

**MONISTAT COMPLETE CARE INSTANT ITCH RELIEF- hydrocortisone cream**  
**Insight Pharmaceuticals 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.*

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**Monistat Care Itch Relief Cream**

***Drug Facts***

**Active Ingredient**

Hydrocortisone 1%

**Purpose**

Anti-itch

**Uses**

- temporarily relieves external genital itching
- other uses of this product should only be under the advice and supervision of a doctor

**Warnings**

**For external use only**

**Ask a doctor before use if**

you have a vaginal discharge

**When using this product**

- avoid contact with eyes
- do not use more than directed
- do not begin use of any other hydrocortisone product unless you have asked a doctor

**Stop use and ask a doctor if**

- condition worsens
- symptoms last for more than 7 days or clear up and occur again within a few days

**Keep out of reach of children.**

If swallowed get medical help or contact a Poison Control Center (1-800-222-1222) right away.

**Directions**

- **adults:** apply to affected area not more than 3-4 times daily
- **children under 12 years of age:** ask a doctor

**Other Information**

- store at 20°-25°C (68°-77°F). Protect from freezing and excessive heat.

**Inactive ingredients**

ammonium acryloyldimethyltaurate/VP copolymer, carbomer, cetareth-6, cetyl alcohol, citric acid, dimethicone, edetate disodium, ethylparaben, glycerin, methylparaben, mineral oil, petrolatum, phenoxyethanol, propylparaben, sodium citrate, sodium hydroxide, stearyl alcohol, VP/eicosene copolymer, water

**Questions?**

1-877-666-4782 Monistat.com

**Dist. by** Insight Pharmaceuticals, LLC.  
Tarrytown, NY 10591

A Prestige Brands Company

**PRINCIPAL DISPLAY PANEL**

**MONISTAT®**

**Care**

**Itch Relief Cream**

Hydrocortisone 1%

NEW WT 1 OZ (28 g)

**MONISTAT.**  
*Care*

**INTENSE ITCH RELIEF**  
*Alivio intenso del picazón*

**MONISTAT.**  
*Care*

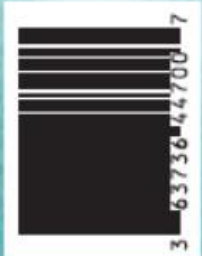
Instant long lasting relief from intense itch associated with:

- Irritating vaginal conditions
- Period
- Perspiration
- Clothing

Alivio instantáneo de la picazón asociada con:

- Afecciones vaginales irritantes
- Periodo
- Sudoración
- Vestimenta

**Hypoallergenic**  
*Hipoalergénico*



**INTENSE ITCH RELIEF**  
*Alivio intenso del picazón*

**MONISTAT.**  
*Care*

**MAXIMUM STRENGTH**

**INSTANT Itch Relief Cream**  
Hydrocortisone 1%

Concentración máxima-Crema para el alivio instantáneo de la picazón  
*Hidrocortisona 1%*

**Long-Lasting**  
*Duradero*  
**Cools, Relieves & Soothes**  
*Refresca, alivia y calma*  
**Fragrance Free**  
*Sin fragancia*



NET WT / PESO NETO 1 OZ (28 g)

**MONISTAT.**  
*Care*

In testing 95% of women AGREE that it relieves external vaginal itching FAST\*  
*\*Compartir aliviar rápido*  
En las pruebas, el 95% ESTÁN DEACUERDO en que alivia la picazón vaginal externa RÁPIDAMENTE\*  
*\*Tamaño de muestra en estudio*

Questions?/¿ Preguntas?  
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Monistat.com

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MNU5015102

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THIS PRODUCT IS NOT INTENDED TO TREAT YEAST INFECTIONS.

ESTE PRODUCTO NO FUE CREADO PARA TRATAR INFECCIONES POR HONGOS

**Drug Facts**

Active ingredient	Purpose
Hydrocortisone 1%	Anti-itch

**Use** ■ temporarily relieves external genital itching ■ other uses of this product should be only under the advice and supervision of a physician

**Warnings** For external use only

**Ask a doctor before use** if you have a vaginal discharge  
**When using this product** ■ avoid contact with eyes  
■ do not use more than directed ■ do not begin use of any other hydrocortisone product unless you have asked a doctor  
**Stop use and ask a doctor** if ■ condition worsens ■ symptoms last more than 7 days or clear up and occur again within a few days  
**Keep out of reach of children.** If swallowed get medical help or contact a Poison Control Center (1-800-222-1222) right away.

**Directions** ■ adults: apply to affected area not more than 3-4 times daily ■ children under 12 years of age: ask a doctor

**Other information** store at 20°-25°C (68°-77°F). Protect from freezing and excessive heat.

**Inactive ingredients** ammonium acryloyldimethylsulfate/VP copolymer, carbomer, ceteareth-6, cetyl alcohol, citric acid, dimethicone, edetate disodium, ethylparaben, glycerin, methylparaben, mineral oil, petrolatum, phenoxethanol, propylparaben, sodium citrate, sodium hydroxide, stearyl alcohol, VP/lecithene copolymer, water

**Información del medicamento**

Ingrediente activo	Objetivo
Hydrocortisone 1%	Antipicazón

**Usos** ■ alivia temporalmente la picazón genital externa ■ otros usos de este producto deben ser solo bajo el asesoramiento y la supervisión de un médico

**Advertencias** Solo para uso externo

Consulte a su médico antes de usar si tiene una secreción vaginal  
**Cuando use este producto** ■ evite el contacto con los ojos  
■ no exceda la dosis ■ no empiece a usar ningún otro producto con hidrocortisona a menos que haya preguntado a un doctor  
Interrompa el uso de este producto y consulte al médico si ■ la afección empeora ■ síntomas persisten durante más de 7 días o desaparecen y vuelven a aparecer a los pocos días  
**Mantenga fuera del alcance de los niños.** En caso de ingesta, obtenga ayuda médica o póngase en contacto con un centro de control de envenenamiento (1-800-222-1222) inmediatamente.

**Instrucciones** ■ adultos: aplique en el área afectada no más de 3 o 4 veces al día ■ niñas menores de 12 años: consulte a un médico

**Información adicional** almacene a 20°-25°C (68°-77°F). Proteja del frío y del calor excesivo.

**Ingredientes inactivos** copolímero de amonio acrilodimetil sulfato/VP, carbómero, cetareto-6, alcohol cetílico, ácido cítrico, dimeticona, disodio ETA, etil parahidroxibenzoato, glicerina, metilparabeno, aceite mineral, petrolato, fenoxietanol, propil parahidroxibenzoato, citrato de sodio, hidróxido de sodio, alcohol estearílico, copolímero VP/lecitina, agua

Sihouette of tube is actual size, / Silueta de tubo es de tamaño real

hydrocortisone cream

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63736-029
<b>Route of Administration</b>	TOPICAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROCORTISONE (UNII: W14X0X7BPJ) (HYDROCORTISONE - UNII:W14X0X7BPJ)	HYDROCORTISONE	1 g in 100 g

### Inactive Ingredients

Ingredient Name	Strength
AMMONIUM ACRYLOYLDIMETHYLTAURATE/VP COPOLYMER (UNII: W59H9296ZG)	
CARBOMER HOMOPOLYMER TYPE A (UNII: F68VH75CJC)	
CETEARETH-6 (UNII: 2RJS3559D3)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERIN (UNII: PDC6A3C0OX)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MINERAL OIL (UNII: T5L8T28FGP)	
PETROLATUM (UNII: 4T6H12BN9U)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
STEARYL ALCOHOL (UNII: 2KR89I4HIY)	
WATER (UNII: 059QF0KO0R)	
VINYLPYRROLIDONE/EICOSENE COPOLYMER (UNII: 035MV9S1C3)	

### 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:63736-029-01	1 in 1 CARTON	11/15/2013	
1		28 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
OTC MONOGRAPH NOT FINAL	part348	11/15/2013	

**Labeler** - Insight Pharmaceuticals LLC (055665422)

Revised: 3/2018

Insight Pharmaceuticals LLC