



Read All the leaflet carefully before you start applying this medicine.
Keep this leaflet you may need to read it again

If you have further question, Please write to us for more details.

DERMACURE NATURAL

(Treat to get back Clear Skin)

DERMACURE NATURAL IS NOT A DRUG DOESN'T NEED ANY MEDICAL PRESCRIPTION

What is in this Leaflet:

1. What Dermacure Natural is and what it is used for
2. What you need to know before you use Dermacure Natural®
3. How to use Dermacure natural®
4. Possible side effects
5. How to store Dermacure Natural®
6. Contents of the pack and other information

1. What Dermacure Natural is and what it is used for:

Brand Name: DERMACURE NATURAL

DERMACURE NATURAL is a polyherbo mineral oil preparation which is used as a topical application on the burns, psoriasis, Eczema and Herpes Infection. Derma Cure is an extremely useful as wound healer as it posses anti microbial Activity. It also useful in various skin affliction. This formulation mainly contains the plants Neem, Azadirachta Indica, Curcuma Longa and different Oil which have been considered Scientifically as anti microbial activity.

Dermacure help to heal unhealed wounds quickly, Diabetic wounds, Bedsores, Venous wounds, Arterial wounds, hemotherapy wounds, Radiotherapy wounds, Gunshot wounds, Bombblast wounds, Wounds due to MRSA infection, chronic non healing wounds, and its very much advisable to use for all types of chronic skin infections such as Alopecia, Crack heels and Skin rejuvenation and others, Its applied over infected Skin area.

Patients returns to Normal Life After application of this oil and get back the clear skin after few days of application on infected area.

Qualitative and Quantitative composition

Product Form:

Oily Lotion
A Slightly Yellowish to brown Oily Lotion.

Presentation/packaging:

OILY (Slightly Yellowish to brown color) 60mlx 1's Bottle.

Each ml of the lotion contains *Azadirachta indica*, *Curcuma longa*, *Rubia cordifolia* and other different types of oils with other natural products as excipients which possess skin conditioning properties.

DermaCure Natural is free from pesticides and heavy metals; DERMACURE NATURAL is in within permissible limits as per World Health Organization (WHO) guidelines.

2. What you need to know before you use Dermacure Natural®

Dermacure Natural® is Multifunctional because:

- It effectively promotes skin wound healing process related to different kind of diseases and disorders
- It can be used in at every stage/grade of a wound.

Dermacure Natural® is Self-sufficient because:

- It has a wide range of properties so as not to require any other primary dressing during treatment.

The Ingredients which is used is having extraordinary therapeutic properties are known for centuries.

DERMACURE NATURAL should not be used continuous on a long term basis. The application of this product should be begin at the first appearance of signs and symptoms, each affected region of the skin should be applied with this DERMACURE NATURAL until lesion are completely clear. If in case at the first sign of recurrence of the infection symptoms, the application of this oil should be re-initiated.

DERMACURE NATURAL shall be applied 3 to 4 time a day and treatment should be continued until the clearance of the lesion, if symptoms recurs, then application of DERMACURE Shall be restarted, an attempt shall be made to reduce the frequency of application to 1 or 2 times in a day.

Generally, improvement is seen within one week of starting treatment. Treatment shall be continued until lesions are completely cleared.

This product can be used on older people, Pediatrics population and adults' population.

If no signs of improvement are seen after two weeks of treatment, continued treatment with Dermacure should be reassessed in the light of supporting medication.

DERMACURE NATURAL should not be used in children aged below 1 year until further data are available.

Indications / Uses

- *Dermacure Natural is very effective against the skin infection such as Psoriasis, eczema, Herpes, Acnes, any bacterial and fungal Infection.*
- *It also has been found that this product has resulted in very effective against the diabetic wounds and foot ulcers which prevent the amputation in diabetic foot ulcer cases.*
- *Additionally its has been found to be hastening healing process of Fresh/Acute Wounds such as stab wounds, skin cuts, surgical wounds, deep wounds, Bombblast, gunshot wounds, pressure ulcers and bed sores too.*

Dosage and method of administration

DERMACURE NATURAL available in 60ml bottle in OILY form.

Dosage for Use:

Dosage for the patient who are suffering from Psoriasis, eczema, herpes, Acnes, any bacterial and fungal Infection:

1. Initially first clean the infected area using cotton which is soaked with Derma cure Natural Oil
2. Apply the oil on infected area and gentle rub on it till it absorb.
3. After the process of absorption, dermacure natural oil has to be applied evenly a uniform thin layer on the affected area ad dripping should be avoided.
4. After applying the product to the lesion/affected area as evenly as possible, spread it out with your finger. Take care to spread the product across the entire surface of the lesion as well as onto the healthy periwound skin.

Missed Dose: In case of a missed dose, continue with the next consecutive dose.

Recommended Dose: The amount of Dermacure to be applied will vary depending upon the size of the Skin infected area/ulcer/wound area. However, dose can be calculated using 4 mL/cm² area formula, where area is the product multiplication of length, breadth and depth of the wound.

Dosage for the patient who are suffering from Diabetic wounds, foot ulcer, pressure ulcer, surgical wounds, deep wounds, bomb blast/gunshot wounds and bed sores:

DermaCure natural should be applied 3-4 times a day to affected areas.

1. Initially first clean the infected area using cotton which is soaked with Derma cure Natural Oil
2. Apply the oil on for minor wounds and major wounds area.
3. Dermacure natural oil has to be applied evenly a uniform thin layer on the affected area ad dripping should be avoided. After applying the product to the lesion/affected area as evenly as possible, spread it out with your finger. Take care to spread the product across the entire surface of the lesion as well as onto the healthy periwound skin.
4. The dressing should be replaced once every day till granulation starts.

Missed Dose: In case of a missed dose, continue with the next consecutive dose.

Recommended Dose: The amount of Dermacure to be applied will vary depending upon the size of the Skin infected area/ulcer/wound area. However, dose can be calculated using 4 mL/cm² area formula, where area is the product multiplication of length, breadth and depth of the wound

Dosage for the patient who are suffering from wounds such as fresh/wound cuts Skin cuts, Stab wounds etc.:

1. DermaCure natural should be applied 3-4 times a day to affected areas on wounds
2. The dressing should be replaced once every day till granulation starts.
3. Dermacure has to be applied evenly ensuring a uniform thin layer on the wound and dripping should be avoided.

Missed Dose: In case of a missed dose, continue with the next consecutive dose.

Recommended Dose: The amount of Dermacure to be applied will vary depending upon the size of the Skin infected area/ulcer/wound area. However, dose can be calculated using 4 mL/cm² area formula, where area is the product multiplication of length, breadth and depth of the wound

BASIC PROTOCOL FOR DERMACURE NATURAL® USE

Applying DERMACURE NATURAL® always involves three simple steps:

- Clean the wound or skin infected area
- Apply the oil over the infected area/wound area
- Cover with a protective or absorbent protective bandage for Major or deep wounds only.

These three actions are to be repeated each time the medication is applied, to various degrees and using various methods.

The **APPLICATION FREQUENCY OF THE MEDICATION** depends on the condition of the lesion and on the STAGE of the lesion below are some recommended steps to be followed:

For the patient who are suffering from Psoriasis, eczema, herpes, Acnes, any bacterial and fungal Infection:

Administration:

1. DermaCure is for external use only (topical).
2. The bottle should be shaken well before use
3. The sterile lid shall be open and thin stream of Dermacure Natural should be applied on the Skin infected area for removing the deberriment/cleansing. Use Sterile Gauzes to clean the area.
4. The required volume of Dermacure natural should be applied directly on Skin infected area (If feasible with gentle rubbing is highly recommended on affected area for few minutes. After applying the product to the lesion/affected area as evenly as possible, spread it out with your finger. Take care to spread the product across the entire surface of the lesion as well as onto the healthy periwound skin.
5. Then again Dermacure natural oil has to be applied evenly a uniform thin layer on the affected area and dripping should be avoided.

For the patient who are suffering from Diabetic wounds, foot ulcer, pressure ulcer, surgical wounds, deep wounds, bomb blast /gunshot wounds and bed sores:

Administration:

1. DermaCure is for external use only (topical).
2. The bottle should be shaken well before use
3. Protective gloves should be worn if the oil need to applied for deep wounds/surgical wounds and diabetic wounds/foot ulcer etc...
4. The lid should be opened and thin stream of Dermacure should be applied on the wound for deberriment/cleansing.
5. The sterile gauge soaked in Dermacure should be used. The required volume of Dermacure should be applied directly (if feasible with gentle rubbing) on the wound/affected part for few seconds, followed by dressing of wound as required.
6. For deep wounds, dressing must be replaced once daily or as per the instructions of treating physician
7. If the ulcer/wound does not decrease in size by approximately 30% or there are no apparent signs of healing in 10-12 weeks, continued treatment with Dermacure should be reassessed in the light of supporting medication.

Dosage for the patient who are suffering from wounds such as fresh/wound cuts Skin cuts, Stab wounds etc.:

1. DermaCure is for external use only (topical).
2. The bottle should be shaken well before use
3. Protective gloves should be worn if the oil need to applied for deep wounds/surgical wounds and diabetic wounds/foot ulcer etc...
4. The lid should be opened and thin stream of Dermacure should be applied on the wound for deberriment/cleansing.
5. The sterile gauge soaked in Dermacure should be used. The required volume of Dermacure should be applied directly (if feasible with gentle rubbing) on the wound/affected part for few seconds, followed by dressing of wound as required.
6. For deep wounds, dressing must be replaced once daily or as per the instructions of treating physician
7. If the ulcer/wound does not decrease in size by approximately 30% or there are no apparent signs of healing in 10-12 weeks, continued treatment with Dermacure should be reassessed in the light of supporting medication.

Special warnings for use:

Important counseling points are listed below:

1. As with any topical medicinal product, patients should wash their hands after application if the hands are not intended for treatment.
2. Consult with your doctor before using DERMACURE NATURAL on open wounds, dry, chapped and irritated or sun burned skin.
3. It is advised to use either DERMACURE NATURAL or normal saline for wound cleansing, and avoid use of sunburning products which may be toxic and irritating. It is advised to use gloves for self protection while dressing infected wounds. The treatment should be stopped, if itching or burning persists for >60min.
4. Clean your hands before and after applying DERMACURE NATURAL lotion, clean and dry the skin area to be treated
5. Do not wash the treated area after immediately applying DERMACURE NATURAL lotion, also avoid the use of other products on treated area unless directed by your doctor.

Precautions for use:

1. DermaCure natural should not be swallowed or taken by mouth.
2. Contact with eyes should be avoided. If this occurs, the affected areas should be rinsed thoroughly with water to avoid local irritation.
3. The hands should be washed thoroughly with water after each application.
4. The use of dermacure natural product is safe during pregnancy, Adult patients, pediatric patients and elderly patients
5. Do not use the product along with disinfectants or other primary dressings because they can partially or fully eliminate the action of Dermacure Natural.
6. During CLEANSE and APPLY operations, it might arises a temporary burning sensation which then progressively decreases. This sensation is still positive even if painful, because it arises from the excitement of the nervous tissue in contact with the gauze and/or the dressing, whether you are applying or cleansing, but also from the action of a revascularization stimulus of the perilesional margin promoted by Dermacure Natural, essential for healing.

4. How to store Dermacure Natural®

STORAGE:

1. Dermacure Natural is an oily lotion and tends to freeze at low temperatures, its highly advisable to store under room temperature (25 to 30°C).
2. Bottle may get damage if its stored below or less than 10°C.
3. If accidentally if product is stored at lower temperature or if the Lotion is frozen then it need to be thawed by keeping the container in hot water for few minutes, Freezing and thawing doesn't adversely affect the potency of DERMACURE NATURAL.
4. Repeated freezing and Thawing may appear darker in color but the potency remains unaffected.

5. Possible side effects

Undesirable effects

1. Patients may experienced some type of skin irritation and tendered reaction at the site of application. Burning sensation and pruritus were very common, usually mild to moderate in severity and tended to resolve within one week after using this product.
2. Sensation of warmth, pain, paraesthesia and rash at the site of application were also commonly observed.
3. Burning sensation may arise in patients who are hypersensitive to any of the ingredient especially in burn cases.
4. Local irritation in cuts and wounds may arise in patient upon the usage of this product. But there is nothing unusual and this should be resolved in after few hours of application. The incidence of local skin burning was higher in the tacrolimus treatment groups than in the hydrocortisone group
5. Skin redness may also appear, but again the redness will reduced after few application.
6. Pain at site and Skin rash of mild intensity are possible. If you develop some Skin bumps/red bumps on other parts do not worry as this will get cleared in few days this is good indication that product is very effective on the skin infected area.

But there is no serious adverse drug reaction may occurs as these are natural products.

BURNING SENSATION

Application of the Dermacure Natural may lead to a temporary sensation of burning, itching or reddening around the damaged area. However, the product will gradually reduce the pain at the site of the lesion and promoting healing.

LESION BLEEDING

After applying the dermacure natural bleeding in a lesion that does not heal easily is a very positive sign as it means that a chronic lesion is in the process of returning to an acute lesion which responds to primary healing.

Contraindications

Hypersensitivity to *Azadirachta indica*, *Curcuma longa*, *Trichosanthes dioica* or to any of the excipients of Dermacure Natural.

Warnings

No other medication to be used for local application along with Dermacure as they may hamper the dermacure natural absorption and healing process. Oral/injectable diabetes control drugs, antibiotics and analgesics may be used simultaneously, on physician's advice. Dermacure is safe during pregnancy, Dermacure Natural is safe for diabetic, hypertensive and patients of all ages from pediatric, adolescent and adult to geriatric.

6. Contents of the pack and other information

Shelf life

4 years

Special precautions for storage

Do not store above 30°C and below 15°C.

Nature and contents of container

Polypropylene bottle with flip Flop caps.
Package sizes: 60ml, 100ml and 150ml. Not all pack sizes may be marketed.

Special precautions for disposal and other handling

No special requirements.
Any unused product or waste material should be disposed of in accordance with local requirements.
Manufactured By

Manufactured by:

CitroPharma Private Limited

5, L.R. Bande, K.B. Sandra, Bangalore - 560032, Karnataka, INDIA

Manufactured for:

Citro Pharma Inc

85 Norfolk St. Guelph Ontario, Canada NIH 4J4

(Manufactured under the technical collaboration with CitroPharma Inc, Canada)