

1 QU'EST-CE QUE DERMOSONE 0,05 %, ET DANS QUELS CAS EST-IL UTILISÉ?

Composition

• DERMOSONE 0,05 %, crème dermique :

Substance active:

Béтамéthасone dipropionate 0,05 g

Excipients : Alcool cétylstéarylique, sorbitan monostéarique, polysorbate 80, spermaceti synthétique, octyl dodécanol, alcool benzilylique, eau purifiée q.s.p. 100 g

Excipient à effet notoire : Alcool cétylstéarylique.

• DERMOSONE 0,05 %, lotion :

Substance active:

Béтамéthасone dipropionate 0,05 g

Excipients : Alcool isopropylique, carboxypoly(méthylène, eau purifiée q.s.p. 100 ml

• DERMOSONE 0,05 %, Pommade dermique:

Substance active:

Béтамéthасone dipropionate 0,05 g

Excipients : Huile de vaseline, vaseline blanche q.s.p. 100 g

Forme pharmaceutique

DERMOSONE 0,05 % crème dermique : Tube de 15 g.

DERMOSONE 0,05 % lotion : Flacon de 15 ml.

DERMOSONE 0,05 % pommade : Tube de 15 g.

Classe pharmacothérapeutique – Code ATC

DERMOCORTICOIDE (D. Dermatologie) – D07AC01

Indications thérapeutiques

–eczéma de contact, dermatite atopique, lichénification
–dermite de stase, psoriasis (à l'exclusion des plaques très étendues), lichen, prurigo non parasitaire, dyshidrose, lichen sclérotrophique génital, granulome annulaire, lupus érythémateux discoïde, dermite séborrhéique à l'exception du visage, traitement symptomatique du prurit du mycosis fongique –piqures d'insectes et prurigo parasitaire après traitement étiologique (pour une durée brève)

La forme crème est destinée aux lésions aiguës, santes, la forme lotion est destinée aux lésions des plis et des zones pilaires et la forme pommade est destinée aux lésions sèches ou squameuses.

2 QUELLES SONT LES INFORMATIONS À CONNAÎTRE AVANT D'UTILISER DERMOSONE 0,05 % ?

Contre-indications

N'utilisez jamais DERMOSONE dans les cas suivants:

•allergie (hypersensibilité) à la substance active ou à l'un des autres composants de ce médicament.
•lésions ulcérées

•acné

•rosacée

•maladies infectieuses de la peau d'origine virale (herpès, zona, varicelle...), bactérienne (exemple: impétigo...), mycosique (dus à des champignons microscopiques) ou parasitaire,

•application sur les paupières.

EN CAS DE DOUTE, IL EST INDISPENSABLE DE DEMANDER L'AVIS

DE VOTRE MÉDECIN OU DE VOTRE PHARMACIEN.

Mises en garde spéciales et précautions d'emploi

Faites attention avec DERMOSONE 0,05% :

Précautions d'emploi

Ce médicament doit être utilisé en respectant les conseils du médecin:

•ne pas appliquer sur le visage sauf en cas de prescription formelle de votre médecin,

•éviter les applications sur une grande surface, sous un pansement occlusif en raison de la possibilité de passage d'une partie du principe actif dans le sang,

•éviter l'application prolongée, sur le visage, dans les plis,

•toute irritation ou infection doit être signalée à votre médecin, si une réaction d'intolérance apparaît, le traitement doit être arrêté,

La forme crème contient de l'alcool cétylstéarylique et peut provoquer des réactions cutanées locales (par exemple : eczéma).

EN CAS DE DOUTE NE PAS HESITER A DEMANDER L'AVIS DE VOTRE MÉDECIN OU DE VOTRE PHARMACIEN.

Interactions avec d'autres médicaments

Compte tenu de l'usage local de ce produit: aux doses recommandées, la Béтамéthасone dipropionate pour usage topique n'est pas susceptible de causer des interactions médicamenteuses significatives d'un point de vue médical. Si vous prenez ou avez pris récemment un autre médicament, y compris un médicament obtenu sans ordonnance, parlez-en à votre médecin ou à votre pharmacien.

Utilisation pendant la grossesse et l'allaitement

En cas de grossesse ou d'allaitement, prévenir votre médecin. Demandez conseil à votre médecin ou à votre pharmacien avant de prendre tout médicament.

3 COMMENT UTILISER DERMOSONE 0,05 % ?

Posologie, Mode et/ou voie(s) d'administration, Fréquence

d'administration et Durée du traitement

Posologie :

Respectez toujours la posologie indiquée par votre médecin. En cas de doute, consultez votre médecin ou votre pharmacien.

1 ما هو درموزون 0,05 %، و في أي الحالات يتم استعماله؟

التركيبية

• درموزون 0,05 %، كريم جلدي:

بيتاميثازون ديبرويونات 0,05 غ

الأسوغة: كحول السيتيلستياريل، صوريثان مونوستياريك، بولييسوربات 80، لطيف الحوت الاصطناعية، أوكثيل دودكانول، كحول البنزيل، ماء مصفى ك.ك.ل. 100 غ

سواغ مع تأثير معروف : كحول السيتيلستياريل.

• درموزون 0,05 %، محلول للغسل:

المادة الفعالة: 0,05 غ

Excipients: Isopropyl alcohol, carboxypoly(methylene, purified water s.q.f. 100 ml

• DERMOSONE 0,05 %, dermic ointment:

Betamethasone dipropionate 0,05 g

Excipients: Vaseline oil, white vaseline s.q.f. 100 g

Pharmaceutical form

DERMOSONE 0,05 %, dermic cream: Tube of 15 g

DERMOSONE 0,05 %, lotion: Bottle of 15 ml.

DERMOSONE 0,05 %, dermic ointment: Tube of 15 g.

Pharmacotheapeutic class – ATC Code

Dermocorticoide (D. Dermatologie) – D07AC01

Therapeutic indications

– Contact eczema, atopic dermatitis, lichenization
– Stasis dermatitis, psoriasis (excluding very large plates), lichen, non-parasitic prurigo, dyshidrosis, sclera-atrophic genital lichen, granuloma annulare, discoid lupus erythematosus, seborrhoeic dermatitis except the face, symptomatic treatment of pruritus mycosis fungoides.

– Insect bites and parasitic prurigo after etiological treatment (for a short time)
Cream form is intended for acute and oozing lesions, the lotion form is intended for lesions at folds and hairy areas and the ointment form is intended for dry or scaly lesions.

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1 WHAT DERMOSONE 0.05 % IS AND WHAT IT IS USED FOR?

Composition

• DERMOSONE 0.05 %, dermic cream:

Active ingredient:

Betamethasone dipropionate 0.05 g

Excipients: Cetylstearyl alcohol, sorbitan monostearic, polysorbate 80, synthetic spermaceti, octyl dodecanol, benzyl alcohol, purified water s.q.f. 100 g

Excipient with known effect: Cetylstearyl alcohol.

• DERMOSONE 0.05 % lotion:

Active ingredient:

Betamethasone dipropionate 0.05 g

Excipients: Isopropyl alcohol, carboxypoly(methylene, purified water s.q.f. 100 ml

• DERMOSONE 0.05 %, dermic ointment:

Active ingredient:

Betamethasone dipropionate 0.05 g

Excipients: Vaseline oil, white vaseline s.q.f. 100 g

Pharmaceutical form

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la posologie est de 1 à 2 applications par jour en couche mince, suivies d'un léger massage.
Ne pas augmenter le nombre d'applications par jour.
Mode et voie d'administration :
Voie cutanée
Il est conseillé d'appliquer le produit en touches espacées, puis de l'étaler en massant légèrement jusqu'à ce qu'il soit entièrement absorbé.
Se laver les mains immédiatement après l'application sauf si vous utilisez ce médicament pour traiter vos mains.
Fréquence d'administration
1 à 2 applications par jour selon l'ordonnance de votre médecin.
Durée du traitement
L'arrêt du traitement se fera de façon progressive, en espaçant les applications et/ou en utilisant un corticoïde moins fort ou moins dosé.
Respecter strictement l'ordonnance de votre médecin et ne pas prolonger le traitement.
Symptômes et instructions en cas de surdosage
Si vous avez utilisé plus de DERMOSONE 0,05 %, que vous n'auriez dû :
Utilisez toujours DERMOSONE comme votre médecin vous l'a indiqué. Si vous avez accidentellement appliqué plus de DERMOSONE que prescrit par votre médecin, ne vous inquiétez pas mais évitez de le reproduire. L'utilisation excessive ou prolongée des corticoïdes locaux peut être à l'origine de manifestations d'hypercorticisme, incluant la maladie de Cushing.
Traitement: un traitement symptomatique approprié est indiqué.
Instructions en cas d'omission d'une ou de plusieurs doses
Si vous avez oublié d'utiliser DERMOSONE 0,05 % :
N'appliquez pas de dose double pour compenser la dose que vous avez oubliée d'appliquer.

4 QUELS SONT LES EFFETS INDESIRABLES EVENTUELS ?
Comme tous les médicaments, DERMOSONE 0,05%, est susceptible d'avoir des effets indésirables, bien que tout le monde n'y soit pas sujet.
En cas d'utilisation prolongée, il y a un risque d'amincissement et de fragilité de la peau, dilatation de petits vaisseaux sanguins, vergetures, poussée d'acné.
Des cas d'hypertrichose, de dépigmentation, et d'infection secondaire en particulier en cas de traitement sous pansement occlusif ou dans les plis, ont été rapportés.
Si vous remarquez des effets indésirables non mentionnés dans cette notice, ou si certains effets indésirables deviennent graves, veuillez en informer votre médecin ou votre pharmacien.
NE PAS HESITER A DEMANDER L'AVIS DE VOTRE MEDECIN OU DE VOTRE PHARMACIEN.

5 COMMENT CONSERVER DERMOSONE 0,05 % ?
Tenir ce médicament hors de la vue et de la portée des enfants.
Date de péremption
Ne pas utiliser DERMOSONE 0,05 %, après la date de péremption mentionnée sur la boîte.
Conditions de conservation
A conserver à une température inférieure à 25°C.
Si nécessaire, mises en garde contre certains signes visibles de détérioration
Les médicaments ne doivent pas être jetés au tout à l'égout ou avec les ordures ménagères. Demandez à votre pharmacien ce qu'il faut faire des médicaments inutilisés. Ces mesures permettront de protéger l'environnement.

6 INFORMATIONS SUPPLEMENTAIRES
Tableau A/ Liste I
Titulaire de l'A.M.M. OPALIA PHARMA (RECORDATI GROUP)
Zone Industrielle Kalâat El Andalous 2022 Ariana - TUNISIE
Site web : www.opaliapharma.com.tn
A.M.M. N° : 902 311 1 DERMOSONE 0,05% crème dermique, tube de 15 g.
A.M.M. N° : 902 311 6 DERMOSONE 0,05 % lotion, flacon de 15 ml.
A.M.M. N° : 902 311 2 DERMOSONE 0,05 % pommade dermique, tube de 15 g.
Date de révision de la notice : Septembre 2016

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Ne pas augmenter le nombre d'applications par jour.
Mode et voie d'administration :
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Tableau A/ Liste I
Titulaire de l'A.M.M. OPALIA PHARMA (RECORDATI GROUP)
Zone Industrielle Kalâat El Andalous 2022 Ariana - TUNISIE
Site web : www.opaliapharma.com.tn
A.M.M. N° : 902 311 1 DERMOSONE 0,05% crème dermique, tube de 15 g.
A.M.M. N° : 902 311 6 DERMOSONE 0,05 % lotion, flacon de 15 ml.
A.M.M. N° : 902 311 2 DERMOSONE 0,05 % pommade dermique, tube de 15 g.
Date de révision de la notice : Septembre 2016

6 INFORMATIONS SUPPLEMENTAIRES
Tableau A/ Liste I
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A.M.M. N° : 902 311 2 DERMOSONE 0,05 % pommade dermique, tube de 15 g.
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4 WHAT ARE THE POSSIBLE SIDE EFFECTS?
As all medicines, DERMOSONE can have side effects, although not everybody gets them.
If prolonged use, there is a risk of thinning and fragility of the skin, dilation of small blood vessels, stretch marks, acne breakout.
Cases of hypertrichosis, depigmentation and secondary infection, particularly in case of treatment under an occlusive dressing or in the folds, have been reported.
If you notice any side effects not listed in this leaflet, or if the side effects get serious, tell your doctor or pharmacist.
DO NOT HESITATE TO ASK YOUR DOCTOR OR YOUR PHARMACIST FOR ADVICE

5 HOW TO STORE DERMOSONE 0.05 %?
Keep this medicine out of the sight and reach of children.
Expiration date
Do not use DERMOSONE 0.05% after the expiry date stated on the packaging.
Storage conditions
Do not store above 25 °C.
If necessary, warning against some visible signs of deterioration
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of unused medicines. These measures will help protect the environment.

6 FURTHER INFORMATION
Table A/ List I
M. A. Holder OPALIA PHARMA (RECORDATI GROUP) Industrial
Zone Kalâat El Andalous - 2022 Ariana-Tunisia
Website: www.opaliapharma.com.tn
M.A. N°: 902 311 1 DERMOSONE 0.05% dermic cream, tube of 15 g.
M.A. N°: 902 311 6 DERMOSONE 0.05 % lotion, bottle of 15 ml.
M.A. N°: 902 311 2 DERMOSONE 0.05 % dermic ointment, tube of 15 g.
Date of the leaflet's revision: September 2016

THIS IS A MEDICINE
- A medicine is a product, but not a product as others.
- A medicine is a product which affects your health, and its consumption contrary to instructions is dangerous.
- Comply strictly with the prescription and instruction of use as prescribed by your doctor.
- Follow the advice of your pharmacist.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not interrupt by your self the period of treatment prescribed for you.
- Neither repeat the prescription nor increase the dose without consulting your doctor.

Keep medicines out of the reach of children



AC 0060/V8

CECI EST UN MEDICAMENT

- Un médicament est un produit, mais non pas comme les autres.
- Un médicament est un produit qui agit sur votre santé et sa consommation non conforme aux prescriptions vous expose à un danger.
- Respectez rigoureusement l'ordonnance de votre médecin et le mode d'emploi qu'il vous prescrit.
- Suivez le conseil de votre pharmacien.
- Votre médecin et votre pharmacien connaissent le médicament ses indications et ses contre-indications.
- N'arrêtez pas de votre propre initiative le traitement durant la période prescrite.
- Ne le reprenez pas, n'en augmentez pas les doses sans consulter votre médecin.

Ne laisser jamais les médicaments à la portée des enfants

إِنَّ هَذَا دَوَاء

- الدواء مستحضر ولكنه ليس كغيره من المستحضرات
- الدواء مستحضر يؤثر على صحتك وإستهلاكه خلافا للتعليمات يعرضك للخطر.
- اتبع بدقة وصفة الطبيب وطريقة الإستعمال التي حددها لك.
- إقتدي بنصائح الصيدلي التي صرفها لك.
- فالطبيب والصيدلي هما الخبراء بالدواء وينبغي و ضرره.
- لا تقطع من تلقا نفسك المداواة خلال المدة المحددة لذلك.
- لا تعد إلى المداوات ولا تزد عليها بدون إستشارة الطبيب.

لا تترك الأدوية أبدا في متناول أيدي الأطفال

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