

**WILLOW BALM- topical pain reliever cream**  
**I Woke Up Well Distributing Inc**

*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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**Willow Balm Nature's Aspirin**

**Active Ingredients**

Menthol 3% Counterirritant

**Warnings**

WARNINGS for external use only. Use only as directed. Avoid contact with eyes and mucus membranes. Do not cover with bandage. Do not use on open wounds or damaged skin.

Keep out of reach of Children. Consult physician for children under 12.

**Uses**

Use for the temporary relief of minor aches and muscle pains associated with arthritis, simple backache, strains, muscle soreness and stiffness

**Other Ingredients**

BOTANICALS White Willow Bark, Camphor, Eucalyptus Oil, Lavender Oil, Geranium Oil, Helichrysum Gymnocephalum Oil, Spearmint Oil OTHER INGREDIENTS water, mineral oil, cetyp alcohol, stearic acid, stearyl alcohol, cetearyl alcohol, cetereth, propylene glycol, isopropyl palmtate, almond oil, glycol monostearate, phenoxy ethanol, caprylyl glycol, jojoba seed oil

**Contact information**

For more informatin contact us at: 888-609-4556, or visit [www.willowbalm.com](http://www.willowbalm.com) Made in the USA I Woke Up Well Distributing, Inc. US Pat. 8765194

**Warnings**

Keep Out Of Reach of Children

**Directions**

Apply the product directly to the affected area. Product may be used as necessary, but should not be used more than four times daily.

**Purpose**

Use for the temporary relief of minor aches and muscle pains.

main label



# WILLOW BALM

topical pain reliever cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71629-035
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	0.03 g in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
PELARGONIUM GRAVEOLENS FLOWER OIL (UNII: 3K0J1S7QGC)	0.013 g in 1 g
LAVENDER OIL (UNII: ZBP1YXW0H8)	0.013 g in 1 g
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	0.095 g in 1 g
WATER (UNII: 059QF0K00R)	0.072 g in 1 g
CETYL ALCOHOL (UNII: 936JST6JCN)	0.0238 g in 1 g
HELICHRYSUM GYMNOCEPHALUM WHOLE (UNII: 0369G6I64W)	0.009 g in 1 g
STEARIC ACID (UNII: 4ELV7Z65AP)	0.238 g in 1 g
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	0.119 g in 1 g
ALMOND OIL (UNII: 66YXD4DKO9)	0.019 g in 1 g
TROLAMINE (UNII: 9O3K93S3TK)	0.013 g in 1 g
CETEARETH-10 (UNII: K9YLE2L8PA)	0.476 g in 1 g
SALIX ALBA BARK (UNII: 205MXS71H7)	0.049 g in 1 g
SPEARMINT (UNII: J7I2T6IV1N)	0.002 g in 1 g
EUCALYPTUS OIL (UNII: 2R04ONI662)	0.078 g in 1 g
HYDROGENATED JO JOBA OIL/JO JOBA OIL, RANDOMIZED (IODINE VALUE 40-44) (UNII: AS2SZ9757N)	0.0095 g in 1 g
.ALPHA.,.ALPHA.-DIBROMO-D-CAMPHOR (UNII: F89Z8SAG3O)	0.078 g in 1 g
ISOPROPYL PALMITATE (UNII: 8CRQ2TH63M)	0.019 g in 1 g
MINERAL OIL (UNII: T5L8T28FGP)	0.571 g in 1 g

## Product Characteristics

<b>Color</b>	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:71629-035-01	1 g in 1 TUBE; Type 0: Not a Combination Product	01/15/2018	

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part356	01/15/2018	

**Labeler** - I Woke Up Well Distributing Inc (025251119)

**Registrant** - I Woke Up Well Distributing Inc (025251119)

Revised: 1/2018

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