

POTASSIUM HYDROXIDE - potassium hydroxide liquid

Gordon Laboratories

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

POTASSIUM HYDROXIDE

Clear liquid solution containing Potassium Hydroxide Solution 5%.

Potassium Hydroxide Solution 5% supplied as 2oz. Amber Glass Bottle.

Potassium Hydroxide Solution 5%, Purified water (usp)

Used as a softener for nail grooves. Also used as a slide medium in Potassium Hydroxide preparations. Apply to nail in office.

May cause skin irritation. Do not get in eyes, on skin, or on clothing. In case of contact, immediately flush skin or eyes with plenty of water for at least 15 minutes. For eyes, contact a Physician. For external use only. Keep out of reach of children. For Physician use only. Poison: Harmful if taken internally.

For Physician use only. Store at room temperature 59°-86°F (15° - 30° C)

The image shows a yellow product label with a dark red header and footer. The central text reads: "NDC 10481-3012-1 POTASSIUM HYDROXIDE SOLUTION 5% For Physician Use Only Gordon Laboratories". Below this is a logo of four stacked bottles. At the bottom, it says "NET CONTENTS: 2 FL. OZ. Gordon Laboratories • Upper Darby, PA 19082 USA". On the left, there is a warning: "WARNING: May cause skin irritation. Do not get in eyes, on skin, on clothing. In case of contact, immediately flush skin or eyes with plenty of water for at least 15 minutes. For eyes, call a Physician. FOR EXTERNAL USE ONLY KEEP OUT OF REACH OF CHILDREN". On the right, there is a poison warning: "POISON: Harmful if taken internally. FIRST AID: Give water with large amounts of vinegar, lemon or orange juice. Do not give emetics or carbonates. Call a Physician at once." and a barcode with the number "50217 00178 5".

POTASSIUM HYDROXIDE

potassium hydroxide liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:1048 1-30 12
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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POTASSIUM HYDROXIDE (UNII: WZH3C48M4T) (POTASSIUM HYDROXIDE - UNII:WZH3C48M4T)		POTASSIUM HYDROXIDE	.05 g in 1 g	
Inactive Ingredients				
Ingredient Name		Strength		
WATER (UNII: 059QF0K00R)				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10481-3012-1	59 g in 1 BOTTLE, GLASS		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		07/16/2010		

Labeler - Gordon Laboratories (002333847)

Registrant - Gordon Laboratories (002333847)

Establishment

Name	Address	ID/FEI	Business Operations
Gordon Laboratories		002333847	manufacture

Revised: 7/2010

Gordon Laboratories