

**SKY WELLNESS MAX PAIN RELIEF- lidocaine hydrochloride, menthol stick  
Prime Enterprises**

*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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**Sky Wellness CBD max Pain Relief Roll-On**

**Active Ingredient**

Lidocaine Hydrochloride 4%, Menthol 1%

**Purpose**

Topical Analgesic

**Use**

Use for temporary relief of minor pain

**Warnings**

For external use only.

**Do not use**

on large areas of the body or on cut, irritated or swollen skin

on puncture wounds

for more than one week without consulting a doctor

**When using this product**

use only as directed

avoid contact with eyes and mucous membranes

do not apply to skin folds

do not apply to wounds or damaged, broken or irritated skin

do not bandage tightly or apply local heat (such as heating pads) or a medicated patch to the area of use

**Stop use and ask a doctor if**

condition worsens

irritation develops

redness appears

symptoms persist for more than 7 days or clear up and occurs again within a few days

**Keep out of reach of children.**

If product is swallowed, get medical help or contact a Poison Control Center right away

**If pregnant or breast-feeding**

ask a health professional before use.

**Directions**

Adults and children over 12 years:

apply a thin layer to affected area every 6 to 8 hours, but no more than 3 to 4 times daily

if product comes in contact hands, wash hands with soap and water

**Inactive ingredients**

Acrylamide/Sodium Acrylate Copolymer, Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Arnica Montana Flower Extract, Borago Officinalis Seed Oil, Boswellia Serrata Extract, Camellia Oleifera (Green Tea) Leaf Extract, Cannabidiol, Chamomilla Recutita (Matricaria) Flower Extract, Curcuma Longa (Turmeric) Root Extract, Glycerin, Harpagophytum Procumbens Root Extract, Mentha Piperita (Peppermint) Oil, Mineral Oil, Oenothera Biennis (Evening Primrose) Oil, Polysorbate 20, Propylene Glycol, Ribes Nigrum (Black Currant) Fruit Extract, Salix Alba (White Willow) Bark Extract, SD Alcohol 40-B, Sodium Hydroxide, Trideceth-6, Water

**Sky wellness CBD Max pain relief Roll-on**



SKYWELLNESS.COM/TCO  
SKYWELLNESS.COM

Product contains a total delta-9-tetrahydrocannabinol concentration that does not exceed 0.3% on a dry weight basis.  
Distributed by Sky Wellness LLC • Scottsdale, AZ 85251 • 480.562.6282

### Drug Facts

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Menthol 1%

**Purpose**  
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#### When using this product

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- avoid contact with eyes and mucous membranes
- do not apply to skin folds
- do not apply to wounds or damaged, broken or irritated skin
- do not bandage tightly or apply local heat (such as heating pads) or a medicated patch to the area of use

**Stop use and ask a doctor if** • condition worsens • irritation develops • redness appears • symptoms persist for more than 7 days or clear up and occurs again within a few days

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

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

#### Directions

Adults and children over 12 years:

- apply a thin layer to affected area every 6 to 8 hours, but no more than 3 to 4 times daily
- if product comes in contact hands, wash hands with soap and water
- children 12 years or younger: ask a doctor

#### Inactive ingredients

Acrylamide/Sodium Acrylate Copolymer, Aesculus Hippocastanum (Horse Chestnut) Seed Extract, Arnica Montana Flower Extract, Borago Officinalis Seed Oil, Boswellia Serrata Extract, Camellia Oleifera (Green Tea) Leaf Extract, Cannabidiol, Chamomilla Recutita (Matricaria) Flower Extract, Curcuma Longa (Turmeric) Root Extract, Glycerin, Harpagophytum Procumbens Root Extract, Mentha Piperita (Peppermint) Oil, Mineral Oil, Oenothera Biennis (Evening Primrose) Oil, Polysorbate 20, Propylene Glycol, Ribes Nigrum (Black Currant) Fruit Extract, Salix Alba (White Willow) Bark Extract, SD Alcohol 40-B, Sodium Hydroxide, Trideceth-6, Water

**Questions and comments**  
480.562.6282



**CBD**  
**MAX PAIN RELIEF**  
**ROLL-ON**  
**4% LIDOCAINE**



**500mg CBD**  
**BROAD SPECTRUM**  
**PER BOTTLE**

**3 FL.OZ (89mL)**

## SKY WELLNESS MAX PAIN RELIEF

lidocaine hydrochloride, menthol stick

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58443-0370
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>MENTHOL</b> (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	9.62 mg in 1 mL
<b>LIDOCAINE HYDROCHLORIDE</b> (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	38.48 mg in 1 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>ARNICA MONTANA FLOWER</b> (UNII: OZ0E5Y15PZ)	
<b>ALCOHOL</b> (UNII: 3K9958V90M)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>CAMELLIA OLEIFERA LEAF</b> (UNII: 5077ELOC60)	
<b>HARPAGOPHYTUM PROCUMBENS ROOT</b> (UNII: 1OYM338E89)	

<b>SALIX ALBA BARK</b> (UNII: 205MXS71H7)
<b>EVENING PRIMROSE OIL</b> (UNII: 3Q9L08K71N)
<b>POLYSORBATE 20</b> (UNII: 7T1F30V5YH)
<b>CHAMOMILE</b> (UNII: FGL3685T2X)
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)
<b>INDIAN FRANKINCENSE</b> (UNII: 4PW41QCO2M)
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)
<b>HORSE CHESTNUT</b> (UNII: 3C18L6RJAZ)
<b>BLACK CURRANT</b> (UNII: 9755T40D11)
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)
<b>WATER</b> (UNII: 059QF0KO0R)
<b>ACRYLAMIDE</b> (UNII: 20R035KLCI)
<b>SODIUM ACRYLATE</b> (UNII: 7C98FKB43H)
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)
<b>TRIDECETH-6</b> (UNII: 3T5PCR2H0C)
<b>BORAGE SEED OIL</b> (UNII: F8XAG1755S)
<b>CANNABIDIOL</b> (UNII: 19GBJ60SN5)
<b>TURMERIC</b> (UNII: 856YO1Z64F)

### Product Characteristics

<b>Color</b>	white (White to Off White)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0370-3	89 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/01/2019	12/31/2024

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	05/01/2019	12/31/2024

**Labeler** - Prime Enterprises (101946028)

**Registrant** - Prime Enterprises (101946028)

### Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises		101946028	manufacture(58443-0370) , label(58443-0370) , analysis(58443-0370) , pack(58443-0370)

