FDASubmissionArtwork_40121027 8_IMODIUM_MSR_4ct_CARTON_R2.pdf 1 11/27/18 1:34 PM

NDC 50580-338-XX

Imodium®

Loperamide HCl, 2 mg / Simethicone, 125 mg Antidiarrheal/Anti-gas

FPO 1 2 of 5

XXXXXXXX

Multi-Symptom Relief

Caplet

Relieves symptoms of diarrhea *plus*

- Cramps & Pressure
- Bloating
- Gas

4 Caplets*

*capsule-shaped tablets

Actual Size

FPO 1 2 of 5

XXXXXXXX

FPO 1 2 of 5

XXXXXXXX

FPO 1 2 of 5

XXXXXXXX

How can we help?

1-877-895-3665

XXXXXXXX

Drug Facts (continued)

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; ½ 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; ½ 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 165 mg, sodium 3 mg**
- store between 20-25°C (68-77°F). Protect from light.
- **do not use if carton is open or if blister unit is open or torn**

Inactive ingredients

acesulfame potassium, croscarmellose sodium, dibasic calcium phosphate, flavor, microcrystalline cellulose, stearic acid

Drug Facts

Active ingredients (in each caplet)	Purposes
Loperamide HCl 2 mg	Anti-diarrheal
Simethicone 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

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 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. (1-800-222-1222)

Distributed by:
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McNeil Consumer Healthcare Division
Fort Washington, PA 19034 USA
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www.imodium.com
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Care To Recycle™

LOT

EXP

Drug Facts (continued)

Questions or comments?

call **1-877-895-3665** (toll-free) or **215-273-8755** (collect)

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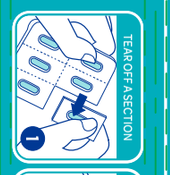

FOLD AND TEAR AT NOTCH

TEAR OFF A SECTION

Labeling Format Information: Fonts: HelveticaDF-Cond Medium, Cond Bold, Cond Bold Italic

Drug Facts: 9.00 pt	Body Text: 6.00 pt	Bullets: 5.00 pt	Horizontal Scale: 75%
Headers: 8.00 pt	Leading: 6.50 pt	Barlines: 2.50 pt	
Subheaders: 6.00 pt	Drug Facts (continued): 8.00 pt	Hairlines: 0.50 pt	Average Tracking: 0

Reference ID: 4361589

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Labeling Format Information: Fonts: HelveticaDF-Cond Medium, Cond Bold, Cond Bold Italic

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Horizontal Scale: 75%
Average Tracking: 0

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Horizontal Scale: 75%

Average Tracking: 0

Reference ID: 4361589

FDASubmissionArtwork_401210462_IMODIUM_MSR_18ct_CARTON_R2.pdf 1 11/27/18 1:30 PM

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Reference ID: 4361589

Labeling Format Information: Fonts: HelveticaDF-Cond Medium, Cond Bold, Cond Bold Italic

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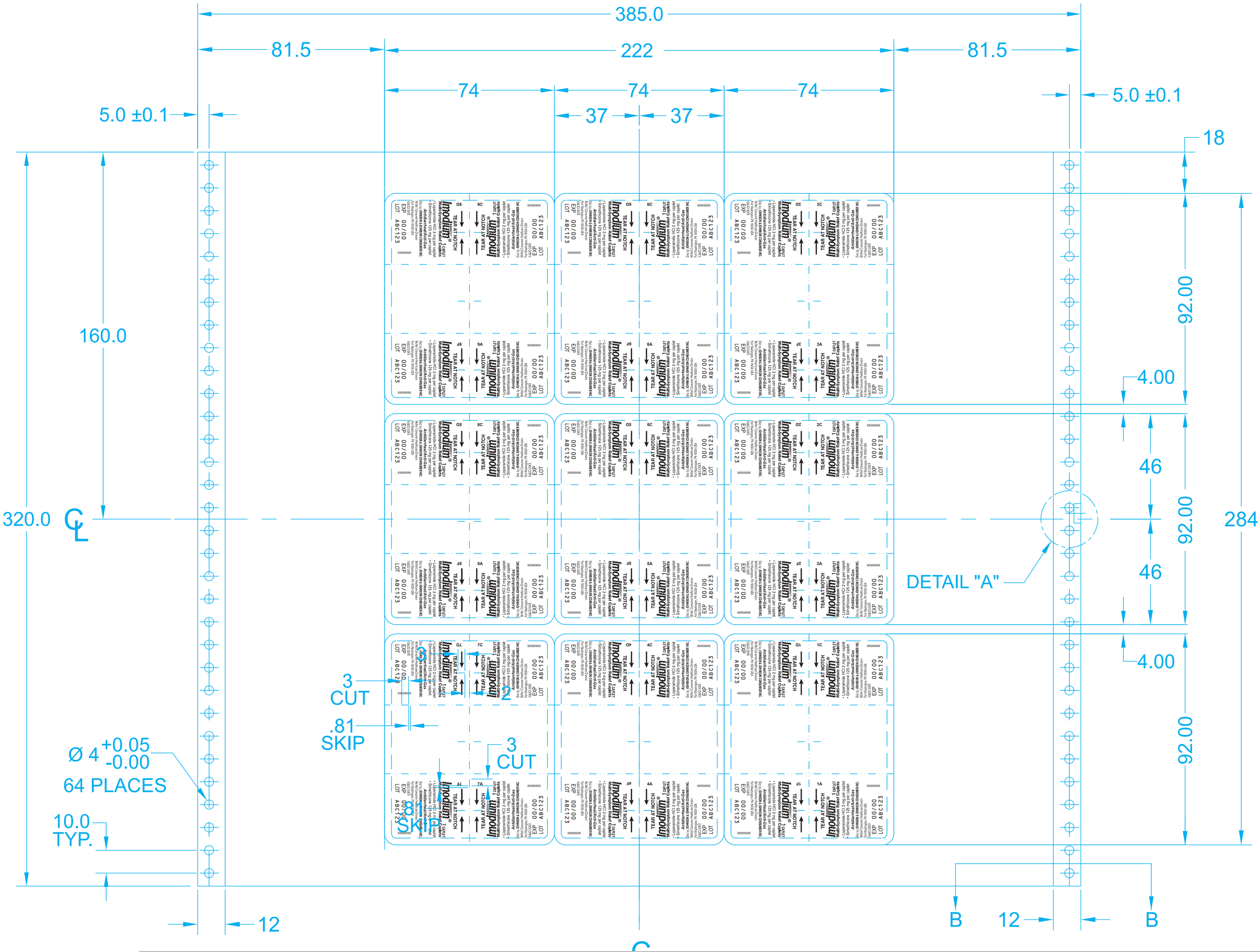
Horizontal Scale: 75%
Average Tracking: 0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92.00
4.00
46
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92.00
284
4.00
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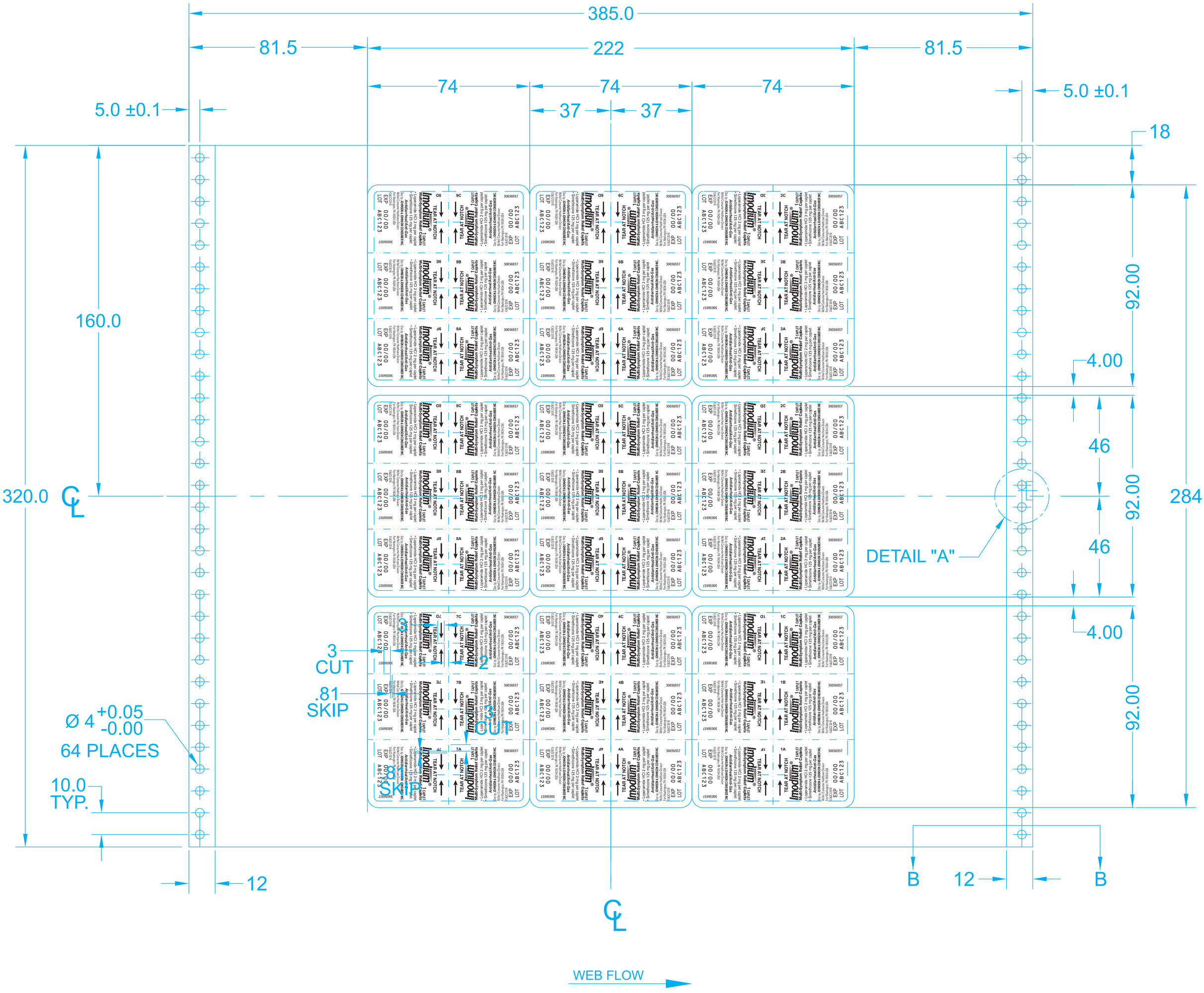

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/s/

VALERIE S PRATT
12/11/2018