

## [GR] Πληροφορίες για τον ασθενή

Το Strataderm είναι μία ταχέως αυτοσταθεροποιούμενη γέλη από σιλικόνη, μη κολλώδης και διαυγής, για τη θεραπεία ουλών, παλαιών και νέων.

Το Strataderm εφαρμόζεται εύκολα σε κάθε περιοχή του δέρματος, ακόμη και σε εκτεθειμένες περιοχές όπως το πρόσωπο και ο αυχέννας, οι αρθρώσεις και περιοχές καλυμμένες από τριχωτό χωρίς να απαιτείται απομάκρυνση των τριχών.

Όταν χρησιμοποιείται κατάλληλα, το Strataderm στερεοποιείται ταχέως δημιουργώντας ένα λεπτό φύλλο σιλικόνης, μία προστατευτική μεμβράνη η οποία είναι ημιδιαπερατή (semi-occlusive). Αυτή ενυδατώνει και προστατεύει τις ουλές από ηλιακή και μικροβιακή διήθηση, επιτρέποντας την ομαλοποίηση της διαδικασίας παραγωγής κολλαγόνου στην ουλή και τελικά τη φυσιολογική επούλωση.

Το Strataderm προκαλεί υποστροφή και ομαλοποίηση των ουλών, ανακουφίζει από τον κνησμό και τη δυσφορία, και μειώνει την ευρυρότητα και τον αποχρωματισμό της επιδερμίδας που προκαλούν οι ουλές.

Το Strataderm αναπτύχθηκε για χρήση σε κάθε είδος ουλής περιλαμβανομένων και αυτών που προκαλούνται από

- γενικές και κοσμητικές χειρουργικές
- επεμβάσεις
- τραύματα
- χρόνια έλκη
- εγκαύματα
- δήγματα
- ακμή
- και άλλες δερματικές παθήσεις.

Οι πρόσφατα Αναθεωρημένες Διεθνείς Κλινικές Συστάσεις για τη Θεραπευτική Αντιμετώπιση των Ουλών επιβεβαιώνουν ότι η γέλη σιλικόνης θα πρέπει να χρησιμοποιείται ως πρώτη γραμμής θεραπεία για την αρχική αντιμετώπιση των ουλών και για την πρόληψη δημιουργίας ουλών και χηλοειδών\*

## Ενδεδειγμένη χρήση

Το Strataderm χρησιμοποιείται για την πρόληψη και τη θεραπεία χηλοειδών και υπερτροφικών ουλών.

Το Strataderm μπορεί επίσης να χρησιμοποιηθεί σε συνδυασμό με επεμβατικές μεθόδους μείωσης των ουλών, ώστε να βελτιώσει το αισθητικό αποτέλεσμα, όπως χειρουργική εκτομή και σύγκλιση, ενδοβλαβική έγχυση στεροειδών και χρήση πιεστικών επιδέσμων (μετά την επιηλιοποίηση του τραύματος).

Το Strataderm δεν περιέχει αλκοόλη, parabens η αρώματα

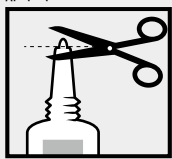
Το Strataderm είναι κατάλληλο για παιδιά ή άτομα με ευαίσθητο δέρμα.

Το Strataderm είναι ασφαλές για χρήση κατά τη διάρκεια της εγκυμοσύνης, σε όλη τη διάρκεια του θηλασμού και σε βρέφη.

## Οδηγίες χρήσης

Όταν χρησιμοποιείτε για πρώτη φορά τα σωληνάρια των 5, 10 & 20 g, αφαιρέστε το καπάκι προστασίας, κόψτε το στόμιο του σωληναρίου και ασφαλίστε μετά τη χρήση.

Στα σωληνάρια των 50 g, αφαιρέστε το καπάκι προστασίας, στη συνέχεια αφαιρέστε το προστατευτικό κάλυμμα και ασφαλίστε μετά τη χρήση.



Βεβαιωθείτε ότι η ουλή είναι καθαρή και στεγνή.

Απλώστε μία πολύ λεπτή στρώση Strataderm στην ουλή και αφήστε να στερεοποιηθεί.

Όταν εφαρμοστεί σωστά σε εκτεθειμένες περιοχές, το Strataderm στερεοποιείται σε 3–4 λεπτά. Εάν παραμένει υγρό πέραν αυτού του χρόνου πιθανά, έχετε εφαρμόσει περισσότερο από όσο χρειάζεται. Απομα-

κρύνετε την περίσσεια με γάζα ή καθαρό χαρτομάντηλο και αφήστε το υπόλοιπο να στερεοποιηθεί.

Αφού στερεοποιηθεί, το Strataderm μπορεί να καλυφθεί από αντηλιακή κρέμα, μακιγιάζ, πιεστικούς επιδέσμους ή εκμαγεία.

Το Strataderm θα πρέπει να εφαρμόζεται μία φορά την ημέρα ή δύο φορές σε εκτεθειμένες περιοχές ή όπως σας έχει συστήσει ο γιατρός σας.

Για καλύτερα αποτελέσματα το Strataderm θα πρέπει να παραμένει σε επαφή με το δέρμα για όλο το 24ωρο.

## Συνιστώμενη διάρκεια θεραπείας

Η χρήση του Strataderm συνιστάται για 60–90 ημέρες κατ'ελάχιστο (24 ωρη/7 ημερη εφαρμογή). Μεγαλύτερες και παλαιότερες ουλές πιθανά να χρειαστούν περισσότερο χρόνο.

Συνιστάται η χρήση έως ότου δεν φαίνεται περαιτέρω βελτίωση της ουλής.

## Πόσο Strataderm θα χρειαστώ

Το Strataderm έχει μια προηγμένη σύνθεση που απαιτεί λιγότερο προϊόν ανά εφαρμογή συγκρινόμενο με άλλα gel ή κρέμες.

- **To Strataderm 5 g** επαρκεί για θεραπεία ευθύγραμμης ουλής μήκους 2–3 εκ για πάνω από 90ημέρες.
- **To Strataderm 10 g** επαρκεί για θεραπεία ευθύγραμμης ουλής μήκους 5–7 εκ για πάνω από 90ημέρες.
- **To Strataderm 20 g** επαρκεί για θεραπεία ευθύγραμμης ουλής μήκους 10–14 εκ για πάνω από 90ημέρες.
- **To Strataderm 50 g** επαρκεί για θεραπεία βλάβης εμβαδού 6×12 εκ για πάνω από 90ημέρες.

## Προσοχή

- Μόνο για εξωτερική χρήση.
- Το Strataderm δεν θα πρέπει να εφαρμόζεται σε εγκαύματα τρίτου βαθμού ή σε ανοιχτά τραύματα (μη επιηλιοποιημένα τραύματα).
- Το Strataderm δεν θα πρέπει να έρχεται σε επαφή με τους βλεννογόνους ή τους οφθαλμούς.
- Το Strataderm δεν θα πρέπει να εφαρμόζεται πάνω από άλλες θεραπείες του δέρματος χωρίς τη συμβουλή του γιατρού σας.
- Το Strataderm μπορεί να ρυπάνει τα ρούχα αν δεν έχει στερεοποιηθεί εντελώς. Εάν αυτό συμβεί, το στεγνό καθάρισμα μπορεί να αφαιρέσει το Strataderm χωρίς να υποστεί κάποια βλάβη το ύφασμα.
- Για σωστή φύλαξη, παρακαλώ ασφαλίστε το σωληνάριο με το καπάκι μετά τη χρήση.
- Εάν παρατηρηθεί ερεθισμός, διακόψτε τη χρήση και συμβουλευθείτε το γιατρό σας.
- Φυλάξτε μακριά από παιδιά.
- Μη χρησιμοποιείτε μετά την ημερομηνία λήξης (EXP) που αναγράφεται στο σωληνάριο. Η ημερομηνία λήξης δεν αλλάζει από τη στιγμή που θα ανοιχθεί το σωληνάριο.
- Δεν απαιτούνται ειδικές μέθοδοι απόρριψης για το Strataderm. Παρακαλώ ακολουθήστε τους εγχώριους κανονισμούς σχετικά με την απόρριψη.
- Εντός της Ευρωπαϊκής ένωσης, σοβαρά συμβάντα σχετιζόμενα με τη χρήση του Strataderm θα πρέπει να αναφέρονται στην Stratapharma και στην αντίστοιχη αρμόδια αρχή στη χώρα που βρίσκεται ο χρήστης.

**Συστατικά:** Polydimethylsiloxanes, siloxanes, alkylmethyl silicones

## [RO] Informații pentru pacienți

Strataderm este o formulă de gel de silicon transparent, care se usucă rapid, nelipicos, pentru tratamentul cicatricilor, atât vechi, cât și noi.

Atunci când este utilizat conform instrucțiunilor, Strataderm se usucă pentru a forma o peliculă de gel de silicon, un strat protector permeabil la gaze și rezistent la apă,

care hidratează și protejează cicatricile de invazia chimică și microbiană, permițând cicatricilor să își normalizeze ciclurile de sinteză a colagenului, producând o cicatrice matură normală.

Strataderm este utilizat pentru a atenua și aplataza cicatricile, pentru a ameliora mâncărimile și disconfortul, precum și pentru a reduce roșeața și decolorarea asociate cu cicatricile.

Strataderm poate fi aplicat cu ușurință pe toate zonele pielii, inclusiv pe zonele expuse, cum ar fi fața și gâtul, precum și pe articulații și zonele acoperite de păr, fără a fi nevoie de îndepărtarea acestuia.

Strataderm a fost dezvoltat pentru utilizarea pe toate tipurile de cicatrici, inclusiv cele rezultate din

- chirurgie generală și cosmetică
- traume
- răni cronice
- arsuri
- mușcături
- acnee
- și alte afecțiuni ale pielii.

Ultimul Ghid Internațional de Protocol Clinic în Managementul Cicatricilor a recomandat gelul siliconic ca terapie de primă intenție în managementul inițial al cicatricilor și în prevenirea cicatricilor hipertrofice și cheloide.\*

## Indicații

Strataderm este utilizat pentru prevenirea și tratamentul cicatricilor cheloide și hipertrofice.

Strataderm poate fi, de asemenea, utilizat împreună cu alte opțiuni de tratament invaziv al cicatricilor pentru a îmbunătăți rezultatele generale, inclusiv excizia chirurgicală și resuturarea, injecțiile intralezionale și bandaje compresive.

Strataderm nu conține alcool, parabeni sau parfumuri.

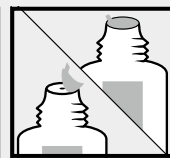
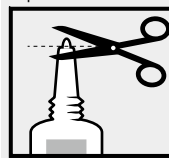
Strataderm este potrivit pentru copii și pentru persoanele cu pielea sensibilă.

Strataderm poate fi utilizat la sugari, în timpul sarcinii și alăptării.

## Mod de administrare

La prima utilizare a tuburilor de 5 g, 10 g și 20 g, îndepărtați capacul, tăiați vârful tubului și reînchideți după administrare.

În cazul utilizării tubului de 50 g, îndepărtați capacul, apoi sigiliul de protecție și reînchideți după administrare.



Asigurați-vă că cicatricea este curată și uscată.

Aplicați un strat foarte subțire de Strataderm pe cicatrice și lăsați să se usuce.

Dacă este aplicat corect, Strataderm ar trebui să se usuce în 3–4 minute. Dacă procesul de uscare durează mai mult, înseamnă că ați aplicat o cantitate prea mare de gel. Îndepărtați ușor excesul cu un tampon curat pentru a permite uscarea produsului.

Odată uscat, Strataderm poate fi acoperit cu cremă de protecție solară, produse cosmetice, bandaje compresive sau ghips.

Strataderm trebuie aplicat o dată pe zi, sau de două ori pe zi pe zonele expuse sau conform recomandării medicului dumneavoastră.

Pentru rezultate optime, Strataderm trebuie să mențină un contact continuu cu pielea (24 de ore pe zi/ 7 zile pe săptămână).

## Durata recomandată de utilizare

Strataderm este recomandat ca tratament de minim 60–90 de zile (24 de ore pe zi/ 7 zile pe săptămână). Cicatricile mari sau cele mai vechi pot necesita o perioadă mai lungă de timp.

Se recomandă continuarea utilizării până când nu se mai observă nicio îmbunătățire.

## De cât Strataderm am nevoie?

Strataderm este o formulă avansată care necesită mai puțin produs pentru fiecare aplicare decât cremele sau gelurile obișnuite.

- **Strataderm 5 g** este suficient pentru a trata o cicatrice liniară de 2–3 cm timp de peste 90 de zile.
- **Strataderm 10 g** este suficient pentru a trata o cicatrice liniară de 5–7 cm timp de peste 90 de zile.
- **Strataderm 20 g** este suficient pentru a trata o cicatrice liniară de 10–14 cm timp de peste 90 de zile.
- **Strataderm 50 g** este suficient pentru a trata o suprafață de 6×12 cm timp de peste 90 de zile.

## Avertizări

- Doar pentru uz extern.
- Strataderm nu trebuie aplicat pe arsuri de gradul trei sau pe răni deschise.
- Strataderm nu trebuie să fie pus în contact cu membranele mucoase sau cu ochii.
- Strataderm nu trebuie aplicat peste alte tratamente pentru piele fără sfatul medicului dumneavoastră.
- Strataderm poate păta hainele dacă nu este complet uscat. În cazul în care apar pete, curățarea chimică ar trebui să fie capabilă să le îndepărteze fără a deteriora țesătura.
- Pentru o păstrare corectă, vă rugăm să închideți bine tubul cu capacul prevăzut.
- În cazul în care apare o iritație cutanată, întrerupeți utilizarea și consultați medicul dumneavoastră.
- A nu se păstra la îndemâna copiilor.
- Nu utilizați după data de expirare (EXP) imprimată pe tub. Data de expirare (EXP) nu se modifică odată ce tubul a fost deschis.
- Strataderm nu necesită metode speciale de distrugere. Vă rugăm să respectați reglementările locale privind distrugerea.
- În cadrul Uniunii Europene, incidentele severe legate de utilizarea Strataderm trebuie raportate către Stratpharma și către autoritatea competentă respectivă din țara în care este stabilit utilizatorul.

**Ingrediente:** Polidimetilsiloxani, Siloxani, Alchilmetil Siliconi

## [EN] Consumer Information

**Strataderm is a rapidly drying, non-sticky, transparent silicone gel formulation for the treatment of scars, both old and new.**

When used as directed Strataderm dries to form a silicone gel sheet, a protective layer that is gas permeable and waterproof which hydrates and protects scars from chemical and microbial invasion, allowing scars to normalise the collagen synthesis cycles, producing a normal mature scar.

Strataderm is used to soften and flatten scars, relieve the itching and discomfort as well as to reduce redness and discolouration associated with scars.

Strataderm can be easily applied to all areas of the skin, including exposed areas like the face and neck as well as joints and hairy areas without the need for shaving.

Strataderm was developed for the use on all types of scars including those resulting from

- general and cosmetic surgery
- trauma
- chronic wounds
- burns
- bites
- acne
- and other diseases of the skin.

The Updated International Clinical Recommendations on Scar Management confirmed that silicone gel should be used as first line therapy in the initial management of scars and in the prevention of hypertrophic scars and keloids.\*

## Intended use

Strataderm is used for the prevention and treatment of keloids and hypertrophic scars.

Strataderm can also be used in conjunction with other invasive scar treatment options to improve overall results, including surgical excision and resuturing, intralesional injections and pressure garments.

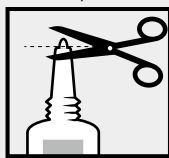
Strataderm contains no alcohol, parabens or fragrances.

Strataderm is suitable for children and people with sensitive skin.

Strataderm may be used on infants, during pregnancy and while breastfeeding.

## Directions for use

On first use of 5 g, 10 g and 20 g tubes remove the cap, cut the nozzle tip of the tube and close with the cap after use.



On 50 g tubes remove the cap, then the protective seal and close with the cap after use.



Ensure that the scar is clean and dry.

Apply a very thin layer of Strataderm to the scar and allow to dry.

When applied correctly, Strataderm should be dry in 3–4 minutes. If it takes longer to dry you have probably applied too much. Gently remove the excess with a tissue and allow the drying process to continue.

Once dry, Strataderm can be covered with sunscreen, cosmetics, pressure garments or casts.

Strataderm should be applied once daily, or twice daily to exposed areas or as advised by your physician.

For best results Strataderm should maintain continuous contact with the skin (24 hours a day / 7 days a week).

## Recommended duration of treatment

Strataderm is recommended as a minimum treatment of 60–90 days (24 hours a day / 7 days a week). Larger and older scars may take longer.

Continued use is recommended until no further improvement is seen.

## How much Strataderm do I need?

Strataderm is an advanced formulation that requires less product per application than typical creams or gels.

- **Strataderm 5 g (0.17 oz)** is enough to treat a 2–3 cm (1–2 inch) linear scar for over 90 days.
- **Strataderm 10 g (0.35 oz)** is enough to treat a 5–7 cm (2–3 inch) linear scar for over 90 days.
- **Strataderm 20 g (0.7 oz)** is enough to treat a 10–14 cm (4–6 inch) linear scar for over 90 days.
- **Strataderm 50 g (1.75 oz)** is enough to treat an area of 6×12 cm (2.5×5 inch) for over 90 days.

## Caution

- For external use only.
- Strataderm should not be applied on third degree burns or to open wounds.
- Strataderm should not be placed in contact with mucous membranes or the eyes.
- Strataderm should not be applied over other skin treatments without the advice of your physician.
- Strataderm may stain clothing if not completely dry.  
If staining occurs, dry cleaning should be able to remove it without damaging the fabric.
- For correct storage please reclose the tube tightly with the cap.
- If irritation occurs, discontinue use and consult your physician.
- Keep out of the reach of children.
- Do not use after the expiration (EXP) date printed on the tube. The expiration (EXP) date does not change once the tube has been opened.

- Strataderm does not require special disposal methods. Please follow your local disposal regulations.
- Within the European Union, serious incidents related to the use of Strataderm should be reported to Stratpharma and the respective competent authority in the country the user is established.

**Ingredients:** Polydimethylsiloxanes, siloxanes, alkylmethyl silicones

<b>MD</b>	Ιατροτεχνολογικό προϊόν Dispositiv medical Medical device
	Συμβουλευθείτε το φύλλο οδηγιών χρήσης Consultați prospectul atașat Consult instructions for use
	Φυλάξτε μακριά από παιδιά A nu se lăsa la îndemâna copiilor Keep out of the reach of children
	Ανάλυση έως A se utiliza până la data de Use by date
<b>LOT</b>	Αριθμός παρτίδας Lot nr. Batch code
	ημερομηνία παραγωγής Data fabricației Date of manufacture

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**EC REP**

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Irlandeză / Republic of Ireland

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info.romania@meditrina.eu

Ημερομηνία τελευταίας αναθεώρησης του  
φύλλου οδηγιών χρήσης  
Data modificării informațiilor  
Date of preparation of this information  
09/2023

\*Gold MH et al. Dermatol Surg 2014;  
40:825–831

meditrina  
GROUP

Stratpharma  
Switzerland

www.strataderm.com



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