

## **CALENDULA- calendula cream**

### **Boiron**

*Disclaimer: This homeopathic product has not been evaluated by the Food and Drug Administration for safety or efficacy. FDA is not aware of scientific evidence to support homeopathy as effective.*

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### **Calendula Cream 0.5oz**

Calendula Officinalis 1X HPUS

- Helps promote healing of cuts, scrapes, chafing, minor burns and sunburn.

Do not use if you are allergic to Calendula officinalis or to this product's inactive ingredients.

- Do not use if the tube seal is broken.

For minor burns, immediately run cool water on the burn for several minutes and dry. For cuts, scrapes, and chafing, first cleanse the area with mild soap, rinse and dry.

- Then apply a thin layer of Calendula Cream to affected area 3 times a day or as needed.

Version With Disodium EDTA:

Alcohol, Caprylyl glycol, carbomer, cetyl palmitate, EDTA disodium, glycerin, lauroyl macrogolglycerides, pegoxol-7 stearate, purified water, sodium hydroxide, sorbic acid, 1,2-hexanediol

Version without Disodium EDTA:

Alcohol, Caprylyl glycol, carbomer, cetyl palmitate, glycerin, lauroyl macrogolglycerides, pegoxol-7 stearate, purified water, sodium hydroxide, sorbic acid, 1,2-hexanediol

Tube .5 OZ (14 G)

Calendula officinalis 1X ... Healing agent

Questions, Comments?

[www.BoironCalendula.com](http://www.BoironCalendula.com)

[www.BoironUSA.com](http://www.BoironUSA.com)

1-800-BOIRON-1

(1-800-264-7661)

Distributed by Boiron Inc.

6 Campus Boulevard  
Newtown Square, PA

19073-3267

Ask a doctor before use in case of deep puncture wounds, animal bites or serious burns.

Stop use and ask doctor if condition persists for more than 3 days or worsens.

Keep out of reach of children

- Soothes
- Moisturizes & Heals
- Paraben-Free

**For external use only.** Avoid contact with eyes.

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

<p><b>Drug Facts</b> (continued)</p> <hr/> <p><b>Other information</b> ■ do not use if the tube seal is broken</p> <p><b>Inactive ingredients</b> alcohol, caprylyl glycol, carbomer, cetyl palmitate, glycerin, lauroyl macroglycolglycerides, pegoxol-7 stearate, purified water, sodium hydroxide, sorbic acid, 1,2-hexanediol</p>	<p><b>Questions or comments?</b> BoironCalendula.com BoironUSA.com 1-800-BOIRON-1 (1-800-264-7661) Distributed by Boiron Inc. 6 Campus Boulevard Newtown Square, PA 19073-3267</p>									
<p>Made in France  please recycle</p>										
<p><b>SOOTHES &amp; HEALS SKIN IRRITATIONS</b></p> <p>Cuts • Scrapes • Chafing Minor Burns • Sunburn*</p> <div style="text-align: center;">  </div> <p><i>Calendula officinalis (Garden marigold) has been used topically for generations to naturally heal skin irritations. Calendula Cream's light texture is both soothing and moisturizing. It is ideal for use on dry or chafed skin.</i></p>										
<p style="text-align: right;">NDC 0220-1109-68</p> <p style="text-align: left;"><b>SAMPLE NOT FOR SALE</b></p> <p style="text-align: center;"><b>FIRST AID*</b></p> <p style="text-align: center;"><b>Calendula Cream</b></p> <p style="text-align: center;">Soothing • Moisturizing • Help Your Body the Natural Way</p> <div style="display: flex; justify-content: space-between;">   <p>HOMEOPATHIC MEDICINE</p> </div> <p style="text-align: center;">World Leader in Homeopathic Medicines</p> <p style="text-align: right;">NET WT. 0.5 oz (14 g)</p>										
<p><b>Drug Facts</b></p> <table border="0" style="width: 100%;"> <tr> <td style="width: 60%;"><b>Active ingredient**</b></td> <td style="width: 40%;"><b>Purpose*</b></td> </tr> <tr> <td>Calendula officinalis _____</td> <td>Healing agent</td> </tr> <tr> <td>1X HPUS-10%</td> <td></td> </tr> <tr> <td colspan="2"><small>The letters HPUS indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States.</small></td> </tr> </table> <p><b>Uses*</b> ■ helps promote healing of cuts, scrapes, chafing, minor burns and sunburn</p>	<b>Active ingredient**</b>	<b>Purpose*</b>	Calendula officinalis _____	Healing agent	1X HPUS-10%		<small>The letters HPUS indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States.</small>		<p><b>Warnings</b> For external use only. Avoid contact with eyes. Do not use if you are allergic to Calendula officinalis or to this product's inactive ingredients. Ask a doctor before use in case of deep or puncture wounds, animal bites or serious burns. Stop use and ask a doctor if condition persists for more than 3 days or worsens. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</p> <p><b>Directions</b> ■ For minor burns, immediately run cool water on the burn for several minutes and dry. For scrapes, skin irritations and sunburn, first cleanse the area with mild soap, rinse and dry. ■ Then apply a thin layer of Calendula Cream to affected area 3 times a day or as needed.</p>	
<b>Active ingredient**</b>	<b>Purpose*</b>									
Calendula officinalis _____	Healing agent									
1X HPUS-10%										
<small>The letters HPUS indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States.</small>										

## Drug Facts

(continued)

### Other information

- Do not use if the tube seal is broken.

### Inactive ingredients

almond, caprylic/capric triglyceride, carbomer, cetyl palmitate, EDTA disodium, glycerin, lanolin, macroglycerol polysebacate, polyoxy-4 stearate, purified water, sodium hyaluronate, sorbic acid, 1,2-hexanediol.

Made in France ♻️ please recycle

### Questions or comments?

BoironCalendula.com  
BoironUSA.com  
1-800-BOIRON-1 (1-800-256-7881)  
Manufactured by Boiron Inc.  
Newtown Square, PA 19073-2628

\*Homeopathic mother tincture made from Calendula officinalis flowering tops. These "tincts" have not been evaluated by the Food and Drug Administration. U.S. K, O, and X are homeopathic dilutions; see BoironUSA.com for details.



## SOOTHES & HEALS SKIN IRRITATIONS

Cuts • Scrapes • Chafing  
Minor Burns • Sunburn\*

Calendula officinalis (Marigold) has been used for generations to naturally heal skin irritations. Calendula Cream's light texture is both soothing and moisturizing. It is ideal for use on dry or chafed skin.



SALE  
NOT FOR

FIRST AID\*

# Calendula Cream



Soothing • Moisturizing • Help Your Body the Natural Way

NDC 0220-1109-88

HOMEOPATHIC  
MEDICINE  
NET WT. 0.5 OZ (14 g)

Boiron®  
World Leader in Homeopathic Medicines

## Drug Facts

### Active ingredient\*\*

Calendula officinalis ————— Healing agent

TX HPUS-10% (indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States)

Use\* ————— Heals prompt healing of cuts, scrapes, chafing, minor burns and sunburn

### Purpose\*

**Warnings** For external use only. Avoid contact with eyes. Do not use if you are allergic to Calendula officinalis or to this product's inactive ingredients. Ask a doctor before use in case of deep or puncture wounds, animal bites or serious burns. Stop use and ask a doctor if condition persists for more than 3 days or worsens. Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

**Directions** For minor burns, immediately run cool water on the burn for several minutes and dry. For scrapes, skin irritations and sunburn, first cleanse the area with mild soap, rinse and dry. Then apply a thin layer of Calendula Cream to affected area 3 times a day or as needed.

natural  
active  
ingredient

## Drug Facts

(continued)

### Other information

■ do not use if the tube seal is broken

### Inactive ingredients

alcohol, caprylyl glycol, carbomer, cetyl palmitate, EDTA disodium, glycerin, lauroyl macroglyglycides, pegoxol-7 stearate, purified water, sodium hydroxide, sorbic acid, 1,2-hexanediol

### Questions or comments?

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**SAMPLE ONLY  
NOT FOR RESALE**

Made In France

 please recycle

NDC 0220-1109-68

## FIRST AID\*

Cuts • Scrapes  
Minor Burns • Chafing  
Sunburn\*

# Calendula Cream

HOMEOPATHIC MEDICINE

Help Your Body  
the Natural Way



NET WT.  
0.5 oz (14 g)

**BOIRON**

World Leader in Homeopathic Medicines

natural  
active  
ingredient

*Calendula officinalis*  
(Garden marigold)  
has been used topically  
for generations to naturally  
heal skin irritations.

*Calendula Cream's light  
texture is both soothing  
and moisturizing. It is ideal  
for use on dry or chafed skin.*

- Soothes
- Moisturizes & Heals
- Paraben-Free



## Drug Facts

**Active ingredient\*\***      **Purpose\***

Calendula officinalis.....Healing agent  
1X HPUS-10%

*The letters HPUS indicate that this ingredient is officially included in the Homeopathic Pharmacopoeia of the United States.*

### Uses\*

■ helps promote healing of cuts, scrapes, chafing, minor burns and sunburn.

### Warnings

**For external use only.** Avoid contact with eyes. **Do not use** if you are allergic to Calendula officinalis or to this product's inactive ingredients. **Ask a doctor before use** in case of deep or puncture wounds, animal bites or serious burns. **Stop use and ask a doctor** if condition persists for more than 3 days or worsens. **Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

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NDC 0220-1109-68

FIRST AID\*

Cuts • Scrapes  
Minor Burns • Chafing  
Sunburn\*

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## Calendula *Cream*

HOMEOPATHIC MEDICINE

Help Your Body  
the Natural Way

- Soothes
- Moisturizes & Heals
- Paraben-Free

NET WT.  
0.5 oz (14 g)



World Leader in Homeopathic Medicines

**Active ingredient\*\***  
Calendula officinalis 1X HPUS-10%

**Uses\*** ■ helps promote healing of cuts, scrapes, chafing, minor burns and sunburn

**Warnings**  
For external use only. Avoid contact with eyes.

**Do not use** if you are allergic to Calendula officinalis or to any of this product's inactive ingredients. Ask a doctor in case of deep or puncture wounds, animal bites or serious burns. Stop use and ask a doctor if condition persists for more than 3 days or worsens.

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**Other information** ■ do not use if the tube seal is broken

**Inactive ingredients:** alcohol, caprylyl glycol, carbomer, cetyl palmitate, EDTA disodium, glycerin, lauryl macroglycerides, pegoxol-7 stearate, purified water, sodium hydroxide, sorbic acid, 1,2-hexanediol

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Newtown Square, PA

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\*C, K, CK, and X are homeopathic dilutions: see [www.boironusa.com/info](http://www.boironusa.com/info) for details.

## CALENDULA

calendula cream

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0220-1109
Route of Administration	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
CALENDULA OFFICINALIS FLOWERING TOP (UNII: 18E7415PXQ) (CALENDULA OFFICINALIS FLOWERING TOP - UNII:18E7415PXQ)	CALENDULA OFFICINALIS FLOWERING TOP	1 [hp_X] in 1 g

### Inactive Ingredients

Ingredient Name	Strength
CAPRYLYL GLYCOL (UNII: 00YIU5438U)	
CARBOMER 934 (UNII: Z135WT9208)	
CETYL PALMITATE (UNII: 5ZA2S6B08X)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
WATER (UNII: 059QF0KO0R)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
SORBIC ACID (UNII: X045WJ989B)	
1,2-HEXANEDIOL (UNII: TR046Y3K1G)	

GLYCERIN (UNII: PDC6A3C0OX)	
LAUROYL PEG-32 GLYCERIDES (UNII: H5ZC52369M)	
PEGOXOL 7 STEARATE (UNII: 3EW5AXE5X5)	
ALCOHOL (UNII: 3K9958V90M)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0220-1109-68	1 in 1 BOX	02/29/2016	
1		14 g in 1 TUBE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved homeopathic		02/29/2016	

**Labeler** - Boiron (282560473)

**Registrant** - Boiron Inc. (014892269)

### Establishment

Name	Address	ID/FEI	Business Operations
Boiron		282560473	manufacture(0220-1109)

Revised: 4/2018

Boiron