ASEPXIA - salicylic acid gel Televisa Consumer Products USA

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 Gel

Active Ingredient

Salicylic Acid 2%

Purpose

Acne Treatment

Uses

- for the treatment of acne
- clears up acne blemishes, acne pimples, blackheads, whiteheads and allows skin to heal
- helps prevent new acne blemishes, acne pimples, blackheads or 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 he same time. If irritation occurs, only use one topical acne medication at a time.

Keep out of the 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 both some 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

Butylene glycol, ethyl alcohol, glycerin, hydroxyethylcellulose, propylene glycol, sodium citrate, water

Questions or Comments?

1 877 99 GENOM (43666)

Made in Mexico

Distributed by: Televisa Consumer Products USA, LLC 4550 Post Oak Place Suite 326 Houston, TX 77027

Asepxia

Acne Gel

For the treatment of Acne Eliminates most pimples and blackheads Net Wt 0.71 oz (20g)

Outer Container Label

For the treatment of acne Para el tratamiento del acné

Drug Facts	Datos del Medicamento	
Active ingredient Purpose	Ingrediente activo Efecto	
Salicylic Acid 2%	Ácido salicítico 2%Tratamiento del acné	
Uses ■ for the treatment of acne ■ clears up acne blemishes, acne pimples, blackheads, whiteheads and allows skin to heal ■ helps prevent new acne blemishes, acne pimples, blackheads or whiteheads from forming	Usos ■ tratamiento para el acné ■ aclara los defectos causados por el acné, espínillas, puntos negros y barros y permite que la piel sane ■ ayuda a prevenir que surjan nuevamente el acné, espínillas, puntos negros y barros que pudieran formarse	
Warnings For external use only	Avisos Para uso externo solamente	

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 the 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

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 Butylene glycol, ethyl alcohol, glycerin, hydroxyethylcellulose propylene glycol, sodium citrate, water.

Questions or comments? 1 877 99 GENOM (43666)

Al usar este producto puede ocurrir irritación y resequedad de la piel al usar otro medicamento tópico para el acné al mismo tiempo. Si esto ocurre, sólo use un medicamento a la vez.

Mantenga fuera del alcance de los niños. En caso de ingestión accidental busque asistencia médica o llame al Centro de Enveneramiento inmediatamente.

Instrucciones Limpie bien la piel antes de aplicar el medicamento ■ cubrir toda el área afectada con una capa fina de una a tres veces al día ■ debido á que puede presentarse resequedad en la piel, empiece con una aplicación diaria, después in en caso de presentarse resequedad o descamación, reduzca la aplicación a una vez al día.

Prueba de sensibilidad para el usuario nuevo: Aplicar un poco de producto en una o dos áreas afectadas durante los primeros 3 días. Si no se presentan molestías, siga las instrucciones arriba citadas.

Ingredientes inactivos Butilenglicol, alcohol etilico, glicerina, hidroxietil celulosa, propilenglicol, citrato de sodio, aqua.

¿Preguntas o comentarios? 1 877 99 GENOM (43666)

Lot No./Lote No.: Exp.



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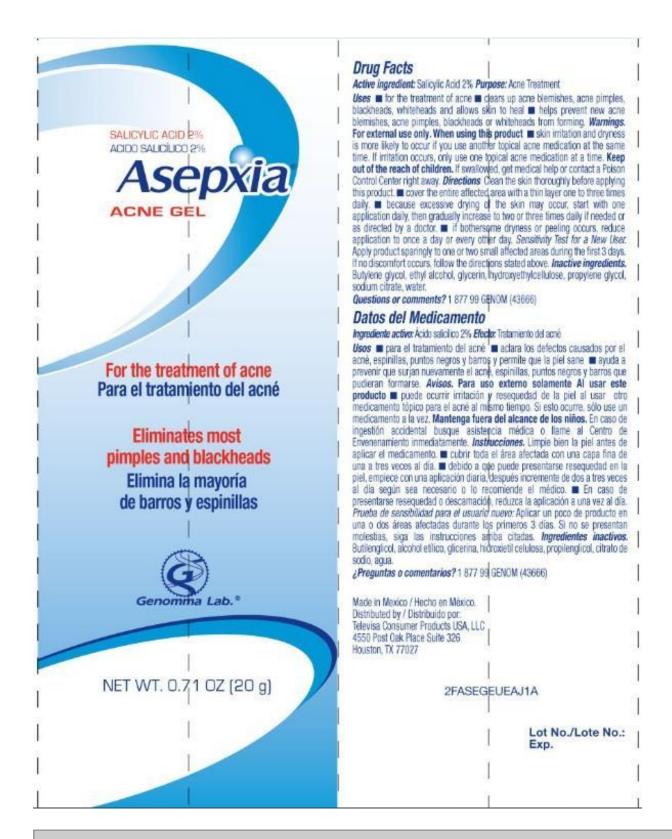


NET WT. 0.71 OZ (20 g)

Eliminates most pimples and blackheads Elimina la mayoria de barros y espinillas

For the treatment of acne Para el tratamiento del acné





ASEPXIA

salicylic acid gel

Product Information			
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:55038-444
Route of Administration	TOPICAL	DEA Sche dule	

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SALICYLIC ACID (SALICYLIC ACID)	SALICYLIC ACID	2 g in 100 g	

Inactive Ingredients				
Ingredient Name	Strength			
BUTYLENE GLYCOL				
ALCOHOL				
GLYCERIN				
PROPYLENE GLYCOL				
SO DIUM CITRATE				
WATER				

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:55038-444-01	20 g in 1 TUBE		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part333D	08/17/2011	

Labeler - Televisa Consumer Products USA (840246230)

Registrant - Laboratorios Kener, S.A. de C.V. (810347658)

Establishment				
Name	Address	ID/FEI	Business Operations	
Laboratorios Kener, S.A. de C.V.		8 10 3476 58	manufacture (550 38 - 444)	

Revised: 4/2013 Televisa Consumer Products USA