

[GR] Πληροφορίες για τον ασθενή

Πλήρως επαφής επίθεμα τραύματος γέλης για την πρόληψη και θεραπεία της δερματίτιδας εξ' ακτινοβολίας.

Το StrataXRT είναι μία ημιδιαπερατή, αυτοσταθεροποιούμενη, μη κολλώδης και διαυγής γέλη.

Όταν χρησιμοποιείται κατάλληλα, το StrataXRT στερεοποιείται ταχέως δημιουργώντας μία προστατευτική μεμβράνη, διαπερατή από αέρια και αδιαπερατή από υγρά (αδιάβροχη), η οποία διατηρεί τη βέλτιστη υγρασία επούλωσης και προστατεύει το προσβεβλημένο δέρμα ή τα ανοιχτά τραύματα από χημική και μικροβιακή διήθηση.

Το StrataXRT μπορεί να χρησιμοποιηθεί στη δερματίτιδα από ακτινοβολία, σε επιφανειακά τραύματα και σε 1ου και 2ου βαθμού εγκαύματα.

Το StrataXRT δεν έχει μετρήσιμο pH και δεν επηρεάζει τον όξινο μανδύα του δέρματος.

Το StrataXRT είναι βακτηριοστατικό και αδρανές.

Πως δρα το StrataXRT

Το StrataXRT στερεοποιείται και σχηματίζει ένα λεπτό επίθεμα τραύματος το οποίο ενυδατώνει και προστατεύει τις προσβεβλημένες περιοχές.

Το StrataXRT δημιουργεί ένα υγρό περιβάλλον επούλωσης πάνω από τα επιφανειακά τραύματα και τα εγκαύματα.

Το StrataXRT δεσμεύεται ήπια πάνω στην επιφανειακή δερματική στιβάδα που έχει υποστεί βλάβη.

Το υγρό περιβάλλον επούλωσης βοηθάει στην ταχύτερη επιθηλιοποίηση και μειώνει σημαντικά την οξεία φλεγμονώδη απόκριση του δέρματος, η οποία παρατηρείται στις φάσεις της ξηρής και υγρής αποφολιδώσης/απολέπισης από τις δόσεις ακτινοβολίας αλλά και στα εγκαύματα πρώτου και δευτέρου βαθμού.

Κατά τη ξηρή φάση, το StrataXRT προστατεύει την εύθραυστη επιδερμίδα και διατηρεί τη συνοχή του δέρματος, αποτρέποντας την υπερβολική αποφολιδώση.

Κατά την υγρή φάση, το StrataXRT προστατεύει τη στιβάδα της δερμίδας από τη μακροπρόθεσμη καταστροφή, ενώ παράλληλα βελτιστοποιεί το περιβάλλον της επούλωσης και μειώνει την πιθανότητα επιμόλυνσης. Το StrataXRT δεσμεύεται ήπια πάνω στην επιφανειακή δερματική στιβάδα που έχει υποστεί βλάβη.

Το StrataXRT είναι ιδανικό για χρήση σε περιοχές μεγάλης επιφάνειας, όπως το στήθος, το πρόσωπο, η πλάτη και η πυελική περιοχή καθώς επίσης και σε περιοχές με αρθρώσεις ή τριχυτού χωρίς να απαιτείται η αφαίρεση των τριχών.

Ενδεδειγμένη χρήση

Το StrataXRT χρησιμοποιείται για να ανακουφίσει από τις χαμηλού βαθμού φλεγμονώδεις αντιδράσεις όπως το ξηρό, ερεθισμένο και απολεπισμένο δέρμα με παρουσία κνησμού.

Το StrataXRT μειώνει τον πόνο, το ερύθημα, το αίσθημα καύσου και βοηθάει στην ανακούφιση των εκτεθειμένων στην ακτινοβολία περιοχών.

Το StrataXRT αναπτύχθηκε για χρήση σε όλους τους τύπους δερματίτιδας από ακτινοβολία, σε ερεθισμένο δέρμα που έχει υποστεί λύση, σε επιφανειακά τραύματα και εγκαύματα, συμπεριλαμβανομένων αυτών που προέρχονται από:

- Ακτινοθεραπεία
- Εγκαύματα πρώτου και δευτέρου βαθμού

Το StrataXRT μπορεί να εφαρμοσθεί σε επιφανειακά τραύματα, εγκαύματα και περιοχές όπου η συνέχεια του δέρματος έχει υποστεί λύση.

Το StrataXRT μπορεί να χρησιμοποιηθεί σε συνδυασμό με άλλες θεραπείες για βελτιστοποίηση του ολικού αποτελέσματος. Το StrataXRT δεν περιέχει στεροειδή, αλκοόλες, parabens ή αρώματα και είναι διαυγής και άοσμο. Το StrataXRT μπορεί να χρησιμοποιηθεί με ή χωρίς δευτερεύουσα περίδεση.

Το StrataXRT είναι κατάλληλο για παιδιά και άτομα με ευαίσθητο δέρμα. Το StrataXRT προορίζεται για χρήση από έναν και μόνο ασθενή.

Οδηγίες χρήσης



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



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

Βεβαιωθείτε ότι η προσβεβλημένη περιοχή είναι στεγνή και καθαρή.

Όταν απλωθεί σωστά σε εκτεθειμένες περιοχές, το StrataXRT θα πρέπει να στερεοποιηθεί σε 5-6 λεπτά. Εάν παραμένει υγρό πέραν αυτού του χρόνου πιθανώς έχετε εφαρμόσει περισσότερο από όσο χρειάζεται.

Απομακρύνετε την περίσσεια με γάζα ή καθαρό χαρτομάντιλο και αφήστε το υπόλοιπο να στερεοποιηθεί.

Απολά αφαιρέστε με ένα χαρτομάντιλο όσο περισσότερο εξίδρωμα ή υγρό από το τραύμα πριν την εφαρμογή.

Εφαρμόστε μια λεπτή στρώση του StrataXRT κατευθείαν πάνω στην προσβεβλημένη περιοχή και αφήστε τη γέλη να στεγνώσει.

Το StrataXRT θα πρέπει να εφαρμόζεται άπαξ ή δις ημερησίως ή όπως σας έχει συμβουλευθεί ο θεράπων ιατρός σας.

Για καλύτερα αποτελέσματα, το StrataXRT θα πρέπει να βρίσκεται σε διαρκή επαφή με το δέρμα. Από τη στιγμή που θα στεγνώσει το StrataXRT, μπορεί να καλυφθεί από αντιληκτά, καλλυντικά και ρούχα.

Το StrataXRT δεν χρειάζεται να αφαιρεθεί πριν την ακτινοθεραπεία.

Συνιστώμενη διάρκεια θεραπείας

Το StrataXRT συστήνεται για προφύλαξη μετά από την αρχική δόση ακτινοβολίας και θα πρέπει να συνεχίζεται για τουλάχιστον 60-90 ημέρες μετά την ακτινοθεραπεία ή έως ότου δεν παρατηρείται περαιτέρω βελτίωση.

Στη χρόνια δερματίτιδα από ακτινοβολία, συστήνεται η συνεχής χρήση έως ότου δεν παρατηρείται περαιτέρω βελτίωση.

Πόσο StrataXRT θα χρειαστώ?

Το StrataXRT έχει μια μοναδική σύνθεση που απαιτεί σημαντικά λιγότερο προϊόν ανά εφαρμογή συγκριτικά με άλλες συνηθισμένες ενυδατικές κρέμες ή γέλες.

- **To StrataXRT 10g** είναι ικανό για τη θεραπεία μιας περιοχής 12x15 cm (5x6 inch) δύο φορές την ημέρα για να χρονικό διάστημα μεγαλύτερο των 15 ημερών.
- **To StrataXRT 20g** επαρκεί για θεραπεία περιοχής 12x15 εκ. και εφαρμογή δύο φορές την ημέρα για πάνω από 30 ημέρες.
- **To StrataXRT 50g** επαρκεί για θεραπεία περιοχής 12x15 εκ. και εφαρμογή δύο φορές την ημέρα για πάνω από 75 ημέρες.

Προσοχή

- Μόνο για εξωτερική χρήση.
- Το StrataXRT δεν θα πρέπει να έρχεται σε επαφή με τους οφθαλμούς.
- Το StrataXRT δεν θα πρέπει να εφαρμόζεται πάνω από άλλες θεραπείες του δέρματος χωρίς την συμβουλή του ιατρού σας.
- Το StrataXRT μπορεί να ρυπάνει τα ρούχα αν δεν έχει στερεοποιηθεί εντελώς. Εάν αυτό συμβεί, το στεγνό καθάρισμα μπορεί να αφαιρέσει το StrataXRT 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 ιατρό σας.
- Εάν παρατηρηθεί ερεθισμός, διακόψτε τη χρήση και συμβουλευθείτε τον ιατρό σας.
- Δεν είναι κατάλληλο για υγρές, έντονα εξιδρωματικές πληγές, εγκαύματα 3ου βαθμού και συρίγγια.
- Να φυλάσσεται σε ασφαλές μέρος μακριά από τα παιδιά.
- Δεν χρησιμοποιείται μετά την ημερομηνία λήξης (EXP) που αναγράφεται στο σωληνάριο. Η ημερομηνία λήξης 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 StrataXRT. Παρακαλώ ακολουθήστε τους εγχώριους κανονισμούς σχετικά με την απόρριψη.
- Εντός της Ευρωπαϊκής ένωσης, σοβαρά συμβάνα σχετιζόμενα με τη χρήση του StrataXRT 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

Pansament flexibil ce asigură contact complet pentru prevenția și tratamentul radiodermitei.

StrataXRT este un gel semiocluziv, transparent, cu auto-uscare, nelipicios.

Când este utilizat corect, StrataXRT se usucă și formează o peliculă protectoare permeabilă la gaze și impermeabilă la apă, care protejează pielea compromisă și plăgile superficiale de contaminarea microbiană sau chimică.

StrataXRT poate fi aplicat direct pe zona afectată de radiodermită, pielea compromisă, răni superficiale și arsuri de gradul 1 și 2.

StrataXRT nu are pH măsurabil și nu afectează stratul protector acid al pielii.

StrataXRT gel este bacteriostatic și inert.

Cum acționează StrataXRT

StrataXRT se usucă și formează o peliculă subțire și flexibilă ce hidratează și protejează pielea compromisă.

StrataXRT favorizează un mediu umed de vindecare a rănilor superficiale și arsurilor extinse.

Vindecarea în mediu umed asigură o reepitelizare rapidă și reduce semnificativ inflamația acută asociată radiodermitei exudative sau uscate cât și arsurilor de gradul 1 și 2.

În cazurile de radiodermită uscată StrataXRT protejează epiderma fragilă și menține integritatea cutanată prevenind descuamarea în exces.

În cazurile de radiodermită exudativă StrataXRT protejează țesutul conjunctiv de afectarea pe termen lung și asigură un mediu optim de vindecare, reducând riscul apariției infecțiilor.

StrataXRT aderă delicat la stratul superficial al țesutului lezată.

StrataXRT este ideal pentru aplicarea pe suprafețe extinse și piele conturată cum ar fi zona șănilor, pe față, pe spate și zona pelvină, precum și pentru articulații și zone acoperite de păr, fără a fi nevoie de îndepărtarea acestuia.

Instrucțiuni de utilizare

StrataXRT este utilizat pentru ameliorarea inflamațiilor moderate asociate pielii uscate, cu prurit, descuamate și iritate.

În cazul afecțiunilor inflamatorii severe utilizarea StrataXRT reduce durerea, eritemul și calmează zonele de piele expuse.

StrataXRT a fost dezvoltat pentru a fi utilizat pe toate tipurile de radiodermită, piele toxică și compromisă, răni superficiale și arsuri, inclusiv pe cele care rezultă din:

- Radioterapie
- Arsuri de gradul 1 și 2.

StrataXRT poate fi aplicat pe răni superficiale, arsuri și zone în care integritatea pielii a fost compromisă. StrataXRT poate fi, de asemenea, utilizat împreună cu alte tratamente pentru a îmbunătăți rezultatul general al terapiei. StrataXRT nu conține steroizi, alcool, parabeni sau parfum și este transparent și inodor. StrataXRT poate fi utilizat cu sau fără pansament secundar. StrataXRT este recomandat copiilor și persoanelor cu pielea sensibilă. StrataXRT este destinat administrării la un singur pacient.

Instrucțiuni de utilizare



La prima utilizare a tubului de 10g, 20g, deschideți capacul, tăiați vârful tubului și închideți după administrare.



În cazul utilizării tubului de 50g deschideți capacul, înlăturați folia protectoare și închideți după administrare.

Asigurați-vă că zona afectată este curată și uscată. Îndepărtați ușor exsudatul în exces înainte de aplicarea gelului. Aplicați un strat foarte subțire de StrataXRT direct pe zona afectată și lăsați gelul să se usuce. Când este aplicat corect, StrataXRT ar trebui să se usuce în 5-6 minute. Dacă procesul de uscare durează mai mult înseamnă că ați aplicat o cantitate prea mare de gel.

Îndepărtați ușor excesul cu un șervețel sau tifon curat și lăsați procesul de uscare să continue. O dată uscat StrataXRT poate fi acoperit cu produse cu factor de protecție solară, cosmetice și îmbrăcăminte.

StrataXRT trebuie aplicat o dată sau de două ori pe zi sau în funcție de indicația medicului curant. Pentru cele mai bune rezultate StrataXRT trebuie menținut permanent în contact direct cu pielea (24 de ore pe zi/7 zile pe săptămână).

Nu este necesară îndepărtarea StrataXRT înainte de efectuarea procedurii de radioterapie.

Durata recomandată a tratamentului

StrataXRT este recomandat ca profilaxie după doza inițială de radioterapie și ar trebui să continue să fie aplicat timp de cel puțin 60-90 de zile (24 de ore pe zi/7 zile pe săptămână) post radioterapie sau până când nu se mai observă nici o îmbunătățire. În cazul radiodermitei cronice se recomandă utilizarea în continuare până când nu se mai observă nicio ameliorare.

Cât StrataXRT este necesar pentru tratament?

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

- **StrataXRT 10g** asigură tratamentul pe o suprafață de 12 x 15 cm, de două ori pe zi, pentru minim 15 de zile.
- **StrataXRT 20g** asigură tratamentul pe o suprafață de 12 x 15 cm, de două ori pe zi, pentru minim 30 de zile.
- **StrataXRT 50g** asigură tratamentul pe o suprafață de 12 x 15 cm, de două ori pe zi, pentru minim 75 de zile.

Avertizări

- Numai pentru uz extern.
- A se evita contactul cu ochii.
- StrataXRT nu trebuie aplicat peste alte tratamente fără autorizarea prealabilă a medicului.
- În cazul în care nu s-a uscat complet, StrataXRT poate păta hainele. În acest caz, petele pot fi îndepărtate prin curățare chimică, fără să fie afectată țesătura.
- Pentru o păstrare corectă, după utilizare închideți bine tubul cu capacul.
- În cazul apariției infecției cutanate sau dacă radiodermita nu se vindecă după 30 de zile consultați imediat medicul curant.
- În cazul apariției iritației cutanate, întrerupeți tratamentul și consultați medicul curant.
- Nu este recomandat în cazul rănilor exudative, rănilor tunelizate sau arsurilor de gradul 3.
- A nu se lăsa la îndemâna copiilor.
- A nu se utiliza după data de expirare (EXP) inscripționată pe tub. Data de expirare (EXP) nu se modifică după deschiderea tubului.
- A nu se utiliza în cazul în care tubul este deteriorat.
- StrataXRT nu necesită metode speciale de distrugere. Vă rugăm să respectați reglementările locale privind distrugerea.
- În cadrul Uniunii Europene, incidentele severe legate de utilizarea StrataXRT 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

A full contact flexible wound dressing for the prevention and treatment of radiation dermatitis.

StrataXRT is a semi-occlusive, self-drying, non-sticky and transparent gel.

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

StrataXRT may be directly applied to radiation dermatitis, compromised skin surfaces, superficial wounds and first and second degree burns.

StrataXRT has no measurable pH value so does not affect the fragile acid mantle of the skin.

StrataXRT gel is bacteriostatic and inert.

How StrataXRT works

StrataXRT dries to form a thin, flexible wound dressing which hydrates and protects affected areas.

StrataXRT helps to promote a moist wound healing environment for widespread superficial wounds and burns.

This moist wound healing environment promotes faster re-epithelialization and significantly reduces the skin's acute inflammatory response seen with both dry and wet desquamation from radiation dosing and first and second degree burns.

In dry desquamation, StrataXRT protects the fragile epidermis and maintains the skin's integrity, preventing the outmost layers from excessive sloughing.

In moist desquamation, StrataXRT protects the dermal stroma from long-term deterioration whilst optimizing the environment for the healing process and reducing the risk of infection. StrataXRT lightly bonds to the most superficial damaged skin layer.

StrataXRT is ideal for large surface areas and contoured skin like the breasts, face, back and pelvic area, as well as joints and hairy areas without the need for shaving.

Intended use

StrataXRT is used to relieve low grade inflammatory changes such as dry, itching, flaking, peeling and irritated skin.

For more severe inflammatory changes, StrataXRT reduces pain, redness, heat sensation and helps soothe the exposed skin areas.

StrataXRT was developed for use on all types of radiation dermatitis, toxic and compromised skin, superficial wounds and burns, including those resulting from:

- Radiation therapy
- First and second degree burns

StrataXRT may be applied to superficial wounds, burns and areas where skin integrity has been compromised.

StrataXRT may also be used in conjunction with other adjunctive treatments to improve overall results. StrataXRT contains no steroids, alcohol, parabens or fragrances and is transparent and odorless. StrataXRT can be used with or without a secondary protective dressing. StrataXRT is suitable for children and people with sensitive skin. StrataXRT is intended for single patient use.

Directions for use



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



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

Ensure that the affected skin superficial wound is clean and dry.

Gently pat dry as much excess exudate or wound fluid from the area as possible prior to gel application.

Apply a very thin layer of StrataXRT directly to the affected area and allow the gel to dry.

When applied correctly to exposed areas, StrataXRT should be 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.

Once dry, StrataXRT may be covered by sunscreen, cosmetics and clothing.

StrataXRT should be applied once or twice daily to affected areas or as advised by your physician.

For best results StrataXRT should be maintained in continuous contact with the skin (24 hours a day/7 days a week).

StrataXRT does not need to be removed prior to radiation therapy.

Recommended duration of treatment

StrataXRT is recommended as prophylaxis following the initial radiation dose and should continue to be applied for a minimum of 60-90 days (24 hours a day/7 days a week) post radiation therapy, or until no further improvement is seen.

For chronic radiation dermatitis, continued use is recommended until no further improvement is seen.

How much StrataXRT do I need?

StrataXRT gel is a unique formulation that requires substantially less product per application than typical moisturizing creams or gels.

- **StrataXRT 10g (0.35 oz)** is enough to treat an area of 12x15 cm (5x6 inch) twice per day for over 15 days.
- **StrataXRT 20g (0.7 oz)** is enough to treat an area of 12x15 cm (5x6 inch) twice per day for over 30 days.
- **StrataXRT 50g (1.75 oz)** is enough to treat an area of 12x15 cm (5x6 inch) twice per day for over 75 days.

Caution

- For external use only.
- StrataXRT should not be placed in contact with the eyes.
- StrataXRT should not be applied over topical medications unless advised by your physician.
- StrataXRT 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 radiation dermatitis show signs of infection or failure 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, tunnelling 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.
- StrataXRT does not require special disposal methods. Please follow your local disposal regulations.
- Within the European Union, serious incidents related to the use of StrataXRT 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



Ιατροτεχνολογικό προϊόν
Dispozitiv medical
Medical device



Συμβουλευθείτε το φύλλο οδηγιών χρήσης
Consultati prospectul atasat
Consult instructions for use



Να φυλάσσεται σε ασφαλές μέρος μακριά από τα παιδιά
Α να se lăsa la îndemâna copiilor
Keep out of the reach of children



Ανάλωση ζωής
Α se utiliza până la data de
Use by date



Αριθμός παρτίδας
Lot nr.
Batch code



ημερομηνία παραγωγής
Data fabricației
Date of manufacture



Αποστειρωμένο με χρήση ακτινοβολίας
Sterilizat prin iradiere
Sterilized using irradiation



Σύστημα μονού στρώρου φραγμού
Sistem unic de protecție sterilă
Single sterile barrier system



Μην χρησιμοποιείται αν το συλληγiario έχει υποστεί φθορά
Α να se utiliza în caz de ambalaj deteriorat
Do not use if the tube is damaged

Stratpharma AG
CH-4051 Basel
Aeschenvorstadt 57
Ελβετία/Elvetia/Switzerland



Freyr Life Sciences GmbH
Marie-Curie-Straße 8
D-79539 Lörrach
Γερμανία / Germania / Germany



Εισαγωγέας στην Ευρωπαϊκή Ένωση / Importator in Uniunea Europeană / Importer to the European Union:
Stratpharma Limited
Clifton House
Fitzwilliam Street Lower
Dublin 2, D02 XT91
Δημοκρατία της Ιρλανδίας / Republica Irlandeză / Republic of Ireland

Εισαγωγή και διανομή για την Ελλάδα / Import și distribuție pentru Grecia / Import and distribution for Greece:
MEDITRINA ΕΠΕ
Ηρακλείου 117,
15238 Χαλάνδρι, Αττικής
Τηλ: 210 6726260
info@meditrina.gr

Εισαγωγή και διανομή για τη Ρουμανία / Distributor și importator în România / Distributor and importer in Romania:
MEDITRINA PHARMACEUTICALS SRL
Intrarea Măguricea Nouă nr. 7-7A
Sector 1, București
Telefon: 021.211.71.83
info.romania@meditrina.eu

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