Stratacel®
advanced dressing
for fractional procedures

[GR] Πληροφορίες για τον ασθενή

Το Stratacel είναι ένα προηγμένο επίθεμα πλήρους κάλυψης, για την αποκατάσταση του τραυματισμένου δέρματος ή του δέρματος που έχει υποστεί λύση μετά από κλασματικές (fractional) διεργασίες όπως η δερματική απόξεση, το resurfacing laser και οι χημικές απολεπίσεις.

Όταν χρησιμοποιείται κατάλληλα, το Stratacel στερεοποιείται για να σχηματίσει μία βακτηριοστατική προστατευτική μεμβράνη διαπερατή από αέρια και αδιάβροχη, η οποία ενυδατώνει και προστατεύει το δέρμα που έχει υποστεί λύση και τα επιφανειακά τραύματα από χημική ή μικροβιακή διήθηση.

Ενδεδειγμένη χρήση

Το Stratacel μπορεί να εφαρμοστεί σε ανοικτά τραύματα και περιοχές όπου υπάρχει λύση του δέρματος, συμπεριλαμβανομένων και των φλεγμονωδών καταστάσεων του δέρματος.

Το Stratacel χρησιμοποιείται για να ανακουφίσει τον κνησμό και τη δυσφορία και για να μειώσει το ερύθημα και τη δυσχρωμία που σχετίζονται με το τραυματισμένο δέρμα.

Το Stratacel σχεδιάστηκε να χρησιμοποιείται ως επίθεμα τραύματος το οποίο δεσμεύεται ήπια στο τραυματισμένο δέρμα ή σε δέρμα που έχει υποστεί λύση.

Το Stratacel μπορεί να χρησιμοποιηθεί μετά από αισθητικές επεμβάσεις όπως:

- Θεραπείες Laser (fractional)
- Χημικές απολεπίσεις (επιφανειακές)
- Αφαίρεση δερματοστιξίας (fractional)
- Δερματική απόξεση
- Microblading
- Microneedling
- Ραδιοσυχνότητες (fractional)
- Κολπική σύσφιξη και αναζωογόνηση
- Άλλες συσκευές fractional

Το Stratacel μπορεί να χρησιμοποιηθεί μετά από ιατρικές επεμβάσεις και καταστάσεις όπως:

- Κρυοχειρουργική (ακτινική κεράτωση)
- Μετά από 5-FU θεραπεία
- Ιατρική δερματοστιξία (π.χ. μετά την αποκατάσταση μαστού)
- Φλεγμονώδεις καταστάσεις του δέρματ
- 1ου και 2ου βαθμού εγκαύματα (με την επιδερμίδα)

Το Stratacel απλώνεται εύκολα σε μεγάλες εκτεθειμένες περιοχές όπως το πρόσωπο, ο λαιμός και το στήθος.

Το Stratacel μπορεί να χρησιμοποιηθεί με ή χωρίς δευτερεύον προστατευτικό επίθεμα.

Το Stratacel μπορεί να χρησιμοποιηθεί σε συνδυασμό με άλλες επιπρόσθετες θεραπείες για τη βελτίωση των τελικών αποτελεσμάτων.

Το Stratacel δεν περιέχει στεροειδή, αλκοόλες, parabens ή αρώματα, και είναι διαυγές και άοσμο, καθιστώντας το κατάλληλο για όλους συμπεριλαμβανομένων των ατόμων με ευαίσθητο δέρμα.

Το Stratacel μπορεί να χρησιμοποιηθεί κατά τη διάρκεια της κύησης και της γαλουχίας.

Το Stratacel προορίζεται για χρήση από έναν και μόνο ασθενή.

Πως δρα το Stratacel

Το Stratacel στερεοποιείται για να σχηματίσει μία προστατευτική μεμβράνη διαπερατή από αέρια και αδιάβροχη.

Το Stratacel προάγει ένα υγρό περιβάλλον επούλωσης για το δέρμα που έχει υποστεί λύση, τα επιφανειακά τραύματα και εγκαύματα. Αυτό το περιβάλλον οδηγεί σε ταχύτερη επανα-επιθηλιοποίηση και μειωμένη φλεγμονώδη αντίδραση, η οποία μειώνει τον χρόνο ανάρρωσης.

Το Stratacel είναι ένα αυτοσταθεροποιούμενο, διαυγές επίθεμα τραύματος, το οποίο δεν δεσμεύεται ισχυρά πάνω στο τραύμα ή στον νεοσύστατο κοκκώδη ιστό.

Οδηγίες χρήσης



Όταν χρησιμοποιείτε για πρώτη φορά τα σωληνάρια των 10 g & 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 το προσβεβλημένο δέρμα ή το τραύμα είναι καθαρό. Απομακρύνετε όσο γίνεται περισσότερο εξίδρωμα ή υγρό από το τραύμα πριν την εφαρμογή του επιθέματος. Εφαρμόστε μια λεπτή στρώση Stratacel πάνω στην προσβεβλημένη περιοχή και αφήστε το να σταθεροποιηθεί.

Όταν εφαρμόζεται σωστά, το Stratacel θα πρέπει να στερεοποιηθεί σε 5–6 λεπτά.

Εάν παραμείνει νωπό πέραν αυτού του χρόνου, πιθανά έχετε εφαρμόσει περισσότερο από όσο χρειάζεται. Απομακρύνετε την περίσσεια με γάζα ή καθαρό χαρτομάντηλο και αφήστε το υπόλοιπο να σταθεροποιηθεί. Εάν χρησιμοποιήσετε δευτερεύον επίθεμα, δεν είναι απαραίτητο να στεγνώσει.

Αφού εφαρμοστεί, το Stratacel μπορεί να καλυφθεί από αντηλιακό, καλλυντικά ή ενδύματα.

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

Για καλύτερα αποτελέσματα, το Stratacel πρέπει να είναι σε συνεχή επαφή με το δέρμα (24 ώρες την ημέρα/7 ημέρες την εβδομάδα).

Η κάθε συσκευασία Stratacel πρέπει να χρησιμοποιείται από μόνο ένα ασθενή.

Προτεινόμενη διάρκεια θεραπείας

Το Stratacel ενδείκνυται για άμεση χρήση μετά από τη θεραπεία και θα πρέπει να συνεχίζεται η χρήση τους μέχρι το δέρμα να έχει αποκατασταθεί πλήρως.

Για resurfacing και επεμβατικές διεργασίες, η συνεχής χρήση συστήνεται για τουλάχιστον 30 ημέρες θεραπείας (24 ώρες την ημέρα/7 ημέρες την εβδομάδα) ή μέχρι να μη παρατηρείται περεταίρω βελτίωση.

Πόσο Stratacel θα χρειαστώ?

Το Stratacel είναι μια προηγμένη σύνθεση, η οποία απαιτεί ουσιαστικά λιγότερο προϊόν ανά εφαρμογή συγκριτικά με τις τυπικές ενυδατικές κρέμες ή γέλες.

- **Το Stratacel 10 g** επαρκεί για θεραπεία τραυματισμένου δέρματος, επιφάνειας 6×6 cm, δύο φορές ημερησίως, για πάνω από 60 ημέρες.
- **Το Stratacel 20 g** επαρκεί για θεραπεία τραυματισμένου δέρματος, επιφάνειας 6×12 cm, δύο φορές ημερησίως, για πάνω από 60 ημέρες.
- **Το Stratacel 50 g** επαρκεί για θεραπεία τραυματισμένου δέρματος, επιφάνειας 12×15 cm, δύο φορές ημερησίως, για πάνω από 60 ημέρες.

Προσοχή

- Μόνο για εξωτερική χρήση.
- Το Stratacel δεν θα πρέπει να έρχεται σε επαφή με τους οφθαλμούς.
- Το Stratacel δεν θα πρέπει να εφαρμόζεται πάνω από άλλες θεραπείες του δέρματος χωρίς τη συμβουλή του γιατρού σας.
- Το Stratacel μπορεί να ρυπάνει τα ρούχα αν δεν έχει στερεοποιηθεί εντελώς. Εάν αυτό συμβεί, το στεγνό καθάρισμα μπορεί να αφαιρέσει το Stratacel χωρίς να υποστεί κάποια βλάβη το ύφασμα.
- Για σωστή φύλαξη, παρακαλώ ασφαλίστε το σωληνάριο με το καπάκι μετά τη χρήση.
- Εάν το τραύμα σας εμφανίσει σημεία λοίμωξης ή καθυστερεί η επούλωση του μετά από 30 ημέρες χρήσης του προϊόντος, συμβουλευθείτε τον γιατρό σας.
- Εάν παρατηρηθεί ερεθισμός, διακόψετε τη χρήση και συμβουλευθείτε τον ιατρό σας.
- Δεν είναι κατάλληλο για έντονα εξιδρωματικές πληγές, συρίγγια ή εγκαύματα 3ου βαθμού.
- Κρατήστε στο μακριά από παιδιά.
- Μη χρησιμοποιείται μετά την ημερομηνία λήξης (EXP) που αναγράφεται στο σωληνάριο. Η ημερομηνία λήξης (EXP) δεν αλλάζει από τη στιγμή που θα ανοιχθεί το σωληνάριο.
- Μην χρησιμοποιείται αν το σωληνάριο έχει υποστεί φθορά.
- Δεν απαιτούνται ειδικές μέθοδοι απόρριψης για το Stratacel. Παρακαλώ ακολουθήστε τους εγχώριους κανονισμούς σχετικά με την απόρριψη.
- Εντός της Ευρωπαϊκής ένωσης, σοβαρά συμβάντα σχετιζόμενα με τη χρήση του Stratacel θα πρέπει να αναφέρονται στην Stratpharma και στην αντίστοιχη αρμόδια αρχή στη χώρα που βρίσκεται ο χρήστης.

ΣΤΕΙΡΟ ΕΩΣ ΤΗ ΧΡΗΣΗ

Συστατικά: Polydimethylsiloxanes, siloxanes, alkylmethyl silicones

[RO] Informații pentru pacienți

Stratacel este un pansament inovator de tip film pentru repararea pielii deteriorate sau compromise în urma procedurilor fracționale, cum ar fi abraziunea dermică, resurfacingul cu laser și peelingul chimic.

Stratacel este o formulă de gel transparent, cu autouscare, neaderent, care se lipește ușor de cea mai superficială piele deteriorată.

Atunci când este utilizat conform instrucțiunilor, Stratacel se usucă pentru a forma un strat protector bacteriostatic, permeabil la gaze și rezistent la apă, care hidratează și protejează zonele cutanate compromise și rănile superficiale împotriva invaziei chimice și microbiene.

Indicații

Stratacel poate fi aplicat pe răni deschise și în zonele în care integritatea pielii a fost compromisă, inclusiv în cazul afecțiunilor inflamatorii ale pielii.

Stratacel este utilizat pentru a ameliora mâncărimile și disconfortul și pentru a reduce roșeața și decolorarea asociate cu pielea deteriorată.

Stratacel a fost dezvoltat ca un pansament pentru răni, care aderă ușor la pielea deteriorată sau compromisă.

Stratacel poate fi utilizat post proceduri estetice, precum:

- Proceduri cu laser fracționat
- Peeling chimic (superficial)
- Proceduri fracționale pentru îndepărtarea tatuajelor
- Abraziune dermică
- Microblading
- Microneedling
- Radiofrecvență fracțională
- Rejuvenare vaginală
- Alte proceduri fracționale

Stratacel poate fi utilizat după proceduri și afecțiuni medicale, precum:

- Criochirurgie (keratoză actinică)
- Post terapie 5-FU
- Tatuaj medical (ex: post reconstrucție mamară)
- Afecțiuni inflamatorii ale pielii
- Arsuri de gradul 1 și 2 (cu epidermă)

Stratacel este ușor de aplicat pe suprafețe mari, expuse și pe pielea conturată, cum ar fi fața, gâtul și pieptul.

Stratacel poate fi utilizat cu sau fără un pansament protector secundar.

Stratacel poate fi, de asemenea, utilizat împreună cu alte tratamente adjuvante pentru a îmbunătăți rezultatul final.

Stratacel este inert, nu conține steroizi, alcool, parabeni sau parfumuri și este transparent și inodor, ceea ce îl face potrivit pentru toată lumea, inclusiv pentru persoanele cu piele sensibilă.

Stratacel poate fi utilizat în timpul sarcinii și alăptării.

Stratacel este destinat utilizării pentru un singur pacient.

Cum acționează Stratacel?

Stratacel se usucă pentru a forma un strat protector care este permeabil la gaze și rezistent la apă.

Stratacel favorizează un mediu umed de vindecare a rănilor pentru zonele cutanate compromise, rănile superficiale și arsurile. Acest mediu duce la o reepitelizare mai rapidă și la un răspuns inflamator redus, ceea ce reduce timpul de recuperare post-procedură.

Stratacel este un pansament transparent, cu autouscare, care nu aderă puternic la patul plăgii sau la țesutul de granulație nou format.

Instrucțiuni de utilizare



La prima utilizare a tuburilor de 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 plaga sau zona afectată este curată. Tamponați delicat cat mai mult exudat sau fluid de pe suprafața plăgii înainte de fiecare aplicare a gelului. Aplicați un strat foarte subțire de Stratacel direct pe zona afectată și lăsați gelul să se usuce. Dacă este aplicat corect, Stratacel ar trebui să se usuce în 5–6 minute.

Dacă durează mai mult să se usuce, probabil că ați aplicat prea mult. Îndepărtați ușor excesul cu

un șervețel sau tifon curat și lăsați procesul de uscare să continue. În cazul în care se utilizează un pansament secundar, nu mai este nevoie să așteptați până la uscarea produsului.

Odată uscat, Stratacel poate fi acoperit cu cremă de protecție solară, produse cosmetice sau îmbrăcăminte.

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

Pentru rezultate optime, Stratacel trebuie să fie în contact continuu cu pielea (24 de ore pe zi/7 zile pe săptămână).

Durata recomandată de tratament

Stratacel este recomandat ca tratament imediat post-procedură și trebuie continuat până la recuperarea completă a zonei afectate.

În cazul procedurilor de resurfacing sau a celor ablative, se recomandă utilizarea continuă pentru un tratament minim de 30 de zile (24 de ore pe zi/7 zile pe săptămână) sau până când nu se mai observă nicio îmbunătățire.

De cât Stratacel gel am nevoie?

Stratacel gel este o formulă avansată care necesită mult mai puțin produs pentru fiecare aplicare decât cremele sau gelurile hidratante obișnuite.

- **Stratacel 10 g** este suficient pentru a trata o suprafață de 6×6 cm, cu aplicare de două ori pe zi timp de peste 60 de zile.
- **Stratacel 20 g** este suficient pentru a trata o suprafață de 6×12 cm, cu aplicare de două ori pe zi timp de peste 60 de zile.
- **Stratacel 50 g** este suficient pentru a trata o suprafață de 12×15 cm, cu aplicare de două ori pe zi timp de peste 60 de zile.

Avertizări:

- Doar pentru uz extern.
- A se evita contactul cu ochii.
- Stratacel nu trebuie aplicat peste alte tratamente topice, fără acordul medicului dumneavoastră.
- Stratacel 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 depozitare corectă, vă rugăm să închideți bine tubul cu capacul.
- În cazul în care rana dumneavoastră prezintă semne de infecție sau nu se vindecă după 30 de zile de la aplicarea inițială a produsului, consultați medicul dumneavoastră.
- În cazul în care apare o iritație cutanată, întrerupeți utilizarea și consultați medicul dumneavoastră.
- Nu este potrivit pentru răni foarte exsudative, răni tunelizate sau arsuri de gradul 3.
- A nu se păstra la îndemâna copiilor.
- Nu utilizați după data de expirare (EXP) imprimată pe tub. Data expirării (EXP) nu se modifică odată ce tubul a fost deschis.
- Nu utilizați dacă tubul este deteriorat.
- Stratacel nu necesită metode speciale de distrugere. Vă rugăm să respectați reglementările locale privind distrugerea.
- În cadrul Uniunii Europene, incidentele severe legate de utilizarea Stratacel trebuie raportate către Stratpharma și către autoritatea competentă respectivă din țara în care este stabilit utilizatorul.

STERIL PÂNĂ LA DESCHIDERE

Ingrediente: Polidimetilsiloxani, siloxani, alchilmetil silicon

[EN] Consumer information

Stratacel is an advanced flexible film forming wound dressing for the repair of damaged or compromised skin following fractional procedures, such as dermal abrasion, laser resurfacing and chemical peels.

When used as directed, Stratacel dries to form a bacteriostatic protective layer that is gas permeable and waterproof which hydrates and protects compromised skin areas and superficial wounds from chemical and microbial invasion.

Intended use

Stratacel can be applied to open wounds and areas where skin integrity has been compromised, including inflammatory skin conditions.

Stratacel is used to relieve itching and discomfort, and to reduce redness and discoloration associated with damaged skin.

Stratacel was developed as a wound dressing, that gently adheres to damaged or compromised skin.

Stratacel can be used in post cosmetic procedures such as:

- Laser procedures (fractional)
- Chemical peel (superficial)
- Tattoo removal (fractional)
- Dermal abrasion
- Microblading
- Microneedling
- Radiofrequency (fractional)
- Vaginal rejuvenation
- Other fractional devices

Stratacel can be used post medical procedures and conditions such as:

- Cryosurgery (actinic keratosis)
- Post 5-FU therapy
- Medical tattooing (i.e. post breast reconstruction)
- Inflammatory skin conditions
- 1st and 2nd degree burns (with epidermis)

Stratacel is easy to apply to large exposed surface areas and contoured skin, like the face, neck and chest.

Stratacel can be used with or without a secondary protective dressing.

Stratacel may also be used in conjunction with other adjunctive treatments to improve overall results.

Stratacel is inert, contains no steroids, alcohol, parabens or fragrances, and is transparent and odorless making it suitable for everyone including people with sensitive skin.

Stratacel may be used during pregnancy and while breastfeeding.

Stratacel is intended for single patient use.

How Stratacel works

Stratacel dries to form a protective layer which is gas permeable and waterproof.

Stratacel promotes a moist wound healing environment for compromised skin areas, superficial wounds and burns. This environment leads to faster re-epithelialization and a reduced inflammatory response, which reduces the recovery time post-procedure.

Stratacel is a self-drying, transparent wound dressing which does not adhere strongly to the wound bed or the newly formed granulating tissue.

Directions for use



On first use of 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 affected skin or superficial wound is clean. Gently pat dry as much excess exudate or wound fluid from the area as possible prior to the gel application. Apply a very thin layer of Stratacel directly to the affected area and allow the gel to dry. When applied correctly, Stratacel should dry in 5–6 minutes.

If it takes longer to dry you have probably applied too much. Gently remove the excess with a clean tissue or gauze and allow the drying process to continue. If a secondary dressing is used, drying time is not necessary.

Once dry, Stratacel may be covered by sunscreen, cosmetics or clothing.

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

For best results Stratacel should be in continuous contact with the skin (24 hours a day/7 days a week). Stratacel is intended for single patient use.

Recommended duration of treatment

Stratacel is recommended as immediate post-procedure treatment and should be continued until the skin has fully recovered.

For resurfacing and ablative procedures, continued use is recommended for a minimum treatment of 30 days (24 hours a day/7 days a week) or until no further improvement is seen.

How much Stratacel do I need?

Stratacel gel is an advanced formulation which requires substantially less product per application than typical moisturizing creams or gels.

- **Stratacel 10 g** is enough to treat an area of 6×6 cm twice per day for over 60 days.
- **Stratacel 20 g** is enough to treat an area of 6×12 cm twice per day for over 60 days.
- **Stratacel 50 g** is enough to treat an area of 12×15 cm twice per day for over 60 days.

Caution

- For external use only.
- Stratacel should not be placed in contact with the eyes.
- Stratacel should not be applied over topical medications unless advised by your physician.
- Stratacel 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.
- Should your wound show signs of infection or fail to heal after 30 days of initial product application consult your physician.
- If irritation occurs, discontinue use and consult your physician.
- Not suitable for highly exudative wounds, tunneling wounds or 3rd degree burns.
- 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.
- Do not use if the tube is damaged.
- Stratacel does not require special disposal methods. Please follow your local disposal regulations.
- Within the European Union, serious incidents related to the use of Stratacel should be reported to Stratpharma and the respective competent authority in the country the user is established.

STERILE UNTIL OPENED

Ingredients: Polydimethylsiloxanes, siloxanes, alkylmethyl silicones

Stratpharma Switzerland
Heal Better™

www.stratacel.com

MD	Ιατροτεχνολογικό προϊόν Dispozitiv medical Medical device
	Συμβουλευθείτε το φύλλο οδηγιών χρήσης Consultați prospectul atașat Consult instructions for use
	Φυλάξετε μακριά από παιδιά A nu se lăsa la îndemâna copiilor Keep out of the reach of children
	Ανάλωση έως A se utiliza până la data de Use by date
LOT	Αριθμός παρτίδας Lot nr. Batch code
	ημερομηνία παραγωγής Data fabricației Date of manufacture
STERILE R	Αποστειρωμένο με χρήση ακτινοβολίας Sterilizat prin iradiere Sterilized using irradiation
	Σύστημα μονού στείρου φραγμού Sistem unic de protecție sterilă Single sterile barrier system
	Μην χρησιμοποιείται αν το σωληνάριο έχει υποστεί φθορά A nu se utiliza în caz de ambalaj deteriorat Do not use if the tube is damaged
	Stratpharma AG, Aeschenvorstadt 57, CH-4051 Basel, Ελβετία / Elveția / Switzerland
EC REP	Freyr Regulatory GmbH Marie-Curie Straße 8, 79539 Lörrach, Γερμανία / Germania / Germany SRN: DE-AR-000047121
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	Υπευθυνος διανομης για την Ελλαδα: Stratpharma Hellas Κλεισθένους 171 κ Αριωνα 15344, Γέρακας Αττικής Τηλ: +30 21 60023683 gr.inquiries@stratpharma.com
	Distribuitor pentru România: Stratpharma România S.R.L. Adresă: Str. Jiului, Nr. 2, Et. 2, Sector 1, București ro.inquiries@stratpharma.com

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