

HYDROGEN PEROXIDE- hydrogen peroxide solution
Laboratorios Jaloma, S.A. de C.V.

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.

Drug Facts

Active Ingredient

Hydrogen Peroxide 3%

Purpose

Antiseptic

Uses

first aid to help prevent infection in minor cuts scrapes • burns

Warnings

For external use only • do not use in the eyes or apply over large areas of the body.

Consult a doctor in case of • deep or puncture wounds • animal bites • serious burns.

Stop use and consult a doctor if the condition persists or gets worse.

Do not use longer than 1 week unless directed by a doctor.

Keep out of the reach of children. In case of accidental ingestion get medical help or contact a Poison Control Center right away.

Directions

clean the affected area • apply a small amount of this product on the area 1 to 3 times daily • may be covered with a sterile bandage • if bandaged, let dry first.

Other information

Store the bottle tightly closed and away from heat.

Inactive ingredients

acetanilide, water

Questions

(33) 3617 5010 (in Guadalajara, Jal., Mexico)

Jaloma Hydrogen Peroxide Topical Solution

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Datos Medicinales
Ingrediente activo Peróxido de Hidrógeno 3%
Propósito Antiséptico
Usos Auxiliar para prevenir infecciones en•heridas superficiales •raspones•quemaduras.
Precauciones
 Solo para uso externo•No aplicar en los ojos o en áreas extensas del cuerpo.
 Consulte a su médico en caso de•heridas profundas•mordidas de animal•quemaduras serias.
 Suspenda su uso y consulte a su médico si la condición persiste o empeora.
 No usar por más de 1 semana, a menos que sea bajo supervisión médica.
 Mantenga este producto fuera del alcance de los niños. En caso de ingestión accidental, busque ayuda médica o contacte a algún Centro de Control de Envenenamientos de inmediato.
Instrucciones Limpie el área afectada•Aplique una pequeña cantidad del producto sobre el área, de 1 a 3 veces al día•Puede ser cubierta con una veda estéril •Si aplica vendaje, deje secar el área afectada antes de hacerlo.
Otra información Guarde la botella perfectamente cerrada y lejos del calor.
Ingredientes inactivos Acetanilida, Agua
Información (33) 3617-5010 (en Guadalajara, Jal. México).

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HYDROGEN PEROXIDE

hydrogen peroxide solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65055-501
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)	HYDROGEN PEROXIDE	30 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
ACETANILIDE (UNII: SP86R356CC)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date

1	NDC:65055-501-01	224 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/18/2013	
2	NDC:65055-501-02	448 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/18/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	09/18/2013	

Labeler - Laboratorios Jaloma, S.A. de C.V. (811122357)

Establishment

Name	Address	ID/FEI	Business Operations
Laboratorios Jaloma, S.A. de C.V.		811122357	manufacture(65055-501)

Revised: 4/2016

Laboratorios Jaloma, S.A. de C.V.