

**WELLY CHILDRENS TRAVEL MEDICINE- acetaminophen, calcium carbonate,
diphenhydramine hydrochloride
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.

Welly Children's Travel Medicine Kit

Children's Pain and Fever Relief, 12 tablets

Drug Facts

Active ingredient (in each chewable tablet)

Acetaminophen 160 mg

Purpose

Pain Reliever/ Fever Reducer

Uses

- for the temporary relief of minor aches and pains associated with
- the common cold
- sore throat
- headache
- toothache
- flu
- and to reduce fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

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

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use

with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if

your child has liver disease.

Ask a doctor or pharmacist before use if

your child is taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- pain persists for more than 5 days or gets worse
- fever persists for more than 3 days or gets worse.
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical even if you do not notice any signs or symptoms.

Directions

- this product does not contain directions or complete warnings for adult use
- do not give more than directed
- find the right dose on the chart below. If possible, use weight to dose; otherwise, use age.
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor

Weight (lb)	Age (yr)	Dose (chewable tablets)*
Under 24	Under 2	Ask a doctor
24-35	2-3	1 tablet
36-47	4-5	1 1/2 tablets
48-59	6-8	2 tablets
60-71	9-10	2 1/2 tablets
72-95	11	3 tablets

*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)
- avoid high humidity
- see label for expiration date and lot number
- use by expiration date on package

Inactive ingredients

citric acid, crospovidone, D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrates

hydrated, ethylcellulose, FD&C blue #1 aluminum lake, flavors, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

Questions or comments?

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

Children's Stomach Soother, 12 tablets

Drug Facts

Active ingredient (in each tablet)

Calcium carbonate 400 mg

Purpose

Antacid

Uses

for the relief of

- heartburn
- sour stomach
- acid indigestion
- upset stomach associated with these symptoms

Warnings

Ask a doctor or pharmacist before use if you are

presently taking a prescription drug. Antacids may interact with certain prescription drugs.

When using this product

- do not take more than 3 chewable tablets (ages 2-5) or 6 chewable tablets (ages 6-11) in a 24-hour period
- do not use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a doctor

Directions

- find the right dose on the chart on the next page based on weight (preferred); otherwise use age
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- repeat dose as needed, not more than 3 times a day

Weight (lb)	Age (yr)	Dose (chewable tablets)*
under 24	under 2	ask a doctor
24-47	2-5	1 tablet
48-95	6-11	2 tablets

*or as directed by a doctor

Other information

- Each chewable tablet contains: calcium 160 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)
- avoid excessive humidity
- see label for expiration date and lot number
- use by expiration date on package

Inactive Ingredients

acacia, cornstarch, D&C red# 27 aluminum lake, D&C red #30 aluminum lake, FD&C red #40 aluminum lake, flavor, magnesium stearate, maltodextrin, silicon dioxide, sodium lauryl sulfate, sucrose, talc

Questions or comments?

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

Children's Allergy Relief, 12 tablets

Drug Facts

Active ingredient (in each chewable tablet)

Diphenhydramine HCl 12.5 mg

Purpose

Antihistamine

Use

temporarily relieves runny nose and relieves sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever or other upper respiratory allergies.

Warnings

Do not use

- with any other product containing diphenhydramine, even one used on skin

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 excitability in children
- may cause marked 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

- find right dose on the chart below
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- take every 4 to 6 hours, or as directed by a doctor
- do not take more than 6 times in 24 hours

Adults and children 12 years of age and over	2 to 4 chewable tablets (25 to 50 mg)
Children 6 to under 12 years of age	1 to 2 chewable tablets (12.5 to 25 mg)
Children under 6 years of age	Consult 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)
- avoid high humidity
- see label for expiration date and lot number
- use by expiration date on package

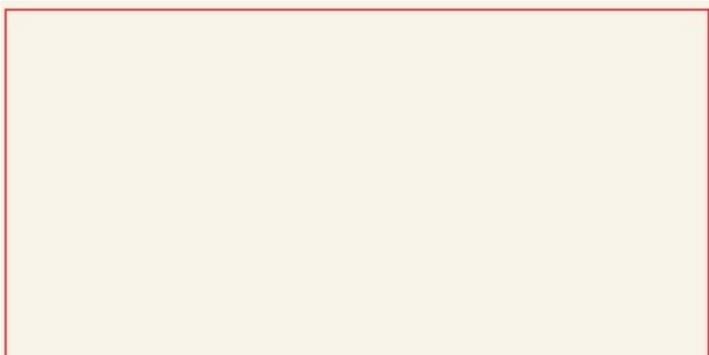
Inactive Ingredients

D&C Red #27 Aluminum Lake, D&C red #30 aluminum lake, dextrates hydrated, ethylcellulose, FD&C Blue #1 aluminum lake, flavor, hydroxypropyl cellulose, magnesium stearate, mannitol, stearic acid, sucralose, sucrose

Questions or comments?

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

Package Labeling:(72663-203-49)



Children's Medicine Travel Kit

KID-FRIENDLY
CHEWABLES



TO HELP
KICK THAT SICK

36 Chewable Tablets

Chew or crush
tablets completely
before using

welly REMEDIES

Children's Medicine Travel Kit

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



Allergy
Relief

Diphenhydramine
HCl 12.5mg,
Antihistamine



Fever Relief
Children's

Acetaminophen
160 mg,
Pain Reliever/
Fever Reducer



Stomach
Soother

Calcium
Carbonate
400 mg,
Antacid

36 Chewable Tablets

(12 DIPHENHYDRAMINE HCL CHEWABLE TABLETS,
12 ACETAMINOPHEN CHEWABLE TABLETS,
12 CALCIUM CARBONATE CHEWABLE 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.

WLY1049



Package Labeling:(72663-233-49)

Drug Facts *Children's Fever Relief*

Active ingredient Purpose (in each chewable tablet)

Acetaminophen 160 mg.....Pain Reliever/
Fever Reducer

Uses

- for the temporary relief of minor aches and pains associated with
 - the common cold
 - headache
 - and to reduce fever
- sore throat
- toothache
- flu

Drug Facts (continued)

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if your child takes

- more than 5 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- skin riddening
- blisters
- rash

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

Sore throat warning: If sore throat is severe, persists for more than 2 days, is accompanied or followed by fever, headache, rash, nausea, or vomiting, consult a doctor promptly.

Do not use with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if your child has liver disease.

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin.

Drug Facts (continued)

Stop use and ask a doctor if

- pain persists for more than 5 days or gets worse
- fever persists for more than 3 days or gets worse.
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical even if you do not notice any signs or symptoms.

Directions

- this product does not contain directions or complete warnings for adult use
- do not give more than directed
- find the right dose on the chart below. If possible, use weight to dose; otherwise, use age.
- chew or crush tablets completely before swallowing; do not swallow tablets whole
- repeat dose every 4 hours while symptoms last
- do not give more than 5 times in 24 hours
- do not give for more than 5 days unless directed by a doctor

Drug Facts (continued)

Weight (lb)	Age (yr)	Dose (chewable tablets)*
Under 24	Under 2	Ask a doctor
24-35	2-3	1 tablet
36-47	4-5	1 ½ tablets
48-59	6-8	2 tablets
60-71	9-10	2 ½ tablets
72-95	11	3 tablets

*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)
- avoid high humidity
- see label for expiration date and lot number
- use by expiration date on package

Inactive ingredients citric acid, crospovidone, D&C red #27 aluminum lake, D&C red #30 aluminum lake, dextrates hydrated, ethylcellulose, FD&C blue #1 aluminum lake, flavors, magnesium stearate, mannitol, polyethylene, stearic acid, sucralose

Questions or comments?
1-833-BE-WELLY (1-833-239-3559)

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

Kid friendly chewables to help kick that sick.

- Allergy Relief Diphenhydramine HCl, 12.5mg
- Stomach Soother Calcium Carbonate, 400mg
- Fever Relief Children's Acetaminophen, 160mg

For full drug facts and appropriate ages peel at the edge or visit getwelly.com/pages/faq/drugfacts

Package Labeling:(72663-225-49)

KEEP DRUG FACT BOOKLET FOR COMPLETE PRODUCT INFORMATION

Drug Facts *Children's Stomach Soother*

Active ingredient (in each tablet) Calcium carbonate 400 mg	Purpose Antacid
---	---------------------------

Uses for the relief of
 ■ heartburn ■ sour stomach
 ■ acid indigestion
 ■ upset stomach associated with these symptoms

Warnings
 Ask a doctor or pharmacist before use if you are presently taking a prescription drug. Antacids may interact with certain prescription drugs.

When using this product
 ■ do not take more than 3 chewable tablets (ages 2-5) or 6 chewable tablets (ages 6-11) in a 24-hour period
 ■ do not use the maximum dosage of this product for more than 2 weeks, except under the advice and supervision of a doctor
 Keep out of reach of children.

Directions
 ■ find the right dose on the chart on the next page based on weight (preferred); otherwise use age ▶

Drug Facts (continued)

- chew or crush tablets completely before swallowing; do not swallow tablets whole
- repeat dose as needed, not more than 3 times a day

Weight (lb)	Age (yr)	Dose (chewable tablets)*
under 24	under 2	ask a doctor
24-47	2-5	1 tablet
48-95	6-11	2 tablets

*or as directed by a doctor

Other information

- Each chewable tablet contains: calcium 160 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)
- avoid excessive humidity
- see label for expiration date and lot number
- use by expiration date on package ▶

Drug Facts (continued)

Inactive Ingredients acacia, cornstarch, D&C red# 27 aluminum lake, D&C red #30 aluminum lake, FD&C red #40 aluminum lake, flavor, magnesium stearate, maltodextrin, silicon dioxide, sodium lauryl sulfate, sucrose, talc

Questions or comments?
 1-833-BE-WELLY (1-833-239-3559)

Package Labeling:(72663-347-49)

Drug Facts *Children's Allergy Relief*

Active ingredient (in each chewable tablet) Diphenhydramine HCl 12.5 mg.	Purpose Antihistamine
---	---------------------------------

Use
 temporarily relieves runny nose and relieves sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever or other upper respiratory allergies. ▶

Drug Facts (continued)

Warnings
 Do not use
 ■ with any other product containing diphenhydramine, even one used on skin

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 excitability in children
 ■ may cause marked 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. ▶

Drug Facts (continued)

Directions
 ■ find right dose on the chart below
 ■ chew or crush tablets completely before swallowing; do not swallow tablets whole
 ■ take every 4 to 6 hours, or as directed by a doctor
 ■ do not take more than 6 times in 24 hours

Adults and children 12 years of age and over	2 to 4 chewable tablets (25 to 50 mg)
Children 6 to under 12 years of age	1 to 2 chewable tablets (12.5 to 25 mg)
Children under 6 years of age	Consult 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)
 ■ avoid high humidity
 ■ see label for expiration date and lot number
 ■ use by expiration date on package ▶

Drug Facts (continued)

Inactive Ingredients
 D&C Red #27 Aluminum Lake, D&C red #30 aluminum lake, dextrates hydrated, ethylcellulose, FD&C Blue #1 aluminum lake, flavor, hydroxypropyl cellulose, magnesium stearate, mannitol, stearic acid, sucralose, sucrose

Questions or comments?
 1-833-BE-WELLY (1-833-239-3559)

WELLY CHILDRENS TRAVEL MEDICINE

acetaminophen, calcium carbonate, diphenhydramine hydrochloride kit

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72663-203
---------------------	----------------	---------------------------	---------------

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
---	-----------	---------------------	----------------------	--------------------

1	NDC:72663-203-49	1 in 1 KIT	04/06/2020
---	------------------	------------	------------

Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	2 BLISTER PACK	12
Part 2	2 BLISTER PACK	12
Part 3	2 BLISTER PACK	12

Part 1 of 3

CHILDRENS PAIN AND FEVER RELIEF

acetaminophen tablet, chewable

Product Information

Item Code (Source)	NDC:72663-233
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	160 mg

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
CROSPVIDONE (UNII: 2S7830E561)	
D&C RED NO. 27 (UNII: 2LRS185U6K)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color	purple	Score	2 pieces
Shape	ROUND	Size	16mm
Flavor		Imprint Code	44449
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72663-233-49	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 mono graph not final	part343	04/06/2020	

Part 2 of 3

CHILDRENS STOMACH SOOTHER

calcium carbonate tablet, chewable

Product Information

Item Code (Source)	NDC:72663-225
Route of Administration	ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALCIUM CARBONATE (UNII: H0G9379FGK) (CALCIUM CATION - UNII:2M83C4R6ZB)	CALCIUM CATION	400 mg

Inactive Ingredients

Ingredient Name	Strength
ACACIA (UNII: 5C5403N26O)	
STARCH, CORN (UNII: O8232NY3SJ)	
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)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SUCROSE (UNII: C151H8M554)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	pink	Score	no score
-------	------	-------	----------

Shape	ROUND	Size	16 mm
Flavor		Imprint Code	44596
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72663-225-49	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	part331	04/06/2020	

Part 3 of 3

CHILDRENS ALLERGY RELIEF

diphenhydramine hydrochloride tablet, chewable

Product Information

Item Code (Source)	NDC:72663-347
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
DIPHENHYDRAMINE HYDROCHLORIDE (UNII: TC2D6JAD40) (DIPHENHYDRAMINE - UNII:8GTS82S83M)	DIPHENHYDRAMINE HYDROCHLORIDE	12.5 mg

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 27 ALUMINUM LAKE (UNII: ZK64F7XSTX)	
D&C RED NO. 30 (UNII: 2S42T2808B)	
ETHYLCELLULOSE, UNSPECIFIED (UNII: 7Z8S9VYZ4B)	
FD&C BLUE NO. 1 ALUMINUM LAKE (UNII: J9EQA3S2JM)	
METHYL SALICYLATE (UNII: LAV5U5022Y)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MANNITOL (UNII: 3OWL53L36A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics

Color	purple	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	44585
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72663-347-49	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 not final	part348	04/06/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	04/06/2020	

Labeler - Welly Health PBC (116766884)

Revised: 4/2020

Welly Health PBC