

**RAY DOL- pain relieving cream cream**  
**Genomma Lab USA 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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**Drug Facts**

**Active Ingredients**

Menthol - 10%

Methyl salicylate - 15%

**Purpose**

Topical Analgesic

Topical Analgesic

**Uses**

Temporary relief of minor aches and pains of muscle and joints associated with

- simple back aches
- arthritis
- strains
- bruises
- sprains

**Warnings**

**For external use only**

**Do not use**

- on wounds, damaged, broken or irritated skin
- with a heating pad

**When using this product**

- use only as directed
- avoid contact with eyes or mucous membranes
- Do not apply bandage tightly

**Stop use and ask doctor if**

- Condition worsens, or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs
- **If pregnant or breast feeding**, ask a health professional before use.

**Keep this and all drugs out of the reach of children.** If swallowed, get medical help or contact a Poison Control Center immediately.

**Directions**

- **Adults and children 2 years of age and older;** Apply to affected area not more than 3 to 4 times daily.
- **Children under 2 years of age;** consult a doctor.

**Other information**

- Store at controlled room temperature 20°- 25°C ( 68° to 77°F)
- Close cap tightly after use.

**Inactive ingredients**

Carbomer, Cetyl Alcohol, Oleth-3 Phosphate, Purified Water, Stearic acid, Triethanolamine

**Principal Display Panel - 3.0 oz Carton****RAY DOL**

Topical Analgesic

**Greaselees Stainless****Temporary Relief**

Penetrating temporary relief of minor muscle aches

For Arthritis, Muscle & Joint Pain

10% Menthol and

15% Methyl Salicylate

**Net WT. 3.0 oz ( 85g)**

**RAY<sup>DOL</sup>**

**PAIN RELIEVING CREAM**  
Crema para el alivio del dolor

**RAY<sup>DOL</sup>**

**TOPICAL ANALGESIC**  
Analgésico Tópico



**GREASELESS STAINLESS TEMPORARY RELIEF**

Penetrating temporary relief of minor muscle aches  
Alivio temporal de dolores musculares menores

For Arthritis, Muscle & Joint Pain  
Para Artritis, Dolor Muscular y de Articulaciones

10% Menthol and  
15% Methyl Salicylate  
Mentol 10% y  
Salicilato de Metilo 15%

NET WT. 3 oz. (85g)

**Drug Facts**

Active ingredients	Purpose
Menthol - 10%	Topical Analgesic
Methyl Salicylate - 15%	Topical Analgesic

**Uses**  
Temporary relief of minor aches and pains of muscles and joints associated with

- simple backache
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For external use only

**Do not use**

- on wounds or damaged, broken or irritated skin
- with a heating pad

**When using this product**

- use only as directed
- avoid contact with eyes or mucous membranes
- do not bandage tightly

**Stop use and ask a doctor if**

- condition worsens or symptoms persist for more than 7 days
- symptoms clear up and occur again within a few days
- excessive skin irritation occurs

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

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

**Directions**  
Adults and children 12 years of age and older:  
Apply to affected area not more than 3 to 4 times daily.

Children under 12 years of age: Consult a doctor.

**Other information**

- Store at controlled room temperature 20° - 25°C (68° - 77°F)
- Close the cap tightly after use

**Inactive ingredients**  
Carbomer, Cetyl Alcohol, Oleth-3 Phosphate, Purified Water, Stearic Acid, Triethanolamine

**Questions or comments?**  
Call toll free: 1 877 99 GENOM (436666)  
Monday to Friday from 8 am to 6 pm

Do not use if tube seal under cap is broken or missing

5088487

**PAIN RELIEVING CREAM**  
Crema para el alivio del dolor

**RAY<sup>DOL</sup>**

**TOPICAL ANALGESIC**  
Analgésico Tópico



**GREASELESS STAINLESS TEMPORARY RELIEF**

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15% Methyl Salicylate  
Mentol 10% y  
Salicilato de Metilo 15%

NET WT. 3 oz. (85g)

**Información del Medicamento**

Ingredientes activos	Propósito
Mentol - 10%	Analgésico Tópico
Salicilato de Metilo - 15%	Analgésico Tópico

**Usos**  
Para el alivio temporal de dolores menores y dolores musculares y de articulaciones asociados con:

- dolor de espalda simple
- moretones
- artritis
- esguinces
- torceduras

**Advertencias**  
Para uso externo solamente

**No se utilice**

- sobre heridas, piel dañada, rasgada o irritada
- en conjunto con una almohadilla térmica

**Cuando use este producto**

- utilizar sólo como se indica
- evitar el contacto con los ojos y membranas mucosas
- no aplicar un vendaje muy ajustado

**Suspenda su uso y consulte a su médico si**

- la condición empeora o el dolor persiste por más de 7 días
- los síntomas desaparecen y vuelven a aparecer dentro de algunos días
- se presenta irritación excesiva de la piel

**En caso de embarazo o lactancia, consulte a un profesional médico antes de su uso.**  
**Manténgase fuera del alcance de los niños.** En caso de ingerirlo, obtenga asistencia médica o contacte a un Centro de Control de Envenenamiento de manera inmediata.

**Indicaciones**  
Adultos y niños mayores de 12 años: Aplicar en el área afectada no más de 3 a 4 veces por día.

Niños menores de 12 años: Consulte a su médico.

**Información Adicional**

- Store at controlled room temperature 20° - 25°C (68° - 77°F)
- Cierre la tapa firmemente después de usar

**Ingredientes inactivos**  
Carbómero, Alcohol cetílico, Oleth-3 Fosfato, Agua purificada, Ácido esteárico, Trietanolamina

**¿Preguntas o comentarios?**  
Lláme cada sin costo 1 877 99 GENOM (436666)  
Lunes a Viernes de 8 am a 6 pm

No usar si el sello de seguridad está roto o falta

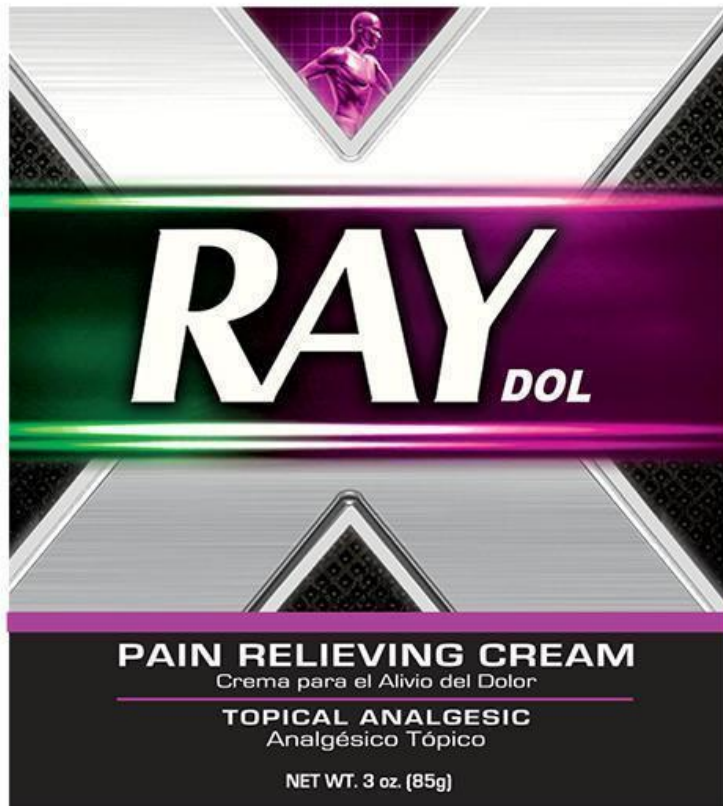
2FX0RC8UEWW1A



Distributed by / Distribuido por:  
Genomma Lab USA, Inc.,  
Houston, TX 77027

Principal Display Panel - 3.0 oz Tube  
RAY DOL  
Pain Relieving Cream  
Topical Analgesic

Net WT. 3.0 oz (85g)



<b>DRUG FACTS</b>	
<b>Active Ingredients</b>	<b>Purpose</b>
Menthol - 10%, Methyl Salicylate - 15%	Topical Analgesic
<b>Uses:</b> Temporary relief of minor aches and pains of muscles and joints associated with: • simple backache • arthritis • strains • bruises • sprains.	
<b>Warnings:</b> For external use only. Do not use • on wounds or damaged skin, broken (open) or irritated skin • with a heating pad. When using this product • use only as directed • avoid contact with eyes or mucous membranes • do not bandage tightly. Stop use and ask a doctor if • condition worsens or symptoms persist for more than 7 days • symptoms clear up and occur again within a few days • excessive skin irritation occurs. If pregnant or breast-feeding, ask a health care professional before use. Keep out of reach of children to avoid accidental ingestion. If swallowed, get medical help or contact a Poison Control Center immediately.	
<b>Directions:</b> • use only as directed. Adults and children 12 years of age and older: Apply to affected area not more than 3 to 4 times daily. Children under 12 years of age: Consult a doctor.	
<b>Questions or comments?</b> Call toll free 1 877 99 GENOM (43666)	
<b>INFORMACIÓN DEL MEDICAMENTO</b>	
<b>Ingredientes activos</b>	<b>Propósito</b>
Mentol - 10%, Silicato de Metilo - 15%	Analgésico Tópico
<b>Usos:</b> Para el alivio temporal de dolores menores y dolores musculares y de articulaciones asociados con: • dolor de espalda simple • artritis • torceduras • moretones • esguinces.	
<b>Advertencias:</b> Para uso externo solamente. No se utilice • sobre heridas, piel dañada, rasgada o irritada • en conjunto con una almohadilla térmica. Cuando use este producto • Utilice únicamente según las indicaciones • evitar el contacto con los ojos y membranas mucosas • no aplicar un vendaje muy ajustado Suspense su uso y consulte a su médico si • la condición empeora o el dolor persiste por más de 7 días • los síntomas desaparecen y vuelven a aparecer dentro de algunos días • se presenta irritación excesiva de la piel. En caso de embarazo o lactancia, consulte a un profesional médico antes de su uso. Manténgase fuera del alcance de los niños. En caso de ingerirlo, obtenga asistencia médica o contacte a un Centro de Control de Envenenamiento de manera inmediata.	
<b>Indicaciones:</b> • utilizar según indicaciones. Adultos y niños mayores de 12 años: Aplicar en el área afectada no más de 3 a 4 veces por día. Niños menores de 12 años: Consulte a su médico.	
<b>¿Preguntas o comentarios?</b> Llame lada sin costo 1 877 99 GENOM (43666)	

For further details look at the box / Para más detalles ver la caja  
See tube crimp for Lot No./Lote No. and Exp.  
Made in the USA Distributed by / Distribuido por: Genomma Lab USA, Inc., Houston, TX 77027  
2504974 ZFXR3UDEAJIA

## RAY DOL

pain relieving cream cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50066-057
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MENTHOL (UNII: L7T10EIP3A) (MENTHOL - UNII:L7T10EIP3A)	MENTHOL	100 mg in 1 g
METHYL SALICYLATE (UNII: LAV5U5022Y) (SALICYLIC ACID - UNII:O414PZ4LPZ)	METHYL SALICYLATE	150 mg in 1 g

### Inactive Ingredients

Ingredient Name	Strength
CARBOMER 940 (UNII: 4Q93RCW27E)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
TROLAMINE (UNII: 9O3K93S3TK)	
WATER (UNII: 059QF0K00R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

OLETH-3 PHOSPHATE (UNII: 8Q0Z18J1VL)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-057-73	1 in 1 CARTON		
1		85 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/15/2013	

**Labeler** - Genomma Lab USA Inc. (832323534)

**Registrant** - Faria LLC dba Sheffield Pharmaceuticals (151177797)

### Establishment

Name	Address	ID/FEI	Business Operations
Faria LLC dba Sheffield Pharmaceuticals		151177797	manufacture(50066-057)

Revised: 1/2014

Genomma Lab USA Inc.