

**DR. OBERON DIAPER RASH BABY CREAM- zinc oxide, dimethicone cream**  
**Oberon Cosmetic 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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**Dr. Oberon Diaper Rash Baby Cream**

**For external use only**

**When using this product**

**Do not get into eyes**

**Stop use and ask a doctor if**

**Condition worsens**

**Symptoms last more than 7 days or clear up and occur within a few days.**

**Zinc Oxide (5%)**

**Dimethicone (1%)**

**Skin protectant**

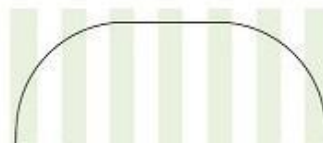
**Keep out of reach of children.**

**If swallowed, get medical help or contact a Poison Control Center right away.**

- ☐ Helps treat and prevent diaper rash**
- ☐ Protects chafed skin due to diaper rash**
- ☐ Helps seal out wetness**

- 1. Change wet or soiled diapers promptly**
- 2. Clean the diaper area**
- 3. Allow to dry**
- 4. Apply cream liberally as often as necessary, with each diaper change, especially at bedtime or any time prolonged exposure to wet diapers may be prolonged.**

**Water, Butylene glycol, Olea europaea (olive) fruit oil, Cetearyl olivate, Sorbitan olivate, Glycerin, Caprylic/capric triglyceride, Beeswax, Cetearyl alcohol, Sodium hyaluronate, Butyrospermum parikli (shea) butter, Theobroma cacao (cocoa) seed butter, Trehalose, Limnanthes alba (meadowfoam) seed oil,, Betula platyphylla japonica juice, glyceryl caprylate, glycerin, portulaca oleracea extract, centella asiatica extract, polyconum cuspidatum root extract, scutellaria baicalensis root extract, camellia sinesis leaf extract, glycyrrhiza glabra (licorice) root extract, Chamomilla ecutita (matricaria) flower extract, Rosmarinus officinalis (rosemary) leaf extract, P-anisic acid, Xanthan gum, Lactic acid, Tocopheryl acetate, Punica granatum fruit extract, Allantoin, Panthenol, Dipotassium glycyrrhizate, Fragrance**



**Drug Facts**

Active Ingredient	Purpose
Zinc Oxide (5%)	—Skin protectant
Dimethicone (1%)	—Skin protectant

**Uses**

- Helps treat and prevent diaper rash
- Protects chafed skin due to diaper rash
- Helps seal out wetness

**Warnings For external use only**

**When using this product**

- Do not get into eyes

**Stop use and ask a doctor if**

- Condition worsens
- Symptoms last more than 7 days or clear up and occur within a few days.

**Keep out of reach of children.**

If swallowed, get medical help or contact a Poison Control Center right away.  
**store at room temperature**

**Directions**

1. Change wet or soiled diapers promptly
2. Clean the diaper area
3. Allow to dry
4. Apply cream liberally as often as necessary, with each diaper change, especially at bedtime or any time prolonged exposure to wet diapers may be prolonged.

**Inactive Ingredients**

Water, Butylene glycol, Olea europaea (olive) fruit oil, Cetearyl olivate, Sorbitan olivate, Glycerin, Caprylic/capric triglyceride, Beeswax, Cetearyl alcohol, Sodium hyaluronate, Butyrospermum parikii (shea) butter, Theobroma cacao (cocoa) seed butter, Trehalose, Limnanthes alba (meadowfoam) seed oil, Betula platyphylla japonica juice, glyceryl caprylate, glycerin, portulaca oleracea extract, centella asiatica extract, polyconum cuspidatum root extract, scutellaria baicalensis root extract, camellia sinensis leaf extract, glycyrrhiza glabra (licorice) root extract, Chamomilla ecfolita (matricaria) flower extract, Rosmarinus officinalis (rosemary) leaf extract, P-anisic acid, Xanthan gum, Lactic acid, Tocopheryl acetate, Punica granatum fruit extract, Allantoin, Panthenol, Dipotassium glycyrrhizate, Fragrance

**Questions or Comments?**

For more information  
 call+82-2-2693-9400

**Manufacture by**

Oberon Cosmetic Co., Ltd.  
 Address: 65 Jungang-ro 53-gil,  
 Yangcheon-gu, Seoul, 158837

**Diaper Rash  
BABY CREAM**

**Diaper Rash  
BABY CREAM**

Caused by the use of  
 diapers to baby's delicate  
 skin, supplying moisture and  
 nutrition to skin a cream to  
 prevent irritation



**[사용상의 주의사항]**

1. 화장품을 사용하여 다음과 같은 이상이 있는 경우에는 사용을 중지하여야 하며, 계속 사용하면 증상이 악화되므로 피부과 전문의 등에게 상담하십시오.  
 1) 사용 중 붉은 반점, 부어오름, 가려움증, 자극 등의 이상이 있는 경우 2) 적용 부위가 직사광선에 의하여 위와 같은 이상이 있는 경우 2. 상처가 있는 부위, 습진 및 피부염 등의 이상이 있는 부위에는 사용을 하지 마십시오. 3. 보관 및 취급 시의 주의사항  
 1) 사용 후에는 반드시 마개를 닫아 주십시오. 2) 유아·소아의 손이 닿지 않는 곳에 보관하십시오. 3) 고온 또는 저온의 장소 및 직사광선이 닿는 곳에는 보관하지 마십시오.



**BABY CARE**

- \* 사용 전 반드시 사용상의 주의사항을 숙지하신 후 사용하십시오.
- \* 환경보전을 위해서 사용하신 용기는 분리수거함에 넣어 주십시오.

**[전성분]** 정제수, 부틸렌 글라이콜, 징크옥사이드, 올리브오일, 글리세린, 카프릴릭/카프릭트리글리세라이드, 비즈왁스, 세타아릴올리베이트, 쉐어버터, 스크비탄올리베이트, 카카오 씨드버터, 트레할로스, 메도우폼씨오일, 디메치콘, 자작나무수액, 글리세릴 카프릴레이트, P-아니식 에씨드, 진탄겔, 락틱에씨드, 마치현추출물, 토코페릴아세테이트, 병풀추출물, 알란토인, 판타놀, 석류추출물, 디포타슘글리시리세이트, 향료, 소듐하이알루로네이트, 호장근추출물, 황금추출물, 녹차추출물, 감초추출물, 케모마일꽃추출물, 로즈마리잎추출물

**[사용기한 및 제조번호]**  
 별도표기

**MADE IN KOREA**

**Dr. OBERON**

# DR. OBERON DIAPER RASH BABY CREAM

zinc oxide, dimethicone cream

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52891-104
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC CATION - UNII:13S1S8SF37)	ZINC CATION	0.75 g in 15 g
DIMETHICONE (UNII: 92RU3N3Y1O) (DIMETHICONE - UNII:92RU3N3Y1O)	DIMETHICONE	0.15 g in 15 g

## Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	
Butylene glycol (UNII: 3XUS85K0RA)	
OLEA EUROPAEA FRUIT VOLATILE OIL (UNII: 8E7358CX1J)	
Cetearyl olivate (UNII: 58B69Q84JO)	
Sorbitan olivate (UNII: MDL271E3GR)	
CAPRYLIC/CAPRIC/LAURIC TRIGLYCERIDE (UNII: FJ1H6M2JG9)	
YELLOW WAX (UNII: 2ZA36H0S2V)	
PEG-9 DIGLYCIDYL ETHER/SODIUM HYALURONATE CROSSPOLYMER (UNII: 788QAG3W8A)	
SHEA BUTTER (UNII: K49155WL9Y)	
THEOBROMA CACAO WHOLE (UNII: EB048G1S9J)	
Trehalose (UNII: B8WCK70T7I)	
LIMNANTHES ALBA WHOLE (UNII: DKY81513ER)	
BETULA PLATYPHYLLA VAR. JAPONICA RESIN (UNII: 1B33PG6N4K)	
glyceryl caprylate (UNII: TM2TZD4G4A)	
glycerin (UNII: PDC6A3C0OX)	
PORTULACA OLERACEA WHOLE (UNII: D5J3623SV2)	
CENTELLA ASIATICA (UNII: 7M867G6T1U)	
POLYGONUM CUSPIDATUM ROOT (UNII: 7TRV45YZF7)	
SCUTELLARIA BAICALENSIS ROOT (UNII: 7J95K7ID2S)	
CAMELLIA SINENSIS WHOLE (UNII: C5M4585ZBZ)	
GLYCYRRHIZA GLABRA (UNII: 2788Z9758H)	
MATRICARIA CHAMOMILLA FLOWERING TOP OIL (UNII: SA8AR2W4ER)	
ROSMARINUS OFFICINALIS WHOLE (UNII: EA3289138M)	
P-ANISIC ACID (UNII: 4SB6Y7DMM3)	
XANTHAN GUM (UNII: TTV12P4NEE)	
LACTIC ACID (UNII: 33X04XA5AT)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
PUNICA GRANATUM WHOLE (UNII: O2ZTS50U5E)	
Allantoin (UNII: 344S277G0Z)	

**Panthenol** (UNII: WV9CM0067Z)

**DIPO TASSIUM GLUCOSE-6-PHOSPHATE** (UNII: ZZW95F4360)

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52891-104-02	1 in 1 CARTON		
1	NDC:52891-104-01	15 g in 1 TUBE		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	06/26/2014	

**Labeler** - Oberon Cosmetic Co., Ltd. (631155194)

**Registrant** - Oberon Cosmetic Co., Ltd. (631155194)

### Establishment

Name	Address	ID/FEI	Business Operations
Oberon Cosmetic Co., Ltd.		631155194	manufacture(5289 1-104)

Revised: 6/2014

Oberon Cosmetic Co., Ltd.