# PEDATOSOL- oatmeal solution Mh Global Co., Ltd.

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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#### ACTIVE INGREDIENT

Active ingredients: Colloidal Oatmeals 4.28 %

#### INACTIVE INGREDIENT

Inactive ingredients:

Lactobacillus Ferment Extract, Water, Cocos Nucifera (Coconut) Oil, 1,2-Hexanediol, Glycerin, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl Taurate Copolymer, Squalene, Polysorbate 60, Beta-Glucan, Citrus Grandis (Grapefruit) Seed Extract

#### **PURPOSE**

Purpose: Skin Protectant

#### **WARNINGS**

Warnings:

For external use only.

When Using this • Do not get into eyes. - In case of the following symptoms, you should cease usage; if the symptoms get worse due to the continued use, visit the professionals for consulting - In case of any abnormal symptoms or side effects such as red spots, swelling or itching by direct sunlight, visit a specialist for consulting when using or after usage. Do not use on wounded sites, from external natures. Keep out of reach of children. Store at room temperature.

#### KEEP OUT OF REACH OF CHILDREN

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#### Uses

Uses

Helps Skin Moisturization and Reproduction of the Childs with Pediatric dermatitis, including atopic dermatitis.

## **Directions**

Directions:

To expect outstanding improvements, please consistently apply the sufficient amount of the solution for two-three times per day at least. That does not mean that you mustn't use it more than the above dates and procedures.

#### PACKAGE LABEL, PRINCIPAL DISPLAY PANEL

#### 페드아토솔 PEDATÕSOL 락토바실러스 귀리 복합 발효 추출물 Daily Moisturizing Lotion PEDATOSOL Drug Facts 진정 및 집중 보습을 원하는 부위에 1일 2~3회 정도 수시로 맛사지 하듯이 펴 발라줍니다. Daily Moisturizing Lotion **Acticve Ingredients** 사용 시의 주의사항 Colloidal Oatmeals 4.28% Skin Protecta 1) 화장품 사용시 또는 사용 후 직사광선에 의하여 상처부위가 붉은 반점, 부어오름 또는 가려움증 등의 이상 증상이나 부작용이 있는 경우 전문의 등과 상의할 것 Uses: Helps Skin Moisturization and Reproduction of the Childs with Pediatric Hydro Colloidal Oatmeals dermatitis, including atopic dermatitis, Skin protection 2) 상처가 있는 부위 등에는 사용을 자제할 것 Warnings For external use only. 3) 보관 및 취급 시의 주의사항: When Using this . Do not get into eyes. 가) 어린이의 손이 닿지 않는 곳에 보관할 것, 나) 직사광선을 피하여 상온에서 보관할 것 In case of the following symptoms, you should cease usage; if the symptom get worse due to the continued use, visit 본 제품에 이상이 있는 경우 공정거래위원회 고시 "소비자분쟁해결기준"에 의해 보상해 드립니다. the professionals for consulting. In case of any abnormal symptoms or side effects such as red spots, swelling itching by direct sunlight, visit a specialis for consulting when using or after usage. Manufacturer 전성분 AJU Cosmetics Co., Ltd. 락토바실러스발효물, 정제수, 코코넛야자오일, Do not use on wounded sites, from 140, Namdongdong-ro, 콜로이달오트밀, 1,2-헥산다이올, external natures. Keep out of reach of Namdong-gu, Incheon, Korea 하이드록시에틸아크릴레이트/소듐아크릴로일다 children. Store at room temperature. 이메틸타우레이트코폴리머, 글리세린, 스쿠알란, R&D Center Directions COSMOS INTERNAITONAL CO., LTD 폴리솔베이트60, 베타-글루칸, 왕귤씨추출물 To expect outstanding improvements Helps Skin Moisturization 1132, 19-45, Gilju-ro 77beon-gil, please consistently apply the sufficient amount of the solution for two-three and Reproduction Bucheon-si, Gyeonggi-do, Korea 제조업자 : ㈜아주화장품 인천광역시 남동구 남동동로 140 of the Childs times per day at least. That does not mean that you mustn't use it more than with Pediatric dermatitis, including atopic dermatitis. MH Global CO., LTD 책임판매업자 : ㈜코스모스인터내셔널 the above dates and procedures. 17-4, Bongeunsa-ro 73gil, 경기도 부천시 길주로 77번길 19-45, 1132호 Gangnam-gu, Seoul, Korea, Inactive Ingredients Lactobacillus 판매총판: 주식회사 엠에이치글로발 Ferment, Water, Cocos Nucifera 서울시 강남구 봉은사로73길 17-4 소비자상담실 (Coconut) Oil, Colloidal Oatmeals, +82-70-4642-9286. 1,2-Hexanediol, Hydroxyethyl Acrylate/Sodium Acryloyldimethyl +82-70-7625-2272 T +82-70-7625-2272, +82-70-4642-9286 Taurate Copolymer, Glycerin, Squalene, Polysorbate 60, Beta-Glucan, 제조번호 및 사용기한 : 별도 표기 2.37oz(70ml) Citrus Grandis(Grapefruit) Seed Extract made in Korea

### **PEDATOSOL**

oatmeal solution

### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:73113-010
Route of Administration	TOPICAL		

ı	Active Ingredient/Active Moiety			
l	Ingredient Name	Basis of Strength	Strength	
ı	Oatmeal (UNII: 8 PI54V663Y) (OATMEAL - UNII:8 PI54V663Y)	Oatmeal	2.99 g in 70 mL	

Inactive Ingredients			
Ingredient Name	Strength		
Water (UNII: 059QF0KO0R)			
Glycerin (UNII: PDC6A3C0OX)			

Packaging					
ı	#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ı	1 N	NDC:73113-010-01	70 mL in 1 TUBE; Type 0: Not a Combination Product	06/01/2019	

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
OTC monograph final	part347	06/01/2019		

## **Labeler -** Mh Global Co., Ltd. (694470757)

## Registrant - Mh Global Co., Ltd. (694470757)

Establishment				
Name	Address	ID/FEI	<b>Business Operations</b>	
Aju cosmetic Co., Ltd.		689847363	manufacture(73113-010)	

Revised: 8/2019 Mh Global Co., Ltd.