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

- fever
- mucus in the stool
- a history of liver disease

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

taking antibiotics.

#### **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 gets worse
- diarrhea lasts for more than 2 days
- you get abdominal swelling or bulging. 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.

#### **Directions**

- **drink plenty of clear fluids to help prevent dehydration caused by diarrhea**
- **not for use in children under 12 years of age**
- adults and children 12 years of age and over: 2 softgels after the first loose stool; 1 softgel after each subsequent loose stool; but no more than 4 softgels in 24 hours

#### **Other information**

- store at 20°-25° C (68°-77° F). Protect from light.
- avoid excessive heat above 40°C (104°F).
- do not use if carton or blister unit is open or torn
- see side panel for lot number and expiration date

#### **Inactive Ingredients**

butylated hydroxyanisole, edible ink, FD&C Blue #1, gelatin, glycerin, glyceryl caprylate, polyoxyl 40 hydrogenated castor oil and purified water.

#### **Questions or comments?**

call 1-877-753-3935 Monday-Friday 9AM-5PM EST

#### **Principal Display Panel**

Anti-Diarrheal

Loperamide HCl, 2mg

Controls the symptoms of diarrhea

Suitable For Adults And Children 12 Years And Over

SOFTGELS\*\*

\*\*EACH LIQUID-FILLED CAPSULE CANTAINS 2 MG LOPERAMIDE HCl

Compare To The Active Ingredients in Imodium® A-D\*

**THIS PRODUCT IS PACKAGED IN A CHILD-RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.**

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.**

\*This product is not manufactured or distributed by McNeil Consumer & Specialty Pharmaceuticals, distributor of Imodium® A-D.

DISTRIBUTED BY: fred's, Inc.

4300 NEW GETWELL RD.,

MEMPHIS, TN 38118

www.fredsinc.com

#### **Product Label**

This product is not manufactured or distributed by McNeil Consumer & Specialty Pharmaceuticals, distributor of Imodium® A-D.

<p><b>Questions or comments?</b> Call 1-877-753-3935 Monday-Friday 9AM-5PM EST</p>	<p><b>Stop use and ask a doctor if</b>  <ul style="list-style-type: none"> <li>■ diarrhea lasts for more than 2 days</li> <li>■ symptoms get worse</li> </ul> </p>
<p><b>Inactive ingredients</b> butylated hydroxyanisole, edible ink, FD&amp;C blue #1, gelatin, glycerin, glyceryl caprylate, polyoxyl 40 hydrogenated castor oil, purified water</p>	<p><b>When using this product</b> tiredness, drowsiness, or dizziness may occur. Be careful when driving or operating machinery.</p>
<p><b>Other information</b>  <ul style="list-style-type: none"> <li>■ store at 20°-25°C (68°-77°F). Protect from light.</li> <li>■ avoid excessive heat above 40°C (104°F)</li> <li>■ do not use if carton or blister unit is open or torn</li> <li>■ see side panel for lot number and expiration date</li> </ul> </p>	<p><b>Ask a doctor or pharmacist before use if you are</b>  <ul style="list-style-type: none"> <li>■ a history of liver disease</li> <li>■ fever</li> <li>■ mucus in the stool</li> </ul> </p>
<p><b>Directions</b>  <ul style="list-style-type: none"> <li>■ drink plenty of clear fluids to help prevent dehydration caused by diarrhea</li> <li>■ not for use in children under 12 years of age</li> <li>■ adults and children 12 years of age and over: 2 softgels after the first loose stool; 1 softgel after each subsequent loose stool; but no more than 4 softgels in 24 hours</li> </ul> </p>	<p><b>Do not use</b>  <ul style="list-style-type: none"> <li>■ if you have bloody or black stool</li> <li>■ in children under 12 years of age</li> </ul> </p>
<p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.</p>	<p><b>Warnings</b>  <b>Allergy alert:</b> Do not use if you have ever had a rash or other allergic reaction to loperamide HCl.  <b>Heart alert:</b> Taking more than directed can cause serious heart problems or death.</p>
<p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p>	<p><b>Use</b> Controls symptoms of diarrhea, including Travelers' Diarrhea.</p>
<p><b>Drug Facts (continued)</b>  <ul style="list-style-type: none"> <li>■ you get abdominal swelling or bulging. These may be signs of a serious condition.</li> </ul> </p>	<p><b>Active ingredient (in each capsule)</b> Loperamide HCl 2 mg.....Anti-diarrheal</p>
<p><b>Purpose</b></p>	<p><b>Drug Facts</b></p>



# Anti-Diarrheal

Loperamide HCl, 2 mg



NDC 55315-520-24



# Anti-Diarrheal

Loperamide HCl, 2 mg

CHILD-RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

ARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

**Controls the Symptoms Of Diarrhea  
Suitable For Adults And Children 12 Years And Over**

**24 SOFTGELS\*\***

\*\*EACH LIQUID-FILLED CAPSULE CONTAINS 2 mg LOPERAMIDE HCl

Compare To The Active Ingredient In  
**Imodium® A-D\***

THIS PRODUCT IS PACKAGED IN A C  
KEEP OUTER C

Lot No.:  
Exp. Date:

DISTRIBUTED BY: fred's, Inc.  
4300 NEW GETWELL RD,  
MEMPHIS, TN 38118  
www.fredsinc.com

**100%** satisfaction  
guaranteed  
Questions or comments:  
1-855-331-FRED (3733)



REV # 9/16  
PLD-F45J FC004405

**FRED'S PHARMACY Anti-Diarrheal**

**ANTI-DIARRHEAL**

loperamide hydrochloride capsule, liquid filled

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55315-520
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
LOPERAMIDE HYDROCHLORIDE (UNII: 77TI35393C) (LOPERAMIDE - UNII:6X9OC3H4II)	LOPERAMIDE HYDROCHLORIDE	2 mg

**Inactive Ingredients**

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOCAPRYLATE (UNII: TM2TZD4G4A)	
POLYOXYL 40 HYDROGENATED CASTOR OIL (UNII: 7YC686GQ8F)	
WATER (UNII: 059QF0K00R)	

**Product Characteristics**

<b>Color</b>	BLUE	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	10 mm
<b>Flavor</b>		<b>Imprint Code</b>	P13
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55315-520-24	2 in 1 CARTON	07/08/2010	
1		12 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
NDA	NDA021855	07/08/2010	

**Labeler** - Freds Inc (005866116)

Revised: 8/2017

Freds Inc