

**OSEA BLEMISH BALM- salicylic acid cream**  
**OSEA International, LLC**

*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.*

-----  
**OSEA Blemish Balm**

**Drug Facts**

**Active ingredient**

Salicylic Acid 1%

**Purpose**

Acne Treatment

**Uses**

- For the treatment of acne
- Clears up acne pimples and allows skin to heal
- Helps prevent new acne pimples, blackheads and whiteheads from forming

**Warnings**

**For external use only.**

**When using this product**

- Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.
- Keep out of eyes. Rinse with water to remove.

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

**Directions**

- Clean the skin thoroughly before applying this product
- Cover the entire affected area with a thin layer one to two times daily
- Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two times daily if needed or as directed by a doctor
- If bothersome dryness or peeling occurs, reduce application to once a day or every other day

**Sensitivity Test for a New User**

Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above.

### **Inactive ingredients**

WATER, TRIHEPTANOIN, HYDROGENATED ETHYLHEXYL OLIVATE, CETEARYL OLIVATE, PROPANEDIOL, GLYCERIN, DIHEPTYL SUCCINATE, SORBITAN OLIVATE, CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER, CITRUS PARADISI (Grapefruit) PEEL OIL, LAVANDULA ANGUSTIFOLIA (Lavender) OIL, GIGARTINA STELLATA/ KAPPAPHYCUS ALVAREZII EXTRACT, CORALLINA OFFICINALIS EXTRACT, FUCUS SPIRALIS EXTRACT, TETRASELMIS CHUI EXTRACT, SIMMONDSIA CHINENSIS (Jojoba) SEED OIL, VITIS VINIFERA (Grape) SEED OIL, HYDROGENATED OLIVE OIL UNSAPONIFIABLES, CAMELINA SATIVA SEED OIL, THYMUS VULGARIS (Thyme) FLOWER/LEAF/STEM WATER, TOCOPHEROL, BACKHOUSIA CITRIODORA LEAF EXTRACT, CITRUS AURANTIFOLIA (Lime) OIL, CITRUS NOBILIS (Mandarin Orange) PEEL OIL, CUPRESSUS SEMPERVIRENS OIL, EUCALYPTUS GLOBULUS LEAF OIL, JUNIPERUS VIRGINIANA OIL, LAVANDULA HYBRIDA OIL, LIMONENE, MENTHA PIPERITA (Peppermint) OIL, MENTHA VIRIDIS (Spearmint) EXTRACT, PELARGONIUM GRAVEOLENS FLOWER OIL, PRUNUS AMYGDALUS DULCIS (Sweet Almond) OIL, ROSMARINUS OFFICINALIS (Rosemary) LEAF OIL, THYMUS VULGARIS (Thyme) OIL, LONICERA JAPONICA (Honeysuckle) FLOWER EXTRACT, LONICERA CAPRIFOLIUM (Honeysuckle) FLOWER EXTRACT, SODIUM STEAROYL GLUTAMATE, BENTONITE, TRISODIUM ETHYLENEDIAMINE DISUCCINATE, XANTHAN GUM, SODIUM HYDROXIDE, CITRIC ACID, POTASSIUM SORBATE

Dist. by  
OSEA Intl. LLC  
Malibu, CA 90265

### **PRINCIPAL DISPLAY PANEL - 60 ml Bottle Carton**

OSEA

blemish  
balm

1% salicylic acid  
acne treatment

2 fl. oz. / 60 ml

### Drug Facts

**Active ingredient.....**

Salicylic Acid 1%

**Purpose.....**Acne Treatment

**Uses** • For the treatment of acne • Clears up acne pimples and allows skin to heal • Helps prevent new acne pimples, blackheads and whiteheads from forming

**Warnings**

For external use only.

**When using this product**

• Skin irritation and dryness is more likely to occur if you use another topical acne medication at the same time. If irritation occurs, only use one topical acne medication at a time.  
• Keep out of eyes. Rinse with water to remove.

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

**Directions** • Clean the skin thoroughly before applying this product • Cover the entire affected area with a thin layer one to two times daily • Because excessive drying of the skin may occur, start with one application daily, then gradually increase to two times daily if needed or as directed by a doctor • If bothersome dryness or peeling occurs, reduce application to once a day or every other day

**Sensitivity Test for a New User:** Apply product sparingly to one or two small affected areas during the first 3 days. If no discomfort occurs, follow the directions stated above.

### Drug Facts (continued)

**Inactive ingredients**

WATER, TRIHEPTANOIN, HYDROGENATED ETHYLHEXYL OLIVATE, CETEARYL OLIVATE, PROPANEDIOL, GLYCERIN, DIHEPTYL SUCCINATE, SORBITAN OLIVATE, CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER, CITRUS PARADISI (Grapefruit) PEEL OIL, LAVANDULA ANGUSTIFOLIA (Lavender) OIL, GIGARTINA STELLATA/ KAPPAPHYCUS ALVAREZII EXTRACT, CORALLINA OFFICINALIS EXTRACT, FUCUS SPIRALIS EXTRACT, TETRAELEMIS CHUI EXTRACT, SIMMONDSIA CHINENSIS (Jojoba) SEED OIL, VITIS VINIFERA (Grape) SEED OIL, HYDROGENATED OLIVE OIL UNSAPONIFIABLES, CAMELINA SATIVA SEED OIL, THYMUS VULGARIS (Thyme) FLOWER/LEAF/STEM WATER, TOCOPHEROL, BACKHOUSIA CITRIODORA LEAF EXTRACT, CITRUS AURANTIFOLIA (Lime) OIL, CITRUS NOBILIS (Mandarin Orange) PEEL OIL, CUPRESSUS SEMPERVIRENS OIL, EUCALYPTUS GLOBULUS LEAF OIL, JUNIPERUS VIRGINIANA OIL, LAVANDULA HYBRIDA OIL, LIMONENE, MENTHA PIPERITA (Peppermint) OIL, MENTHA VIRIDIS (Spearmint) EXTRACT, PELARGONIUM GRAVEOLENS FLOWER OIL, PRUNUS AMYGDALUS DULCIS (Sweet Almond) OIL, ROSMARINUS OFFICINALIS (Rosemary) LEAF OIL, THYMUS VULGARIS (Thyme) OIL, LONICERA JAPONICA (Honeysuckle) FLOWER EXTRACT, LONICERA CAPRIFOLIUM (Honeysuckle) FLOWER EXTRACT, SODIUM STEAROYL GLUTAMATE, BENTONITE, TRISODIUM ETHYLENEDIAMINE DISUCCINATE, XANTHAN GUM, SODIUM HYDROXIDE, CITRIC ACID, POTASSIUM SORBATE

# OSEA

## blemish balm

1% salicylic acid  
acne treatment

2 fl. oz. / 60 ml

## Acne Control Moisturizer

Lightweight, fast-absorbing moisturizer clears acne and allows skin to heal, while simultaneously delivering nourishing hydration. A natural salicylic acid helps prevent new acne pimples, blackheads and whiteheads from forming. The secret lies in the synergy between five types of nutrient-rich seaweed that keeps skin looking healthy.

CLEAN  
VEGAN & CRUELTY-FREE  
GLUTEN-FREE  
BORN IN CALIFORNIA

Dist by  
OSEA Intl. LLC  
Malibu, CA 90265  
+1 310 361 0547

oseamalibu.com



RBX-BLMSH-60

# OSEA BLEMISH BALM

salicylic acid cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:73432-002
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>Salicylic Acid</b> (UNII: O414PZ4LPZ) (Salicylic Acid - UNII:O414PZ4LPZ)	Salicylic Acid	1 mg in 100 mL

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>water</b> (UNII: 059QF0KO0R)	
<b>Triheptanoin</b> (UNII: 2P6O7CFW5K)	
<b>CETEARYL OLIVATE</b> (UNII: 58B69Q84JO)	
<b>PROPANEDIOL</b> (UNII: 5965N8W85T)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	
<b>DIHEPTYL SUCCINATE</b> (UNII: 057N7SS26Y)	
<b>SORBITAN OLIVATE</b> (UNII: MDL271E3GR)	
<b>CAPRYLOYL GLYCERIN/SEBACIC ACID COPOLYMER (2000 MPA.S)</b> (UNII: N7YC58165T)	
<b>GRAPEFRUIT OIL</b> (UNII: YR377U58W9)	
<b>LAVENDER OIL</b> (UNII: ZBP1YXW0H8)	
<b>Mastocarpus stellatus</b> (UNII: 6T087FC66H)	
<b>Kappaphycus alvarezii</b> (UNII: T479H08K2O)	
<b>CORALLINA OFFICINALIS</b> (UNII: 4004498D06)	
<b>FUCUS SPIRALIS</b> (UNII: 3W9AY2P26F)	
<b>TETRASELMIS CHUI</b> (UNII: T9C83Z6363)	
<b>JOJOBA OIL</b> (UNII: 724GKU717M)	
<b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)	
<b>HYDROGENATED OLIVE OIL UNSAPONIFIABLES</b> (UNII: B8MIX97W95)	
<b>CAMELINA SATIVA SEED OIL</b> (UNII: 12824X01L0)	
<b>THYME</b> (UNII: CW657OBU4N)	
<b>TOCOPHEROL</b> (UNII: R0ZB2556P8)	
<b>BACKHOUSIA CITRIODORA LEAF</b> (UNII: FKN73KG747)	
<b>LIME OIL, COLD PRESSED</b> (UNII: UZH29XGA8G)	
<b>MANDARIN OIL</b> (UNII: NJO720F72R)	
<b>CUPRESSUS SEMPERVIRENS LEAF OIL</b> (UNII: M7QUY89S4O)	
<b>EUCALYPTUS OIL</b> (UNII: 2R04ONI662)	
<b>JUNIPERUS VIRGINIANA OIL</b> (UNII: PAD4FN7P2G)	
<b>LAVANDIN OIL</b> (UNII: 9RES347CKG)	
<b>LIMONENE, (+)-</b> (UNII: GFD7C86Q1W)	
<b>PEPPERMINT OIL</b> (UNII: AV092KU4JH)	
<b>SPEARMINT</b> (UNII: J7I2T6IV1N)	
<b>PELARGONIUM GRAVEOLENS FLOWER OIL</b> (UNII: 3K0J1S7QGC)	

<b>ALMOND OIL</b> (UNII: 66YXD4DKO9)	
<b>ROSEMARY OIL</b> (UNII: 8LGU7VM393)	
<b>THYME OIL</b> (UNII: 2UK410MY6B)	
<b>LONICERA JAPONICA FLOWER</b> (UNII: 4465L2WS4Y)	
<b>LONICERA CAPRIFOLIUM FLOWER</b> (UNII: 5N1WD9784U)	
<b>SODIUM STEAROYL GLUTAMATE</b> (UNII: 65A9F4P024)	
<b>BENTONITE</b> (UNII: A3N5ZCN45C)	
<b>TRISODIUM ETHYLENEDIAMINE DISUCCINATE</b> (UNII: YA22H34H9Q)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	
<b>CITRIC ACID MONOHYDRATE</b> (UNII: 2968PHW8QP)	
<b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:73432-002-01	1 in 1 CARTON	10/01/2023	
1		60 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		
2	NDC:73432-002-02	1 in 1 CARTON	10/01/2023	
2		18 mL in 1 BOTTLE, GLASS; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	10/01/2023	

**Labeler** - OSEA International, LLC (015193384)

Revised: 9/2023

OSEA International, LLC