**WELLY TRAVEL MEDICINE KIT- meclizine hydrochloride, ibuprofen, loperamide hydrochloride, doxylamine succinate**
**Welly Health PBC**

*Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.*

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**Welly Travel Medicine Kit**

***Motion Sickness Relief, 8 tablets***

***Drug Facts***

***Active ingredient (in each tablet)***

Meclizine HCI 25 mg

**Purpose**

Antiemetic

***Use***

for the prevention and treatment of the nausea, vomiting, or dizziness associated with motion sickness

***Warnings***

**Do not use**

for children under 12 years of age unless directed by a doctor

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

a breathing problem such as emphysema or
- chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland.

**Ask a doctor or pharmacist before use**

if you are taking sedatives or tranquilizers.

**When using this product**
- may cause drowsiness
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery

**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***

- to prevent motion sickness, take the first dose ½ hour to 1 hour before starting activity
- to treat motion sickness, take at first signs of symptoms
- adults and children 12 years and over: 1 to 2 tablets once daily, or as directed by a doctor

***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from heat and humidity
- see label for expiration date and lot number
- use by expiration date on package

***Inactive ingredients***

corn starch, D&C yellow #10 aluminum lake, lactose anhydrous, magnesium stearate, silicon dioxide

***Questions or comments?***

**1-833-BE-WELLY (1-833-239-3559)**

***Pain Relief and Fever Reducer, 16 tablets***

***Drug Facts***

***Active ingredient (in each brown tablet)***

Ibuprofen USP, 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever/fever reducer

***Uses***

- temporarily relieves minor aches and pains due to:
- muscular aches
- backache
- toothache
- menstrual cramps
- headache
- the common cold
- minor pain of arthritis
- temporarily reduces fever

***Warnings***

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- shock
- facial swelling
- asthma (wheezing)
- rash
- skin reddening
- blisters
- hives

If an allergic reaction occurs, stop use and seek medical help right away.

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you

- take more or for a longer time than directed
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product
  **Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**Do not use**

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

**Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn.
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers

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

- under a doctor’s care for any serious condition
- taking aspirin for heart attack or stroke, because uprofen may decrease this benefit of aspirin
- taking any other drug

**When using this product**

- take with food or milk if stomach upset occurs

**Stop use and ask a doctor if**

- you experience any of the following signs of stomach bleeding.
- Feel faint
- have bloody or black stools
- vomit blood
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
- chest pain
- slurred speech

- leg swelling
- trouble breathing
- weakness in one part or side of body
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

**If pregnant or breastfeeding,**

ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

**Keep out of reach of children.**

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

***Directions***

- do not take more than directed
- the smallest effective dose should be used
- adults and children 12 years and over: take 1 tablet every 4 to 6 hours while symptoms persist
- If pain or fever does not respond to 1 tablet, 2 tablets may be used
- do not exceed 6 tablets in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

***Other information***

- **TAMPER EVIDENT: DO NO USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store between 20°-25°C (68°-77°F)
- avoid excessive heat 40°C (104°F)
- see label for expiration date and lot number
- use by expiration date on package

***Inactive ingredients***

carnauba wax, colloidal silicon dioxide, corn starch, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide

***Questions or comments?***

1-833-BE-WELLY

***Gas Relief, 12 chewable tablets***

***Drug Facts***

***Active ingredient (in each chewable tablet)***

Simethicone 125 mg

***Purpose***

Antigas

***Use***

relieves bloating, pressure, and fullness commonly referred to as gas.

***Warning***

**Keep out of reach of children.**

***Directions***

- chew or crush tablets completely before swallowing; do not swallow tablets whole
- adults: take 1 or 2 chewable tablets as needed after meals and at bedtime
- do not exceed 4 chewable tablets in 24 hours unless directed by a doctor

***Other information***

- each chewable tablets contains: calcium 90 mg
- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from moisture
- see label for expiration date and lot number
- use by expiration date on package

***Inactive ingredients***

D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrates hydrated, FD&C red #40 aluminum lake, flavor, silicon dioxide, sorbitol, starch, stearic acid, talc, tribasic calcium phosphate

***Questions or comments?***

1-833-BE-WELLY (1-833-239-3559)

***Anti-Diarrheal, 12 tablets***

***Drug Facts***

***Active ingredient (in each caplet)***

Loperamide HCI 2 mg

***Purpose***

Anti-diarrheal

***Use***

controls symptoms of diarrhea, including Travelers' Diarrhea

*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**

you have bloody or black stool.

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

- A 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.

**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 (1-800-222-1222) right away.

*Directions*

- **drink plenty of clear fluids to help prevent dehydration caused by diarrhea**
- find right dose on chart. 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 (34-47 lbs) | ask a doctor |
| Children under 2 years (up to 33 lbs) | do not use |

*Other information*

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**

- store between 20°-25°C (68°-77°F)
- see label for expiration date and lot number
- use by expiration date on package

***Inactive ingredients***

corn starch, D&C yellow #10 aluminum lake, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, silicon dioxide

***Questions or comments?***

**1-833-BE-WELLY**

***Sleep Aid, 8 tablets***

***Drug Facts***

***Active ingredient (in each tablet)***

Doxylamine succinate 25 mg

***Purpose***

Nighttime sleep-aid

***Use***

helps to reduce difficulty in falling asleep

***Warnings***

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

- a breathing problem such as asthma, emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- glaucoma

**Ask a doctor or pharmacist before**

use if you are taking any other drugs.

**When using this product**

- avoid alcoholic beverages
- take only at bedtime

**Stop use and ask a doctor**

if sleeplessness persists continuously for more than two weeks. Insomnia may be a symptom of a serious underlying medical illness.

**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 (1-800-222-1222) right away.

***Directions***

- adults and children 12 years and over: take one tablet 30 minutes before going to bed; take once daily or as directed by a doctor
- children under 12 years: do not use

***Other information***

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at controlled room temperature 20°-25°C (68-77°F)
- see label for expiration date and lot number
- use by expiration date on package

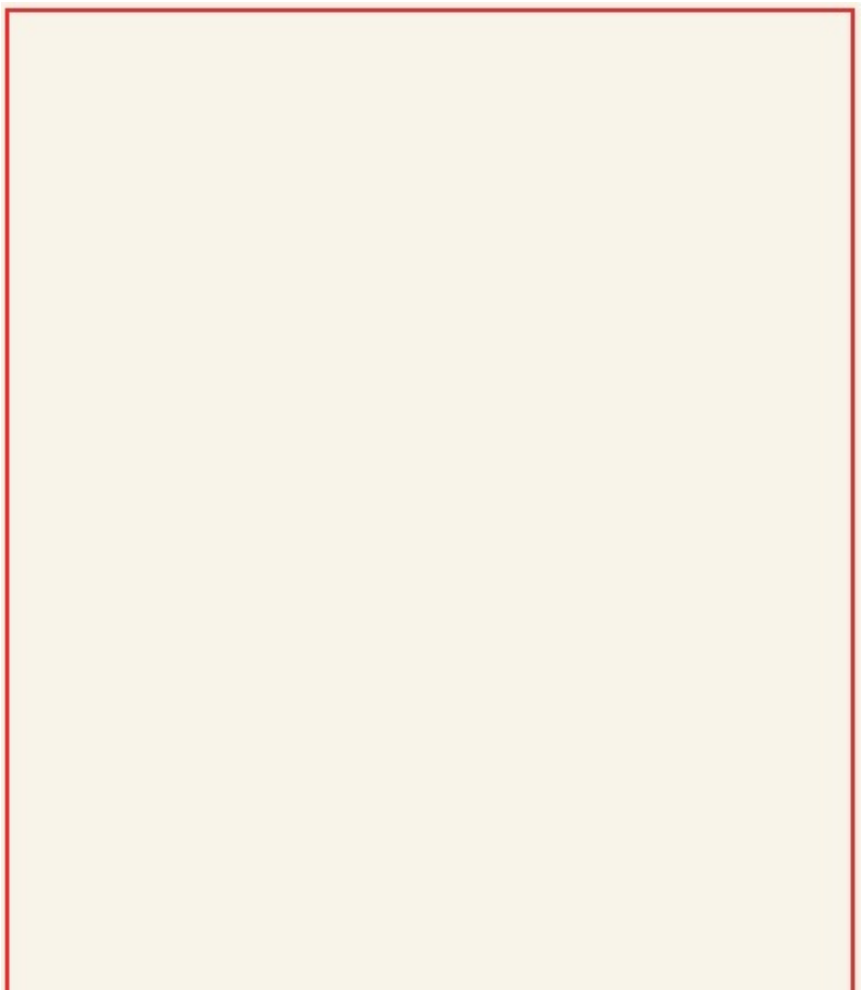
***Inactive ingredients***

dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

***Questions or comments?***

**1-833-BE-WELLY**

**Package Labeling:(72663-205-48)**



# Travel Medicine Kit

FOR WHEN YOU HAVE STUFF TO DO ✖ AND YOU NEED TO POWER THROUGH

## 56 Tablets

welly REMEDIES™

# Travel Medicine Kit

**INDIVIDUALLY WRAPPED REMEDIES**
to tackle your symptoms one-by-one

**Motion Sickness Relief**
Meclizine HCl 25mg, *Antiemetic*

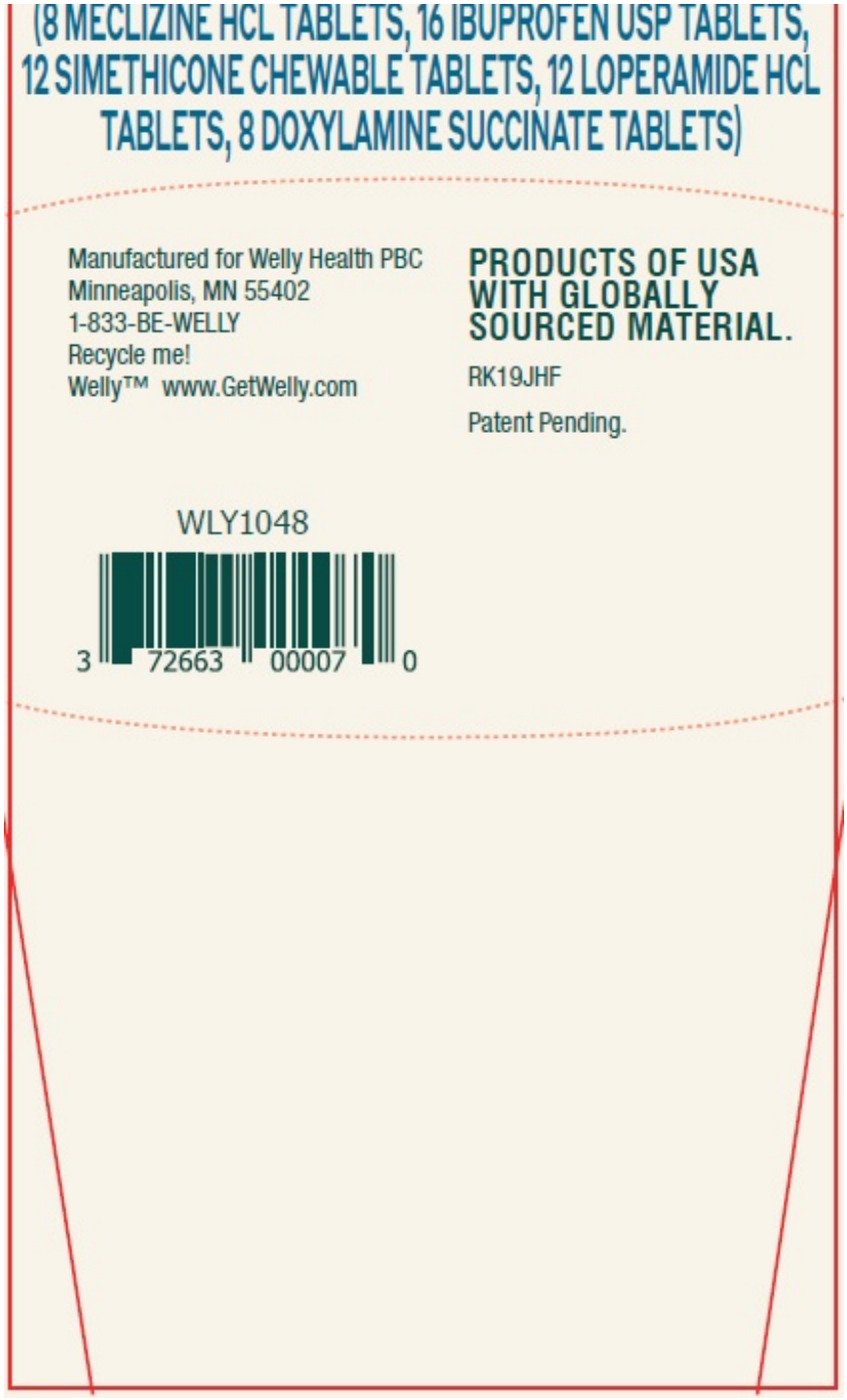
**Pain Relief**
Ibuprofen USP 200mg, *Pain Reliever/Fever Reducer (NSAID)*

**Gas Relief**
Simethicone 125mg, *Antigas*

**Anti-Diarrheal**
Loperamide HCl 2mg, *Anti-Diarrheal*


**Sleep Aid**
Doxylamine Succinate 25mg, *Nighttime Sleep Aid*

## 56 Tablets


(8 MECLIZINE HCL TABLETS, 16 IBUPROFEN USP TABLETS, 12 SIMETHICONE CHEWABLE TABLETS, 12 LOPERAMIDE HCL TABLETS, 8 DOXYLAMINE SUCCINATE TABLETS)
Manufactured for Welly Health PBC
Minneapolis, MN 55402
1-833-BE-WELLY
Recycle me!
Welly™ www.GetWelly.com
PRODUCTS OF USA WITH GLOBALLY SOURCED MATERIAL.
RK19JHF
Patent Pending.
WLY1048
3 72663 00007 0

**undefined**

## Drug Facts — Motion Sickness Relief

**Active ingredient (in each tablet) Purpose**
Meclizine HCl 25 mg.....Antiemetic

**Use** for the prevention and treatment of the nausea, vomiting, or dizziness associated with motion sickness

### Warnings

Do not use for children under 12 years of age unless directed by a doctor

**Ask a doctor before use if you have**
a breathing problem such as emphysema or
- chronic bronchitis
- glaucoma
- difficulty in urination due to enlargement of the prostate gland.

**Ask a doctor or pharmacist before use if you are** taking sedatives or tranquilizers.

**When using this product**
- may cause drowsiness
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- avoid alcoholic beverages
- use caution when driving a motor vehicle or operating machinery

▶

## Drug Facts (continued)

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

- to prevent motion sickness, take the first dose ½ hour to 1 hour before starting activity
- to treat motion sickness, take at first signs of symptoms
- adults and children 12 years and over: 1 to 2 tablets once daily, or as directed by a doctor

### Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from heat and humidity
- see label for expiration date and lot number
- use by expiration date on package

### Inactive ingredients

corn starch, D&C yellow #10 aluminum lake, lactose anhydrous, magnesium stearate, silicon dioxide

▶

## Questions or comments?

1-833-BE-WELLY (1-833-239-3559)

# Package Labeling:(72663-428-48)

## Drug Facts — Pain Reliever & Fever Reducer

**Active ingredient (in each brown tablet) Purpose**
**Ibuprofen USP, 200 mg (NSAID)***.....Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

**Uses**
- temporarily relieves minor aches and pains due to:
- muscular aches
- backache
- toothache
- menstrual cramps
- headache
- the common cold
- minor pain of arthritis
- temporarily reduces fever

### Warnings

**Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
- shock
- facial swelling
- asthma (wheezing)
- rash
- skin reddening
- blisters
- hives

If an allergic reaction occurs, stop use and seek medical help right away.

**Stomach bleeding warning:** This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you
- take more or for a longer time than directed ▶

## Drug Facts (continued)

- take a blood thinning (anticoagulant) or steroid drug
- are age 60 or older
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have had stomach ulcers or bleeding problems
- have 3 or more alcoholic drinks every day while using this product

**Heart attack and stroke warning:** NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

**Do not use**
- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

**Ask a doctor before use if**
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn.
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic
- you have problems or serious side effects from taking pain relievers or fever reducers ▶

## Drug Facts (continued)

**Ask a doctor or pharmacist before use if you are**
- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

**When using this product**
- take with food or milk if stomach upset occurs

**Stop use and ask a doctor if**
- you experience any of the following signs of stomach bleeding.
- Feel faint
- have bloody or black stools
- vomit blood
- have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
- chest pain
- slurred speech
- leg swelling
- trouble breathing
- weakness in one part or side of body
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present in the painful area
- any new symptoms appear

**If pregnant or breastfeeding,** ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless definitely directed to do so by a ▶

## Drug Facts (continued)

doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

### Directions

- do not take more than directed
- the smallest effective dose should be used
- adults and children 12 years and over: take 1 tablet every 4 to 6 hours while symptoms persist
- If pain or fever does not respond to 1 tablet, 2 tablets may be used
- do not exceed 6 tablets in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

### Other information

- TAMPER EVIDENT: DO NO USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store between 20°-25°C (68°-77°F)
- avoid excessive heat 40°C (104°F)
- see label for expiration date and lot number
- use by expiration date on package ▶

## Drug Facts (continued)

**Inactive ingredients** carnauba wax, colloidal silicon dioxide, corn starch, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, red iron oxide, sodium starch glycolate, stearic acid, titanium dioxide

**Questions or comments?**
1-833-BE-WELLY ▶

# Package Labeling:(72663-746-48)

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

## Gas Relief

### Drug Facts

**Active ingredient (in each chewable tablet)** — **Purpose**

Simethicone 125 mg.....Antigas

**Use** relieves bloating, pressure, and fullness commonly referred to as gas.

**Warning**

Keep out of reach of children.

**Directions**

- chew or crush tablets completely before swallowing; do not swallow tablets whole
- adults: take 1 or 2 chewable tablets as needed after meals and at bedtime
- do not exceed 4 chewable tablets in 24 hours unless directed by a doctor ▶

### Drug Facts (continued)

**Other information**

- each chewable tablets contains: calcium 90 mg
- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- protect from moisture
- see label for expiration date and lot number
- use by expiration date on package

**Inactive ingredients** D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrates hydrated, FD&C red #40 aluminum lake, flavor, silicon dioxide, sorbitol, starch, stearic acid, talc, tribasic calcium phosphate

**Questions or comments?**

1-833-BE-WELLY (1-833-239-3559) ▶

**Package Labeling:(72663-567-48)**

### Drug Facts — Anti-Diarrheal

**Active ingredient (in each caplet) Purpose**

Loperamide HCl 2 mg.....Anti-diarrheal

**Use** controls symptoms of diarrhea, including Travelers' 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 problems or death.

**Do not use** if you have bloody or black stool.

**Ask a doctor before use if you have** ■ A 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.

**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 (1-800-222-1222) right away.

**Directions**

- **drink plenty of clear fluids to help prevent dehydration caused by diarrhea**
- find right dose on chart. 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 (34-47 lbs) | ask a doctor |
| Children under 2 years (up to 33 lbs) | do not use |

### Drug Facts (continued)

**Other information**

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store between 20°-25°C (68°-77°F)
- see label for expiration date and lot number
- use by expiration date on package

**Inactive ingredients** corn starch, D&C yellow #10 aluminum lake, dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, silicon dioxide

**Questions or comments?**

1-833-BE-WELLY ▶

**Package Labeling:(72663-369-48)**

## Sleep Aid

### Drug Facts

**Active ingredient (in each tablet)** — **Purpose**

Doxylamine succinate 25 mg..... Nighttime sleep-aid

**Use** helps to reduce difficulty in falling asleep

### Warnings

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

- a breathing problem such as asthma, emphysema or chronic bronchitis
- difficulty in urination due to enlargement of the prostate gland
- glaucoma

**Ask a doctor or pharmacist** before use if you are taking any other drugs.

**When using this product**

- avoid alcoholic beverages
- take only at bedtime

**Stop use and ask a doctor** if sleeplessness persists continuously for more than two weeks. Insomnia may be a symptom of a serious underlying medical illness.

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

### Drug Facts (continued)

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

### Directions

- adults and children 12 years and over: take one tablet 30 minutes before going to bed; take once daily or as directed by a doctor
- children under 12 years: do not use

### Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at controlled room temperature 20°-25°C (68-77°F)
- see label for expiration date and lot number
- use by expiration date on package

### Inactive ingredients

dibasic calcium phosphate dihydrate, FD&C blue #1 aluminum lake, magnesium stearate, microcrystalline cellulose, sodium starch glycolate

### Questions or comments?

1-833-BE-WELLY

# WELLY TRAVEL MEDICINE KIT

meclizine hydrochloride, ibuprofen, loperamide hydrochloride, doxylamine succinate kit

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:72663-205 |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:72663-205-48 | 1 in 1 KIT | 04/06/2020 | |

| Quantity of Parts | | |
|---|---|---|
| **Part #** | **Package Quantity** | **Total Product Quantity** |
| **Part 1** | 1 BLISTER PACK | 8 |
| **Part 2** | 1 BOTTLE | 16 |

| | | |
|---|---|---|
| **Part 3** | 2 BLISTER PACK | 12 |
| **Part 4** | 1 BLISTER PACK | 12 |
| **Part 5** | 1 BLISTER PACK | 8 |

## Part 1 of 5

## MOTION SICKNESS RELIEF

meclizine hydrochloride tablet

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:72663-632 |
| **Route of Administration** | ORAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **MECLIZINE HYDROCHLORIDE** (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570) | MECLIZINE HYDROCHLORIDE | 25 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **D&C YELLOW NO. 10 ALUMINUM LAKE** (UNII: CQ3XH3DET6) | |
| **ANHYDROUS LACTOSE** (UNII: 3SY5LH9PMK) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | yellow | **Score** | no score |
| **Shape** | ROUND | **Size** | 9mm |
| **Flavor** | | **Imprint Code** | 44403 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:72663-632-48 | 8 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 |
|---|---|---|---|
| OTC monograph final | part336 | 04/06/2020 | |

## Part 2 of 5

# PAIN RELIEF AND FEVER REDUCER

ibuprofen tablet

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:72663-428 |
| **Route of Administration** | ORAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **IBUPROFEN** (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | IBUPROFEN | 200 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **CARNAUBA WAX** (UNII: R12CBM0EIZ) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **HYPROMELLOSE, UNSPECIFIED** (UNII: 3NXW29V3WO) | |
| **ANHYDROUS LACTOSE** (UNII: 3SY5LH9PMK) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **POLYDEXTROSE** (UNII: VH2XOU12IE) | |
| **POLYETHYLENE GLYCOL, UNSPECIFIED** (UNII: 3WJQ0SDW1A) | |
| **FERRIC OXIDE RED** (UNII: 1K09F3G675) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TITANIUM DIOXIDE** (UNII: 15FIX9V2JP) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | brown | **Score** | no score |
| **Shape** | ROUND | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | 44291 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:72663-428-48 | 16 in 1 BOTTLE; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|

| | | | |
|---|---|---|---|
| OTC monograph not final | part343 | 04/06/2020 | |

## Part 3 of 5

## GAS RELIEF

dimethicone tablet, chewable

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:72663-746 |
| **Route of Administration** | ORAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **DIMETHICONE** (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O) | DIMETHICONE | 125 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **D&C RED NO. 27 ALUMINUM LAKE** (UNII: ZK64F7XSTX) | |
| **D&C RED NO. 30** (UNII: 2S42T2808B) | |
| **FD&C RED NO. 40** (UNII: WZB9127XOA) | |
| **METHYL SALICYLATE** (UNII: LAV5U5022Y) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |
| **SORBITOL** (UNII: 506T60A25R) | |
| **STEARIC ACID** (UNII: 4ELV7Z65AP) | |
| **TALC** (UNII: 7SEV7J4R1U) | |
| **TRIBASIC CALCIUM PHOSPHATE** (UNII: 91D9GV0Z28) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | pink | **Score** | no score |
| **Shape** | ROUND | **Size** | 14mm |
| **Flavor** | | **Imprint Code** | 44608 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:72663-746-48 | 2 in 1 KIT | | |
| **1** | | 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 |
|---|---|---|---|

| | | | |
|---|---|---|---|
| OTC monograph final | part332 | 04/06/2020 | |

## Part 4 of 5

## ANTI DIARRHEAL

loperamide hydrochloride tablet

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:72663-567 |
| **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 |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **STARCH, CORN** (UNII: O8232NY3SJ) | |
| **D&C YELLOW NO. 10 ALUMINUM LAKE** (UNII: CQ3XH3DET6) | |
| **DIBASIC CALCIUM PHOSPHATE DIHYDRATE** (UNII: O7TSZ97GEP) | |
| **FD&C BLUE NO. 1 ALUMINUM LAKE** (UNII: J9EQA3S2JM) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |
| **SILICON DIOXIDE** (UNII: ETJ7Z6XBU4) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | green (Light) | **Score** | 2 pieces |
| **Shape** | OVAL | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | 44375 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:72663-567-48 | 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 |
|---|---|---|---|
| ANDA | ANDA076497 | 04/06/2020 | |

## Part 5 of 5

## SLEEP AID

doxylamine succinate tablet

| Product Information | |
|---|---|
| **Item Code (Source)** | NDC:72663-369 |
| **Route of Administration** | ORAL |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **DOXYLAMINE SUCCINATE** (UNII: V9BI9B5YI2) (DOXYLAMINE - UNII:95QB77JKPL) | DOXYLAMINE SUCCINATE | 25 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **DIBASIC CALCIUM PHOSPHATE DIHYDRATE** (UNII: O7TSZ97GEP) | |
| **FD&C BLUE NO. 1 ALUMINUM LAKE** (UNII: J9EQA3S2JM) | |
| **MAGNESIUM STEARATE** (UNII: 70097M6I30) | |
| **MICROCRYSTALLINE CELLULOSE** (UNII: OP1R32D61U) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | blue | **Score** | 2 pieces |
| **Shape** | OVAL | **Size** | 10mm |
| **Flavor** | | **Imprint Code** | 44386 |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:72663-369-48 | 8 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 |
|---|---|---|---|
| OTC monograph final | part341 | 04/06/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph not final | part336 | 04/06/2020 | |

**Labeler -** Welly Health PBC (116766884)

Revised: 4/2020 Welly Health PBC