

**EXTRA STRENGTH BODY- colloidal oatmeal cream**  
**Skinfix, Inc.**

*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 Ingredients**

Colloidal Oatmeal 2%

**Purpose**

Skin protectant

**Uses**

Temporarily protects and helps relieve minor skin irritations and itching due to eczema rash and dermatitis.

**Warnings**

For external use only.

When using this product, avoid contact with eyes.

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days.

When using this product

- Avoid contact with eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children. If swallowed get medical help or contact a Poison Control Center right away.

**Directions**

Apply generously to affected areas, especially after bathing.

**Inactive Ingredients**

Water/Eau/Aqua, Glycerin, Caprylic/Capric Triglyceride, Prunus Amygdalus Dulcis (Sweet

Almond) Oil, Stearyl Alcohol, Butyrospermum Parkii (Shea) Butter, Polyglyceryl-2 Stearate, Caprylyl Caprylate/Caprates, Glyceryl Stearate, Vitis Vinifera (Grape) Seed Oil, Helianthus Annuus (Sunflower) Seed Oil, Phenoxyethanol, Oryza Sativa (Rice) Bran Extract, Avena Sativa (Oat) Kernel Oil, Allantoin, Xanthan Gum, Avena Sativa (Oat) Bran Extract, Potassium Sorbate, Citric Acid, Rosmarinus Officinalis (Rosemary) Leaf Extract, Ethylhexylglycerin, Moringa Oil/Hydrogenated Moringa Oil Esters, Simmondsia Chinensis (Jojoba) Seed Oil, Trisodium Ethylenediamine Disuccinate, Aloe Barbadensis Leaf Juice, Tocopherol, Helianthus Annuus (Sunflower) Extract.

## **Principal Display Panel**

consciously clean  
clinically active.

skifix.

total skin  
needs.

| targets                |         |
|------------------------|---------|
| symptoms of eczema     | dryness |
| itchy & irritated skin |         |
| all skin types         |         |

free from steroids, antibiotics, fragrances, parabens, petrolatum, formaldehyde, phthalates, silicones, lanolin, propylene glycol, PEGs and gluten

sans stéroïdes, antibiotiques, parfums, parabènes, pétrolatum, formaldéhyde, phtalates, silicones, lanoline, propylène glycol, P.E.G. et gluten

Medicinal ingredients/ingrédients médicinaux : Coloidal Oatmeal 2%

Non-medicinal ingredients/ingrédients non-médicinaux : Water/Eau, Ethyl Oleate, Caprylic/Capric Triglyceride, Prunus Amygdalus Dulcis (Sweet Almond Oil, Sweet Almond), Butyrospermum Parkii (Shea) Butter, Polyglyceryl-2 Sebacate, Caprylic/Capric Triglyceride, Oryza Sativa (Rice Bran) Oil, Helianthus Annuus (Sunflower) Seed Oil, Phenoxyethanol, Oryza Sativa (Rice) Bran Extract, Avocado Sativa (Olive) Kernel Oil, Alantoin, Xanthan Gum, Avocado Sativa (Olive) Bran Extract, Potassium Sorbate, Citric Acid, Rosmarinus Officinalis (Rosemary) Leaf Extract, Ethylhexylglycerin, Moringa Oil/Hydrogenated Moringa Oil Ester, Simmondsia Chinensis (Jojoba) Seed Oil, Theobroma Ethylhexadecanoate Diacetate, Aloe Barbadensis Leaf Juice, Tocopherol, Helianthus Annuus (Sunflower) Extract.

cible : symptômes d'eczéma, sécheresse, peau inconfortable et irritée, pour tous les types de peau

protecteur cutané

produit testé et recommandé par des dermatologues expérimentés

VÉGÉTALIEN + SANS CRUAUTÉ

emballage respectueux de la planète

notre planète est précieuse et notre respect envers elle influence chacune de nos décisions, ce carton imprimé avec de l'encre d'origine végétale, est composé de papiers entièrement recyclés, ce tube, bouchon et carton sont tous recyclables.

planet love packaging

our planet is precious and our respect for it influences every decision we make. this carton is made from 100% recycled paper using vegetable based inks. it is also recyclable and biodegradable. this tube and cap are recycle ready.



skifix.

eczema<sup>+</sup>

EXTRA STRENGTH  
BODY CREAM

CRÈME POUR LE CORPS  
EXTRA-PUISSANTE

temporarily protects and helps  
relieve minor skin irritation  
and itching due to eczema

skin protectant

tested & recommended  
by unbiased derms

2%  
colloidal  
oatmeal

VEGAN + CRUELTY FREE  
236 mL e 8 oz

UPC FPO  
661430003223



2% colloidal oatmeal temporarily protects and helps relieve minor skin irritation and itching due to eczema

avoine colloïdale à 2 % offre une protection temporaire et aide à soulager l'irritation cutanée et les démangeaisons mineures causées par l'eczéma

this richly textured, all over moisturizing body cream uses sweet almond oil and an extra strength triple oat complex with colloidal oatmeal, oat oil and oat extract to soothe dry, sensitive and eczema-prone skin. provides deep hydration and lasting protection with moringa oil and shea butter. allergy tested and pH balanced.

directions: apply to affected area as needed. warning: for external use only. when using this product avoid contact with eyes. if contact occurs, rinse thoroughly with water. stop use and consult a health care practitioner if symptoms worsen or last for more than 7 days. keep out of reach of children. if swallowed, call a poison control centre or get medical help right away.

hydrate et soulage les démangeaisons et l'irritation causées par l'eczéma et la peau sèche

cette crème hydratante pour le corps à la texture onctueuse contient de l'huile d'amande douce et un complexe triple d'avoine extra fort avec de l'avoine colloïdale, de l'huile d'avoine et de l'extract d'avoine pour apaiser la peau sèche, sensible et sujette à l'eczéma. hydrate en profondeur et protège durablement grâce à l'huile de moringa et au beurre de karité, soumis à des tests d'allergie et pH équilibré.

mode d'emploi : appliquer généralement sur les zones affectées, aussi souvent que possible. avis : usage externe seulement. lors de l'utilisation de ce produit, éviter tout contact avec les yeux. en cas de contact, rincer abondamment à l'eau. cesser l'utilisation et consulter un professionnel de la santé si les symptômes s'aggravent ou durent plus de 7 jours. garder hors de la portée des enfants. en cas d'ingestion, appeler un centre antipoison ou obtenir une aide médicale immédiatement.



SKIFIX, INC. 1791 HULLS STREET, SUITE 806, HAIFA, NB, CANADA B3J 3M4  
1.866.937.2783 SKIFIX.COM MADE IN CANADA WITH GLOBALLY SOURCED COMPONENTS. FABRIQUÉ AU CANADA AVEC DES INGRÉDIENTS PROVENANT DU MONDE ENTIER

Drug Facts

Active Ingredients Colloidal Oatmeal 2% Purpose Skin protectant

Uses

Temporarily protects and helps relieve minor skin irritations and itching due to eczema, rash and dermatitis.

Warnings

For external use only.

When using this product Avoid contact with eyes.

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days.

Keep out of reach of children.

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

Directions

Apply generously to affected areas, especially after bathing.

Other Information

Store at 65-80°F. May stain fabric. For adults and children two years of age and older.

Inactive Ingredients

Water/Eau/Aqua, Glycerin, Caprylic/Capric Triglyceride, Prunus Amygdalus Dulcis (Sweet Almond Oil, Sweet Almond), Butyrospermum Parkii (Shea) Butter, Polyglyceryl-2 Sebacate, Caprylic/Capric Triglyceride, Glyceryl Stearate, Vitis Vitifera (Grape) Seed Oil, Helianthus Annuus (Sunflower) Seed Oil, Phenoxyethanol, Oryza Sativa (Rice) Bran Extract, Avocado Sativa (Olive) Kernel Oil, Alantoin, Xanthan Gum, Avocado Sativa (Olive) Bran Extract, Potassium Sorbate, Citric Acid, Rosmarinus Officinalis (Rosemary) Leaf Extract, Ethylhexylglycerin, Moringa Oil/Hydrogenated Moringa Oil Ester, Simmondsia Chinensis (Jojoba) Seed Oil, Theobroma Ethylhexadecanoate Diacetate, Aloe Barbadensis Leaf Juice, Tocopherol, Helianthus Annuus (Sunflower) Extract.

Questions? 1.866.927.2783

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eczema<sup>+</sup>

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free from steroids, antibiotics, fragrances,  
parabens, petrolatum, formaldehyde, phthalates,  
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pétrolatum, formaldéhyde, phtalate, silicone,  
lanoline, propylène glycol, P.E.G. et gluten

Medicinal ingredients/ingrédients médicinaux : Colloidal  
Oatmeal 2%.

Non-medicinal ingredients/ingrédients non-médicinaux :  
Water/Aqua/Eau, Glycerin, Caprylic/Capric Triglyceride,  
Prunus Amygdalus Dulcis (Sweet Almond Oil), Shea Oil,  
Alcohol, Butyrospermum Parkii (Shea) Butter, Polyglyceryl-2  
Sebacate, Caprylic/Capric Triglyceride, Oryza Sativa  
Vita Wafers (Rice), Seed Oil, Helianthus Annuus (Sunflower)  
Seed Oil, Phenoxyethanol, Oryza Sativa (Rice) Bran Extract,  
Avena Sativa (Oat) Kernel Oil, Alantoin, Xanthan Gum,  
Avena Sativa (Oat) Bran Extract, Potassium Sorbate, Citric  
Acid, Rosmarinus Officinalis (Rosemary) Leaf Extract,  
Ethylhexylglycerin, Moringa Oil/Hydroponated Moringa Oil  
Ester, Simmondsia Chinensis (Jojoba) Seed Oil, Theobroma  
Ethylhexadecanoate Diacetate, Aloe Barbadensis Leaf Juice,  
Toocopherol, Helianthus Annuus (Sunflower) Extract.

cible : symptômes d'eczéma, sécheresse, peau  
inconfortable et irritée, pour tous les types de  
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protecteur cutané

produit testé et recommandé par  
des dermatologues impartiaux

VEGÉTALIEN + SANS CRUAUTÉ

emballage respectueux de la planète

notre planète est précieuse et notre respect envers elle  
influence chacune de nos décisions, ce carton,  
imprimé avec de l'encre d'origine végétale, est  
composé de papiers entièrement recyclés, ce tube,  
bouchon et carton sont tous recyclables.

planet love packaging

our planet is precious and our respect for it  
influences every decision we make. this carton  
is made from 100% recycled paper using  
vegetable based ink. it is also recyclable  
and biodegradable. this tube and cap are  
recycle ready.



SKU: EKO0290

UPC FPO  
661430003223



2% colloidal oatmeal  
temporarily protects and helps relieve  
minor skin irritation and itching due to  
eczema

avoine colloïdale à 2 %  
offre une protection temporaire et aide  
à soulager l'irritation cutanée et les  
démangeaisons mineures causées par  
l'eczéma

this richly textured, all over  
moisturizing body cream uses sweet  
almond oil and an extra strength  
triple oat complex with colloidal  
oatmeal, oat oil and oat extract to  
soothe dry, sensitive and  
eczema-prone skin. provides deep  
hydration and lasting protection with  
moringa oil and shea butter. allergy  
tested and pH balanced.

directions: apply to affected area as needed.  
warning: for external use only. when using this  
product avoid contact with eyes. if contact occurs,  
rinse thoroughly with water. stop use and consult a  
health care practitioner if symptoms worsen or last for  
more than 7 days. keep out of reach of children. if  
swallowed, call a poison control centre or get medical  
help right away.

hydrate et soulage les démangeaisons  
et l'irritation causées par l'eczéma et  
la peau sèche

cette crème hydratante pour le corps  
à la texture onctueuse contient de  
l'huile d'amande douce et un  
complexe triple d'avoine extra fort  
avec de l'avoine colloïdale, de l'huile  
d'avoine et de l'extrait d'avoine pour  
apaiser la peau sèche, sensible et  
sujette à l'eczéma. hydrate en  
profondeur et protège durablement  
grâce à l'huile de moringa et au  
beurre de karité, soumis à des tests  
d'allergie et pH équilibré.

mode d'emploi : appliquer généralement  
sur les zones affectées, aussi souvent que possible,  
éviter tout contact avec les yeux. en cas de contact,  
rincer abondamment à l'eau. cesser l'utilisation et  
consulter un professionnel de la santé si les  
symptômes s'aggravent ou durent plus de 7 jours.  
garder hors de la portée des enfants. en cas  
d'ingestion, appeler un centre antipoison ou obtenir  
une aide médicale immédiatement.



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COMPONENTS. FABRIQUÉ AU CANADA AVEC DES ÉLÉMENTS PROVENANT  
DU MONDE ENTIER

EXTRA STRENGTH BODY  
colloidal oatmeal cream

**Product Information**

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:61328-119 |
| <b>Route of Administration</b> | TOPICAL        |                           |               |

**Active Ingredient/Active Moiety**

| <b>Ingredient Name</b>  | <b>Basis of Strength</b> | <b>Strength</b> |
|---|--------------------------|-----------------|
| <b>OATMEAL</b> (UNII: 8PI54V663Y) (OATMEAL - UNII:8PI54V663Y) | OATMEAL                  | 2 g in 100 mL   |

**Inactive Ingredients**

| <b>Ingredient Name</b>  | <b>Strength</b> |
|---|-----------------|
| <b>ALLANTOIN</b> (UNII: 344S277G0Z)                             |                 |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)                        |                 |
| <b>AVENA SATIVA WHOLE</b> (UNII: 5P8D0Z74RG)                    |                 |
| <b>OAT KERNEL OIL</b> (UNII: 3UVP41R77R)                        |                 |
| <b>SHEA BUTTER</b> (UNII: K49155WL9Y)                           |                 |
| <b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)            |                 |
| <b>CAPRYLYL CAPRYLATE/CAPRATE</b> (UNII: 22MCG4RSMR)            |                 |
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL)                 |                 |
| <b>ETHYLHEXYLGLYCERIN</b> (UNII: 147D247K3P)                    |                 |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)                              |                 |
| <b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)                 |                 |
| <b>SUNFLOWER OIL</b> (UNII: 3W1JG795YI)                         |                 |
| <b>HELIANTHUS ANNUUS WHOLE</b> (UNII: 17S27ZT6KR)               |                 |
| <b>MORINGA OLEIFERA SEED OIL</b> (UNII: REM6A5QMC0)             |                 |
| <b>RICE BRAN</b> (UNII: R60QEP13IC)                             |                 |
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)                        |                 |
| <b>POLYGLYCERYL-2 STEARATE</b> (UNII: 253MC0P0YV)               |                 |
| <b>POTASSIUM SORBATE</b> (UNII: 1VPU26JZZ4)                     |                 |
| <b>ALMOND OIL</b> (UNII: 66YXD4DKO9)                            |                 |
| <b>ROSEMARY</b> (UNII: IJ67X351P9)                              |                 |
| <b>JOJOBA OIL</b> (UNII: 724GKU717M)                            |                 |
| <b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)                       |                 |
| <b>TOCOPHEROL</b> (UNII: R0ZB2556P8)                            |                 |
| <b>TRISODIUM ETHYLENEDIAMINE DISUCCINATE</b> (UNII: YA22H34H9Q) |                 |
| <b>GRAPE SEED OIL</b> (UNII: 930MLC8XGG)                        |                 |
| <b>WATER</b> (UNII: 059QF0KO0R)                                 |                 |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)                           |                 |

**Packaging**

| <b>#</b> | <b>Item Code</b> | <b>Package Description</b>                          | <b>Marketing Start Date</b> | <b>Marketing End Date</b> |
|----------|------------------|---|-----------------------------|---------------------------|
| 1        | NDC:61328-119-28 | 236 mL in 1 TUBE; Type 0: Not a Combination Product | 01/30/2022                  |                           |

## Marketing Information

| Marketing Category  | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------|--|----------------------|--------------------|
| OTC monograph final | part347                                  | 01/30/2022           |                    |

**Labeler** - Skinfix, Inc. (203158183)

**Registrant** - Skinfix, Inc. (203158183)

## Establishment

| Name                              | Address | ID/FEI    | Business Operations    |
|-----------------------------------|---------|-----------|------------------------|
| Canadian Custom Packaging Company |         | 207062514 | manufacture(61328-119) |

Revised: 1/2022

Skinfix, Inc.