

**WELLY SUPERHERO SUPPLIES KIT- alcohol, bacitracin zinc, neomycin sulfate, polymyxin b sulfate, lidocaine hydrochloride, hydrocortisone**  
**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 Superhero Supplies Kit**

**Instant Hand Sanitizer Gel**

***Drug Facts***

***Active ingredient***

Ethyl Alcohol 66.5%

***Purpose***

Antiseptic

***Use***

For handwashing to decrease bacteria on skin without soap and water.

***Warnings***

**For external use only**

**Flammable, keep away from fire or flame.**

**Do not use** in eyes, if this happens, rinse thoroughly with water.

**Stop use, ask a doctor if,** irritation develops and persists for 72 hours.

**Keep out of reach of children.** If ingested, get medical help or contact a Poison Control Center right away.

***Directions***

- Wet hands & wrists thoroughly with product and allow to dry without wiping

***Inactive ingredients***

aloe vera, carbomer, D&C green #5, D&C yellow #10, fragrance, purified water, triethanolamine

## **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

## **Burn Gel**

## ***Drug Facts***

### ***Active ingredient***

Lidocaine HCl 2.0%

### ***Purpose***

Topical pain relief

### ***Uses***

Temporary pain relief for minor burns

### ***Warnings***

#### **External use only**

#### **Do not use**

- near eyes, if this happens, rinse thoroughly with water
- in large quantities, particularly over raw or blistered areas

#### **Stop use, ask doctor**

- if conditions worsen or last more than 7 days or clears up and returns.

**Keep out of reach of children.** If ingested contact a Poison Control Center directly

### ***Directions***

- adults and children 2 years and older: apply to affected area not more than 3 to 4 times daily
- children under 2: do not use, ask a doctor

### ***Inactive ingredients***

aloe vera, carbomer, germaben II, menthol, propylene glycol, purified water, triethanolamine, vitamin E acetate

## **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

ASSORTED FIRST AID OINTMENTS

ASSORTED SINGLE USE PACKETS

Distributed by: Welly Health PBC

Minneapolis, MN 55402

1-833-BE-WELLY

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## **Superhero Supplies**

**9** - HAND SANITIZER 0.9g (1/32 OZ)

- 9 - TRIPLE ANTIBIOTIC 0.5g (1/57 OZ)
- 9 - BURN GEL 0.9G (1/32 OZ)
- 9 - 1% HYDROCORTISONE 0.9g (1/32 OZ)

**Packaging**

KIT COMPONENTS LABEL

**welly** <sup>TM</sup> ✕

Instant Hand Sanitizer  
0.9g / 1/32 OZ

<b>Drug Facts</b>
<b>Active ingredient Purpose</b> Ethyl Alcohol 66.5%... Antiseptic
<b>Use</b> For handwashing to decrease bacteria on skin without soap and water.
<b>Warnings</b> For external use only Flammable, keep away from fire or flame. Keep out of reach of children. ▶ Do not use in eyes, if this happens, rinse thoroughly with water.

<b>Drug Facts (continued)</b>
<b>Warnings (continued)</b> Stop use, ask a doctor if, irritation develops and persists for 72 hours. If ingested, get medical help or contact a Poison Control Center right away.
<b>Directions</b> •Wet hands & wrists thoroughly with product and allow to dry without wiping
<b>Inactive ingredients</b> aloe vera, carbomer, D&C green #5, D&C yellow #10, fragrance, purified water, triethanolamine

Welly Health PBC, Minn., MN 55402  
1-833-BE-WELLY

**welly** <sup>TM</sup> ✕

Triple Antibiotic Ointment  
0.5g / 1/57 OZ

<b>Drug Facts</b>
<b>Active ingredient Purpose</b> (in each gram) Bacitracin zinc 400 units Neomycin sulfate (3.5mg Neomycin) Polymyxin B sulfate First Aid 5000 units ..... Antibiotics
<b>Uses</b> First aid to help

<b>Drug Facts (continued)</b>
<b>Warnings (continued)</b> 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
<b>Stop use and ask a doctor if</b> • a rash or allergic reaction develops • condition worsens or persists
<b>Keep out of reach of children.</b> If ingested, contact a Poison Control Center right away.
<b>Directions</b> •clean affected area •apply a small amount

prevent infection in minor cuts, scrapes, and burns

**Warnings**  
For external use only ▶

1 to 3 times daily • may cover with a sterile bandage

**Inactive Ingredients**  
petrolatum

Welly Health PBC, Minn., MN 55402  
1-833-BE-WELLY

welly™ x

Burn Gel  
0.9g / 1/32 OZ

**Drug Facts**

Active ingredient	Purpose
Lidocaine	Topical
HCl 2.0%	pain relief

**Uses** Temporary pain relief for minor burns

**Warnings**  
External use only. Keep out of reach of children.

**Do not use** • near eyes, if this happens, rinse thoroughly with water • in large quantities, particularly over raw or blistered areas ▶

**Drug Facts** (continued)

**Warnings (continued)**  
**Stop use, ask a doctor**  
• if conditions worsen or last more than 7 days or clears up and returns. If ingested contact a Poison Control Center directly

**Directions** • adults and children 2 years and older: apply to affected area not more than 3 to 4 times daily  
• children under 2: do not use, ask a doctor

**Inactive ingredients**  
aloe vera, carbomer, germaben II, menthol, propylene glycol, purified water, triethanolamine, vitamin E acetate

Welly Health PBC, Minn., MN 55402  
1-833-BE-WELLY

welly™ x

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**

**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,

**For external use only**

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

propylparaben, purified  
water, white wax

Welly Health PBC, Minn., MN 55402  
1-833-BE-WELLY

## KIT LABEL



### Superhero Supplies

- 9 – HAND SANITIZER 0.9g (1/32 OZ)
- 9 – TRIPLE ANTIBIOTIC 0.5g (1/57 OZ)
- 9 – BURN GEL 0.9g (1/32 OZ)
- 9 – 1% HYDROCORTISONE 0.9g (1/32 OZ)



*welly*<sup>™</sup> FIRST AID

Superhero Supplies

ASSORTED FIRST AID OINTMENTS





## WELLY SUPERHERO SUPPLIES KIT

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

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72663-140
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### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72663-140-32	1 in 1 KIT; Type 0: Not a Combination Product	03/01/2019	

### Quantity of Parts

Part #	Package Quantity	Total Product Quantity
Part 1	9 POUCH	8.1 mL
Part 2	9 POUCH	4.5 mL



<b>Part 3</b>	9 POUCH	8.1 mL
<b>Part 4</b>	9 POUCH	8.1 mL

## Part 1 of 4

### ANTISEPTIC

alcohol gel

#### Product Information

<b>Item Code (Source)</b>	NDC:72663-111
<b>Route of Administration</b>	TOPICAL

#### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ALCOHOL</b> (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	666 mg in 1 mL

#### Inactive Ingredients

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CARBOMER INTERPOLYMER TYPE A (ALLYL SUCROSE CROSSLINKED)</b> (UNII: 59TL3WG5CO)	
<b>D&amp;C GREEN NO. 5</b> (UNII: 8J6RDU8L9X)	
<b>D&amp;C YELLOW NO. 10</b> (UNII: 35SW5USQ3G)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	

#### 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	part333E	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
<b>BACITRACIN ZINC</b> (UNII: 89Y4M234ES) (BACITRACIN - UNII:58H6RWO52I)	BACITRACIN	6 mg in 1 mL
<b>NEOMYCIN SULFATE</b> (UNII: 057Y626693) (NEOMYCIN - UNII:I16QD7X297)	NEOMYCIN SULFATE	3.5 mg in 1 mL
<b>POLYMYXIN B SULFATE</b> (UNII: 19371312D4) (POLYMYXIN B - UNII:J2VZ07J96K)	POLYMYXIN B	0.77 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>PETROLATUM</b> (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

### ANALGESIC

lidocaine hydrochloride gel

### Product Information

**Item Code (Source)** NDC:72663-500

**Route of Administration** TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	2 g in 1 mL

**Inactive Ingredients**

Ingredient Name	Strength
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>CARBOXYPOLYMETHYLENE</b> (UNII: 0A5MM307FC)	
<b>DIAZOLIDINYL UREA</b> (UNII: H5RIZ3MPW4)	
<b>MENTHOL, UNSPECIFIED FORM</b> (UNII: L7T10EIP3A)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>TROLAMINE</b> (UNII: 9O3K93S3TK)	
<b>.ALPHA.-TOCOPHEROL, D-</b> (UNII: N9PR3490H9)	

**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 4 of 4****ANTI-ITCH**

hydrocortisone cream

**Product Information**

<b>Item Code (Source)</b>	NDC:72663-580
<b>Route of Administration</b>	TOPICAL

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>HYDROCORTISONE</b> (UNII: W4X0X7BPJ) (HYDROCORTISONE - UNII:W4X0X7BPJ)	HYDROCORTISONE	1 g in 1 mL

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

<b>Packaging</b>				
<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1		0.9 mL in 1 POUCH; Type 0: Not a Combination Product		

<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part348	02/25/2019	

<b>Marketing Information</b>			
<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part333E	03/01/2019	

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