

ASEPXIA ACNE TREATMENT- benzoyl peroxide 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.

Asepxia® Acne Treatment Cream Acne Treatment

Drug Facts

Active ingredient

Benzoyl Peroxide 10%

Purpose

Acne Treatment

Uses

- ◆ for the treatment of acne
- ◆ dries and clears acne blemishes
- ◆ penetrates pores to eliminate most acne blemishes
- ◆ helps prevent new acne blemishes

Warnings

For external use only

Do not use

- ◆ if you have very sensitive skin
- ◆ if you are sensitive to benzoyl peroxide

When using this product

- ◆ avoid unnecessary sun exposure and use a sunscreen
- ◆ avoid contact with eyes, lips and mouth
- ◆ avoid contact with hair and dyed fabrics, which may be bleached by this product
- ◆ skin irritation and dryness is more likely to occur if you use another acne medication at the same time. If irritation occurs, use only one topical acne medication at a time
- ◆ skin irritation may occur, characterized by redness, burning, itching, peeling or possibly swelling. Irritation may be reduced by using this product less frequently or at a lower concentration

Stop use and ask a doctor if

- ◆ irritation becomes severe

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 three times daily
- ◆ because excessive drying of the skin may occur, start with one application daily, then gradually increase to two or three 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
- ◆ if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor

Sensitivity test for 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

Other information

- ◆ Keep tightly closed
- ◆ Store at room temperature

Inactive ingredients

carbomer, disodium EDTA, hydroxypropyl methylcellulose, Laureth-4, sodium hydroxide, water

Questions or comments?

1 877 994 3666. Monday to Friday, 8am to 6pm, Central time.

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

PRINCIPAL DISPLAY PANEL - 28 g Tube Carton

Asepxia®

ACNE TREATMENT CREAM

10% BENZOYL PEROXIDE

> ELIMINATES MOST PIMPLES AND BLACKHEADS

NET WT./ CONT. NET.
1 OZ (28 g)

Asepxia®

ACNE TREATMENT CREAM
CREMA PARA EL TRATAMIENTO DEL ACNÉ

10% BENZOYL PEROXIDE/ PERÓXIDO DE BENZOILO

FIGHTS ACNE-CAUSING BACTERIA
RAPID MAXIMUM STRENGTH

HELPS STOP ACNE BREAK-OUTS BEFORE THEY BECOME VISIBLE

COMBATE LAS BACTERIAS QUE CAUSAN EL ACNÉ
RÁPIDA Y MÁXIMA POTENCIA

AYUDA A DETENER LAS ERUPCIONES DEL ACNÉ ANTES DE QUE SEAN VISIBLES

Asepxia®

ACNE TREATMENT CREAM
CREMA PARA EL TRATAMIENTO DEL ACNÉ

10% BENZOYL PEROXIDE/ PERÓXIDO DE BENZOILO

► **ELIMINATES MOST PIMPLES AND BLACKHEADS**
ELIMINA LA MAYORÍA DE BARROS Y ESPINILLAS

NET WT./ CONT. NET.
1 OZ (28 g)

Asepxia®



Genomma Lab.®

Made in Canada / Hecho en Canadá
Distributed by / Distribuido por: Genomma Lab USA Inc., Houston, TX 77098
www.genomalab.us

Lot No./Lote No.:
Exp.

2000005651



Asepxia®

Active Ingredient Benzoyl peroxide 10%	Purpose Acne Treatment	Usos For the treatment of acne ■ dries and clears acne blemishes ■ penetrates pores to eliminate most acne blemishes ■ helps prevent new acne blemishes	Warnings For external use only	Do not use ■ if you have very sensitive skin ■ if you are sensitive to benzoyl peroxide	When using this product ■ avoid unnecessary sun exposure and use a sunscreen ■ avoid contact with eyes, lips and mouth ■ avoid contact with hair and avoid fabrics, which may be bleached by this product ■ skin irritation may occur ■ if irritation occurs, use one repeat acne medication at time ■ skin irritation may be reduced by rinsing, during, drying, peeling or possibly sweating ■ friction may be reduced by using this product less frequently or at lower concentration	Stop use and ask a doctor if ■ irritation becomes severe	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 three times daily ■ because exfoliation may occur, start with one application daily, then gradually increase to two or three 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 ■ if going outside, apply sunscreen after using this product. If irritation or sensitivity develops, stop use of both products and ask a doctor	Sensitivity test for 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	Other information ■ Keep tightly closed ■ Store at room temperature ■ Benzoyl peroxide, sodium hydroxide, water	Inactive ingredients carbonic acidum (E170), hydroxypropyl methylcellulose, Laureth-4, sodium hyaluronate, water	Questions or comments? 1 877 994 3666, Monday to Friday, 9am to 8:00 a.m. a 6:00 p.m., horario central.
Drug Facts	Purpose	Usos	Warnings	Do not use	When using this product	Stop use and ask a doctor if	Keep out of reach of children	Directions	Other information	Inactive ingredients	Questions or comments?	
Propósito Tratamiento del acné	Ingrediente activo Peróxido de benzilo 10%	Usos ■ parte de tratamiento para el acné ■ seca y borra las manchas del acné ■ penetra en los poros para eliminar la mayoría de las manchas causadas por el acné ■ ayuda a prevenir nuevas manchas del acné	Advertencias Uso externo para uso externo	No se utilice ■ si no puede muy sensible ■ si usted es sensible al peróxido de benzilo	Al usar este producto ■ evite la exposición al sol innecesaria y use un protector solar ■ evite el contacto con los ojos, los labios y la boca ■ evite el contacto con el pelo y con los tejidos blandos, los cuales se pueden decolorar con este producto ■ existe una mayor probabilidad de que su piel se irrite y se resaque al usar un medicamento contra el acné al mismo tiempo. En caso de resaca, utilice solo un medicamento contra el acné a la vez ■ puede producirse una irritación de la piel, que se caracteriza por enrojecimiento, picazón, descamación o una posible hinchazón. La irritación se puede reducir usando este producto con menos frecuencia o en menor concentración	Suspenda el uso y consulte a un médico si ■ la irritación se vuelve severa	Mantenga fuera del alcance de los niños ■ En caso de ingestión, obtenga ayuda médica o contacte de inmediato a un Centro de Control de Intoxicación	Instrucciones de uso ■ limpie bien la piel antes de aplicar este producto ■ cubra toda el área afectada con una capa delgada de una a tres veces al día ■ debido a que la piel se puede resacar excesivamente, comience con una sola aplicación diaria, y luego aumente gradualmente a dos o tres veces al día si es necesario o según las instrucciones de su médico ■ si se produce resaca, reduzca la aplicación a una vez al día o cada dos días ■ si va a salir al calle, aplique protector solar después de usar este producto. Si se descolora la irritación o la sensibilidad, suspenda el uso de ambos productos y consulte a su médico	Información adicional ■ mantenga el envase bien cerrado ■ almacene a temperatura ambiente	Ingredientes inactivos ácido carbónico, EDTA, disódico, hidroxi-propil metilcelulosa, lauret-4, hidróxido de sodio, agua	Preguntas o comentarios? 1 877 994 3666, De lunes a viernes, de 9:00 a.m. a 6:00 p.m., horario central.	

ASEPXIA ACNE TREATMENT

benzoyl peroxide cream

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50066-052
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Benzoyl Peroxide (UNII: W9WZN9A0GM) (Benzoyl Peroxide - UNII:W9WZN9A0GM)	Benzoyl Peroxide	100 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
Edetate Disodium (UNII: 7FLD91C86K)	
Hypromellose, Unspecified (UNII: 3NXW29V3WO)	
Laureth-4 (UNII: 6HQ855798J)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Water (UNII: 059QF0KO0R)	

Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50066-052-01	1 in 1 CARTON	03/06/2015	
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 FINAL	part333D	03/06/2015	

Labeler - Genomma Lab USA Inc. (832323534)

Registrant - Garcoa, Inc. (036464697)

Establishment

Name	Address	ID/FEI	Business Operations
Sigan Industries INC		255106239	MANUFACTURE(50066-052) , LABEL(50066-052) , PACK(50066-052)

Revised: 2/2023

Genomma Lab USA Inc.