WELLY ADVENTURE FIRST AID KIT- hydrocortisone, bacitracin zinc, neomycin sulfate, polymyxin b sulfate, lidocaine hydrochloride, ibuprofen
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 Adventure First Aid Kit

1% Hydrocortisone Cream

Drug Facts

Active ingredient

Hydrocortisone 1.0%

Purpose

Anti-itch

Uses

- For temporary relief of itching associated with minor skin irritations, inflammation, or rashes.
- Other uses of product should be only under the advice and supervision of a doctor.

Warnings

For external use only

Do not use

- in eyes
- for treatment of diaper rash
- for feminine itching

Stop use, ask a doctor

- if condition worsens or lasts more than 7 days, or clears up and occurs again within a few days
- with use of other hydrocortisone products

Keep out of reach of children. If ingested, contact a Poison Control Center right away

Directions

- apply to affected area not more than 3 to 4 times daily
- children under 2: ask a doctor

Inactive ingredients

emulsifying wax, ethanol, methylparaben, mineral oil, paraffin, petrolatum, propylparaben, purified water, white wax

Triple Antibiotic Ointment

Drug Facts

***Active Ingredient* (in each gram)**

Bacitracin zinc 400 units

Neomycin sulfate (3.5mg Neomycin)

Polymyxin B sulfate 5000 units

Purpose

First Aid Antibiotics

Uses

First aid to help prevent infection in minor cuts, scrapes and burns

Warnings

For external use only

Do not use

- internally
- in eyes
- over large areas of the body or on puncture wounds, animal bites or serious burns
- for more than 1 week unless directed by a doctor
- if you are allergic to any of the ingredients

Stop use and ask a doctor if

- a rash or allergic reactions develops
- condition worsens or persists

Keep out of reach of children. If ingested, contact a Poison Control Center right away.

Directions

- clean affected area
- apply a small amount 1 to 3 times daily
- may cover with a sterile bandage

Inactive Ingredients

petrolatum

Pain Relief and Fever Reducer

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 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 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

Adventure First Aid Kit

LARGE FIRST AID KIT TO COVER ANY BUMP, BRUISE OR SCRAPE.

Everything you need for when the unbeaten path gets the best of you.

Flexible fabric bandages that can move with your every move.

Durable metal case keeps it all together.

Cleansing wipes, tape and ibuprofen to help you get back out there.

Triple Antibiotic ointment helps prevent infection.

KIT INCLUDES

48 COUNT - STANDARD FABRIC BANDAGES

30 COUNT - SMALL FABRIC BANDAGES

3 COUNT - LARGE BANDAGES (3"x4")

12 COUNT - WATERPROOF BANDAGES

1 COUNT - ROLL OF TAPE

5 COUNT - NON STICK PADS

10 COUNT - CLEANSING WIPES

10 COUNT - BUTTERFLY STRIPS

5 COUNT - TRIPLE ANTIBIOTIC PACKETS

5 COUNT - HYDROCORTISONE PACKETS

1 VIAL - IBUPROFEN

Manufactured for: Welly Health PBC
Minneapolis, MN 55402
1-833-BE-WELLY

Recycle me!

Welly™ www.GetWelly.com

Products of USA and China with globally sourced materials

Product not made with natural rubber latex

Sterile unless individual wrapper opened or damaged.

Patent Pending

Packaging

KIT COMPONENTS LABEL

welly™

1% Hydrocortisone Cream

0.9g / 1/32 oz

Drug Facts

Active ingredient Purpose

Hydrocortisone 1.0% ... Anti-itch

Uses For temporary relief of itching associated with minor skin irritations, inflammation, or rashes. Other uses of product should be only under the advice and supervision of a doctor.

Warnings

For external use only

Do not use • in eyes • for treatment of diaper rash • for feminine itching ▸

Drug Facts (continued)

Warnings *(continued)*

Stop use, ask a doctor

• if condition worsens or lasts more than 7 days, or clears up and occurs again within a few days • with use of other hydrocortisone products

Keep out of reach of children. If ingested, contact a Poison Control Center right away

Directions • apply to affected area not more than 3 to 4 times daily • children under 2: ask a doctor

Inactive ingredients emulsifying wax, ethanol, methylparaben, mineral oil, paraffin, petrolatum, propylparaben, purified water, white wax

Welly Health PBC, Minn., MN 55402

1-833-BE-WELLY

welly™

Triple Antibiotic Ointment

0.5g / 1/57 oz

Drug Facts

Active ingredient Purpose

(in each gram)

Bacitracin zinc 400 units

Neomycin sulfate (3.5mg Neomycin) Polymyxin B sulfate 5000 units ..... First Aid Antibiotics

Uses First aid to help prevent infection in minor cuts, scrapes, and burns

Warnings

For external use only ▸

Drug Facts (continued)

Warnings *(continued)*

Do not use • internally • in eyes • over large areas of the body or on puncture wounds, animal bites or serious burns • for more than 1 week unless directed by a doctor • if you are allergic to any of the ingredients

Stop use and ask a doctor if • a rash or allergic reaction develops • condition worsens or persists

Keep out of reach of children. If ingested, contact a Poison Control Center right away.

Directions • clean affected area • apply a small amount 1 to 3 times daily • may cover with a sterile bandage

Inactive Ingredients petrolatum

Welly Health PBC, Minn., MN 55402

1-833-BE-WELLY

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 ▸

KIT LABEL

WELLY ADVENTURE FIRST AID KIT

hydrocortisone, bacitracin zinc, neomycin sulfate, polymyxin b sulfate, lidocaine hydrochloride, ibuprofen kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:72663-150

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72663-150-05	1 in 1 KIT; Type 0: Not a Combination Product	04/06/2020	

Quantity of Parts		
Part #	Package Quantity	Total Product Quantity
Part 1	5 POUCH	4.5 mL
Part 2	5 POUCH	2.5 mL
Part 3	1 BOTTLE	16
Part 4	10 POUCH	10

Part 1 of 4

ANTI-ITCH

hydrocortisone cream

Product Information	
Item Code (Source)	NDC:72663-580
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: WI4X0X7BPJ) (HYDROCORTISONE - UNII:WI4X0X7BPJ)	HYDROCORTISONE	1 g in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PARAFFIN (UNII: I9O0E3H2ZE)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
WHITE WAX (UNII: 7G1J5DA97F)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.9 mL in 1 POUCH; 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	02/25/2019	

Part 2 of 4

ANTIBIOTIC

bacitracin zinc, neomycin sulfate, polymyxin b sulfate ointment

Product Information

Item Code (Source)	NDC:72663-560
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BACITRACIN ZINC (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	6.0 mg in 1 mL
NEOMYCIN SULFATE (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1 mL
POLYMYXIN B SULFATE (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	0.77 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.5 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333B	02/25/2019	

Part 3 of 4

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		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 4 of 4

WELLY CLEANSING WIPE

cleansing (cold creams, cleansing lotions, liquids, and pads)

Product Information

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		1 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Cosmetic			

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	04/06/2020	

Labeler - Welly Health PBC (116766884)

Revised: 5/2020 Welly Health PBC