

CENTRIX
E-LieveTM

Post-Bleaching Vitamin E Treatment

ENGLISH

INSTRUCTIONS FOR USE
E-LIEVE VITAMIN E MOISTURIZER

Contains:

120 x .3ml Single-use LolliPacks™

Instructions for Use

E-Lieve is a unit-dose Vitamin E post-bleaching moisturizer for gingival tissue. The convenient single-dose LolliPack package allows for easy application and take home use.

Storage Conditions

Best if stored away from light and high humidity.
Store in temperatures between 10°C – 25°C / 50°F – 80°F.

Clinical Applications

To be used on soft tissue irritation after bleaching, tissue surgery with a laser, scalpel or electro surge unit.

DIRECTIONS FOR USE

- Grip the foil cover of the LolliPack and slowly peel back, exposing the brush applicator and Vitamin E well.
- Remove applicator brush and dip into material.
- Check mouth for blanched areas and apply E-Lieve.
- Discard used package and brush.

ITALIANO

ISTRUZIONI PER L'USO
IDRATANTE E-LIEVE ALLA VITAMINA E

Contiene

120 LolliPacks™ monouso da 0,3 ml

Indicazioni d'impiego

E-Lieve è un idratante post-sbiancamento a dose singola con vitamina E per il tessuto gengivale. La pratica confezione monodose LolliPack facilita l'applicazione e consente l'uso domestico.

Condizioni di conservazione

Si consiglia di tenere il prodotto al riparo dalla luce e dall'umidità elevata. Tenere il prodotto a una temperatura compresa tra 10°C e 25°C.

Applicazioni cliniche

Da usare sui tessuti molli irritati dopo gli interventi di sbiancamento e di chirurgia mediante laser, bisturi o unità elettrochirurgica.

ISTRUZIONI D'USO

- Afferrare la protezione in foglio di alluminio del LolliPack e rimuoverla lentamente, scoprendo lo spazzolino applicatore e la vaschetta contenente la vitamina E.
- Estrarre lo spazzolino applicatore e immergerlo nella sostanza.
- Applicare il prodotto E-Lieve sulle aree sbiancate della bocca.
- Dopo l'uso, gettare la confezione e lo spazzolino.

REF 360084

10°C -25°C / 50°F -50°F



FRANÇAIS

MODE D'EMPLOI
HYDRATANT E-LIEVE À LA VITAMINE E

Contenu

120 LolliPacks™ de 0,3 ml à usage unique

Utilisation

E-Lieve est un hydratant monodose à la vitamine E, à utiliser sur les tissus gingivaux après le blanchiment. Le conditionnement en monodoses LolliPack, pratique, facilite l'application et l'utilisation au domicile.

Conditions de stockage

Conserver préférablement à l'abri de la lumière et d'une humidité élevée.
Conserver à des températures de 10 °C – 25 °C

Applications cliniques

Utiliser sur les tissus mous irrités après le blanchiment, l'utilisation d'un laser pour une chirurgie des tissus, le travail au scalpel ou l'emploi d'un appareil d'électrochirurgie.

MODE D'EMPLOI

- Saisir la feuille métallique qui forme le couvercle du LolliPack et la décoller lentement, pour exposer le pinceau applicateur et le puits qui contient l'hydratant à la vitamine E.
- Sortir le pinceau applicateur et le tremper dans le matériau.
- Vérifier où se trouvent les zones blanchies dans la bouche et appliquer E-Lieve.
- Jeter l'emballage et le pinceau usagé.

ESPAÑOL

INSTRUCCIONES DE USO
HIDRATANTE VITAMINA E E-LIEVE

Contiene:

120 x .3ml LolliPacks™ de un solo uso

Instrucciones de uso

E-Lieve es un hidratante unidosis postblanqueamiento con Vitamina E para el tejido gingival. El cómodo envase unidosis LolliPack permite una aplicación sencilla y su uso no supervisado.

Condiciones de almacenamiento

Se recomienda guardar en un lugar protegido de la luz y de la humedad excesiva. Temperatura de almacenamiento 10°C - 25°C / 50°F – 80°F.

Aplicaciones clínica

Indicado para irritaciones de los tejidos blandos tras blanqueamiento, cirugía de tejido con láser, bisturí o dispositivo electroquirúrgico.

INSTRUCCIONES DE USO

- Sujete el envoltorio laminado del LolliPack y despéguelo cuidadosamente, exponiendo bien el aplicador del cepillo y la Vitamina E.
- Retire el cepillo aplicador e introdúzcalo en el material.
- Localice las áreas blanqueadas en la boca y aplique E-Lieve.
- Deseche el envase y cepillo usados.

FINNISH

KÄYTTÖOHJEET
E-LIEVE E-VITAMIINIA SISÄLTÄVÄ KOSTUTUSAINE

Sisältö

120 x 0,3 ml kertakäyttöinen LolliPacks™

Käyttöohjeet

E-Lieve on yksittäispakattu E-vitamiinia sisältävä valkaisuun jälkeen käytettävä ienkudoksen kostutusaine. Kätevä yksittäispakattu LolliPack-pakkaus mahdollistaa helpon käytön myös kotona.

Säilytys

Säilytettävä suojassa auringonvalolta ja kosteudelta.
Säilytyslämpötila: 10 °C – 25 °C

Kliininen käyttö

Käytettäväksi pehmeän kudoksen ärsytyksen lievittämiseen valkaisuun, kudoksen laser-, skalpelli- tai sähkökirurgialeikkauksen jälkeen.

KÄYTTÖOHJEET

- Tartu LolliPack-pakkauksen kalvoon ja irrota se hitaasti, jolloin harja ja E-vitamiinisäiliö tulevat näkyviin.
- Irrota harja ja upota se aineeseen.
- Etsi suusta valkaistut alueet ja levitä niihin E-Lieve-ainetta.
- Hävitä käytetty pakkaus ja harja.

PORTUGUÊS

INSTRUÇÕES DE UTILIZAÇÃO
HUMIDIFICADOR COM VITAMINA E E-LIEVE

Contém:

LolliPacks™ descartáveis, 120 unidades x 0,3 ml

Instruções de utilização

E-Lieve é um humidificador com Vitamina E, em dose unitária, para aplicação no tecido gengival após o branqueamento dentário. A prática embalagem LolliPack de dose única permite uma fácil aplicação e o doente pode levá-la para casa.

Condições de conservação:

Proteger da luz e da humidade elevada.
Conservar a temperaturas entre 10°C - 25°C / 50°F – 80°F.

Aplicações clínicas

Indicado para a irritação dos tecidos moles após um branqueamento, uma cirurgia tecidual com laser, bisturi ou unidade de electrocirurgia.

INDICAÇÕES DE UTILIZAÇÃO

- Levante o revestimento de alumínio do LolliPack e destaque-o lentamente, expondo o pincel aplicador e o reservatório de Vitamina E.
- Remova o pincel aplicador e molhe-o no produto.
- Procure as zonas branqueadas na boca e aplique E-Lieve.
- Elimine a embalagem e o pincel depois da utilização.

INSTRUCTIONS FOR USE

For Professional Use Only

DANSK

BRUGSANVISNING
E-LIEVE E-VITAMIN FUGTIGHEDSMIDDEL

Indhold

120 x 0,3 ml LolliPacks™ til engangsbrug

Brugsanvisning

E-Lieve er en E-vitamin fugtighedsmiddel i enhedsdoser til brug på tandkodet efter tandblegning. Den praktiske LolliPack-pakke med enkeltdoser gør det produktet let anvendeligt, også derhjemme.

Opbevaring

Bevares bedst beskyttet mod lys og høj fugtighed.
Opbevares i temperaturer mellem 10 °C – 25 °C

Klinisk anvendelse

Til brug på irriterationer på blodvæv efter tandblegning, tandkødskirurgi med laser, skalpel eller et elektrokirurgisk apparat.

BRUGSANVISNING

- Tag fat i folieovertrækket på LolliPack'en og træk det langsomt tilbage, så applikatorbørsten og E-vitaminpreparatet kommer helt til syne.
- Tag applikatorbørsten og dyp den ned i materialet.
- Kontroller munden for blegnede områder og påfør E-lieve.
- Kasser brugt pakke og børste.

NEDERLANDS

AANWIJZINGEN VOOR HET GEBRUIK
VOCHTINBRENGENDE E-LIEVE MET VITAMINE E

Bevat

120 x 0,3 ml LolliPacks™ voor eenmalig gebruik

Gebruiksaanstructies

E-Lieve is een vochtinbrengende crème voor tandvlees, die na het bleken wordt gebruikt en één dosis bevat. Door de handige LolliPack-verpakking met één dosis is het gemakkelijk aan te brengen en mee naar huis te nemen.

Bewaarcondities

Bij voorkeur niet in het licht en bij hoge vochtigheid bewaren.
Bewaren bij een temperatuur van 10 °C – 25 °C

Klinische toepassingen

Voor gebruik bij irritatie van zachte weefsels na het bleken en na operatieve weefselbehandeling met een laser, scalpel of elektrochirurgisch apparaat.

AANWIJZINGEN VOOR HET GEBRUIK

- Pak de foliebekleding om de LolliPack vast en trek die langzaam naar achteren, waarbij de borstelapplicator en het vitamine E-bad vrijkomen.
- Haal de applicatorborstel uit de verpakking en doop hem in het materiaal.
- Controleer de mond op ontkleurde plekken en breng daar E-Lieve aan.
- Gooi de gebruikte verpakking en borstel weg.

NORSK

GEBRUIKSAANWIJZING

E-LIEVE VITAMIN E FUKTIGHETSMIDDEL

Inneholder:

120 x 0,3 ml Loll iPacks™ til engangsbruk

Bruksanvisning

E-Lieve er et vitamin E fuktighetsmiddel i enhetsdoser, til bruk på tannkjøttet etter tannbleking.

Den praktiske Loll iPack-pakningen med enhetsdoser gjør produktet lett anvendelig, også i eget hjem.

Lagringsforhold

Bør helst oppbevares skjermet mot lys og høy fuktighet.

Oppbevares ved temperaturer mellom 10°C – 25°C.

Kliniske anvendelser

Til bruk på iritasjoner i bløtvev etter tannbleking, tannkjøttkirurgi med laser, skalpell eller elektrokirurgisk utstyr.

VEILEDNING

1. Ta tak i folielokket på Loll iPack og dra det langsomt bakover slik at applikatorbørsten og vitamin E-preparatet kommer til syne.

2. Ta ut applikatorbørsten og dypp den i preparatet.

3. Sjekk munnen for bleknede områder og påfør E-Lieve.

4. Kast brukt forpakning og børste.

SVENSKA

ANVÄNDARINSTRUKTIONER

E-LIEVE FUKTIGHETSKRÄM MED VITAMIN E

Innehåller

120 x 0,3 ml Loll iPacks™ för engangsbruk

Bruksanvisning

E-Lieve är en fuktighetskräm med vitamin E som tillhandahålls i engångsdoser och som används på tandkötet efter blekning. Den behändiga engångsförpackningen Loll iPack underlättar applicering och hemmabruk.

Förvaring

Bör förvaras torrt och skyddat från ljus.

Förvaras i en temperatur på 10 – 25°C.

Klinisk tillämpning

Avsedd att användas på irriterat tandkött efter blekning eller efter mjukvävnadskirurgi med laser, skalpell eller elektrokirurgisk utrustning.

BRUKSANVISNING

1. Ta tag i folieöverdraget på Loll iPack-förpackningen och dra av det långsamt, så att applikatorborsten och E-vitaminkrämen exponeras.

2. Ta upp applikatorborsten och doppa den i krämen.

3. Applicera E-Lieve på alla vita områden på tandkötet.

4. Kasta förpackningen och borsten efter användning.

DEUTSCH

GEBRAUCHSANWEISUNGEN

E-LIEVE VITAMIN E-BEFEUCHTUNGSMITTEL

Enthält

120 x 0,3 ml Einweg-Loll iPacks™

Gebrauchsanweisung

E-Lieve ist ein Einzeldosis-Vitamin E-Befeuchtungsmittel für das Zahnfleisch nach dem

Bleichen. Die praktische Einzeldosis-Loll iPack-Verpackung ermöglicht eine problemlose

Anwendung und Verwendung zu Hause.

Lagerbedingungen

Am besten dunkel und bei geringer Luftfeuchtigkeit lagern.

Bei Temperaturen zwischen 10°C und 25°C lagern.

Klinische Anwendungen

Zur Verwendung bei leichter Gewebereizung nach dem Bleichen sowie bei

Gewebebehandlungen mit einem Laser, Skalpell oder Stromstoßgerät.

GEBRAUCHSANWEISUNG

1. Ziehen Sie die Folie des Loll iPack langsam zurück, so dass der Bürstenapplikator und das Vitamin E-Behältnis freigelegt werden.

2. Entfernen Sie die Bürste und tauchen Sie sie in das Material ein.

3. Kontrollieren Sie den Mund auf gebleichte Stellen und tragen Sie das E-Lieve auf.

4. Entsorgen Sie die Verpackung und die Bürste.

| MATERIAL SAFETY DATA SHEET (MSDS) | |
|---|--|
| <p>SECTION I - PRODUCT/ COMPANY IDENTIFICATION Product Name: REF 360084 E-Lieve™ Post-Bleaching Vitamin E Treatment, 120 x 0.3ml units CENTRIX, INC., 770 RIVER ROAD, SHELTON, CT 06484 Emergency / Information Telephone Numbers: 203-929-5582 Toll-Free: 800-235-5862 (USA & Canada)</p> | |
| <p>SECTION II - COMPOSITION/INFORMATION ON INGREDIENTS Characterization: Fat-soluble vitamin; additive for use in food, pharmaceuticals and cosmetics Chemical Name: 3,4-Dihydro-2,5,7,8-tetramethyl-2-(4,8,12-trimethyltridecyl)-2H-1-benzopyran-6-ol acetate Synonyms: 2,5,7,8-Tetramethyl-2-(4,8,12-trimethyltridecyl)-6-chromanol acetate, Vitamin E acetate CAS Number: 7695-91-2 EINECS Number: 231 710 0 Ro Number: Ro 01-4213/000 Empirical Formula: C₃₁H₅₂O₃ Molecular Mass: 472.73 g/mol</p> | |

SECTION III - HAZARDS IDENTIFICATION

Most important hazards - No particular hazards known.

SECTION IV - FIRST AID MEASURES

| | | |
|---------------|--|---|
| Eye Contact: | Rinse with tap water for 10 minutes - open eyelids forcibly | Consult a physician if irritation persists |
| Skin Contact: | Remove immediately contaminated clothes Do not use any solvents | Wash affected skin with water and soap Consult a physician if skin irritation persists |
| Inhalation: | Remove the casualty to fresh air and keep him/her calm | In the event of symptoms get medical treatment |

SECTION V - FIRE-FIGHTING MEASURES

Suitable Extinguishing Media: Foam, dry powder, carbon dioxide, water mist

Unsuitable Extinguishing media: Use water spray and water jet for cooling purposes only (fat explosion hazard)

Protection of Fire-Fighters: Precipitate gases/vapours/mists with water spray

SECTION VI - ACCIDENTAL RELEASE MEASURES

| | |
|---------------------------|---|
| Environmental Protection: | Do not allow to enter drains or waterways Nontoxic and biodegradable, but very slow biodegradation due to low water solubility |
| Methods for cleaning up: | Collect spills with inert adsorbent and hand over to waste removal Clean contaminated areas with little ethanol |

SECTION VII - HANDLING AND STORAGE

Handling

Technical Measures: Processing in closed systems, if possible superposed by inert gas (e.g. nitrogen)
Take precautionary measures against electrostatic charging

Suitable Materials: Stainless steel, aluminium, enamel, glass, polyethylene - test plastics before use

Storage

Storage Conditions: Protected from light and humidity
Validity: 36 months, < 25 °C, in the unopened original container, see "best use before" date stated on the label
Packaging Materials: Tightly closing; material: stainless steel, aluminium, enamel, glass, food-approved plastics

SECTION VIII - EXPOSURE CONTROLS / PERSONAL PROTECTION

Engineering Measures: See 7.

Monitoring

Threshold Value (Roche) Air: IOEL: 10 mg/m³

Analytics: Sampling on filter or impinger and chemical determination (consider possible autooxidation)

Personal Protective Equipment

Respiratory Protection: Respiratory protection not necessary during normal operations

Hand Protection: Protective gloves (neoprene, nitrile or butyl rubber)

Eye Protection: Safety glasses

SECTION IX - PHYSICAL AND CHEMICAL PROPERTIES

| | | | |
|------------|--------------------|-------------|---|
| Colour: | Slightly yellowish | Form: | Liquid, viscous |
| Odour: | Almost odourless | Density: | ~ 0.96 g/cm³ |
| Viscosity: | 6589 cP (20 °C) | Solubility: | < 0.8 mg/l, water (20 °C, OECD No. 105) |

See next column

| | | | |
|------------------------|---|--------------------------|---------------------|
| Well Soluble: | ethanol, acetone, chloroform, diethyl ether, vegetable oils | | |
| Partition Coefficient: | Log P _{ow} 12.2 (n-octanol/water)(calculated) | | |
| Melting Temperature: | -27.5 °C | Boiling Temperature: | 443 °C (1 bar) |
| Flash Point (liquid): | 243 °C (DIN 51'728) | Ignition Point (liquid): | 320 °C (DIN 51'794) |

SECTION X - STABILITY AND REACTIVITY

Conditions to Avoid: Light, humidity

Materials to Avoid: Bases, strong acids, Oxidizing agents

Iron, silver and metal salts, Alkalis *1

*1 referring to: d-α-Tocopheryl Acetate

SECTION XI - TOXICOLOGICAL INFORMATION

Acute Toxicity: LD₅₀ > 4'000 mg/kg (oral, rat), LD₅₀ > 4'000 mg/kg (oral, mouse)
LD₅₀ 840 mg/kg (i.p., rat), LD₅₀ > 3'000 mg/kg (dermal, rat)

Local Effects: Eye: non-irritant (rabbit)

Skin: May be slightly irritating (several species)

Sensitization: Very few cases of sensibilisation are known (human) *2

Subchronic Toxicity: NOAEL 2000 mg/kg/d (oral, rat; 13 weeks) *1

Mutagenicity: Not mutagenic (various test systems) Carcinogenicity: Not carcinogenic

Reproduction Toxicity: Not teratogenic Note: Natural radical scavenger and antioxidant *2

Therapeutic dosage: 100-300 mg/d *2

High doses may cause nausea, vomiting, diarrhoea, fatigue and weakness *2

Intensive skin contact may cause contact dermatitis *2

RDA (Recommended Dietary Allowance): 8-10 mg/day *2

*1 referring to: d-α-Tocopheryl Acetate *2 referring to: dl-α-Tocopherol

SECTION XII - ECOLOGICAL INFORMATION

Ready Biodegradability: Not readily biodegradable
17%, 28 days
(Manometric Respirometry Test, OECD No. 301 F)

Inherent Biodegradability: Well inherently biodegradable 84%, 28 days
(MITI Test II, OECD No. 302 C)

Ecotoxicity: Barely toxic for algae (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Selenastrum capricornutum), EC₅₀ (72 h) > 100 mg/l (nominal concentration) NOEC (72 h) 100 mg/l (nominal concentration) (OECD No. 201) *1. Barely toxic for planktonic crustaceans (nominal concentration = 100 mg/l), test performed with water accommodated fractions (Daphnia magna), NOEC (48 h) 100 mg/l (nominal concentration), EC₅₀ (48 h) > 100 mg/l (nominal concentration) (OECD No. 202).

Barely toxic for fish (nominal concentration = 100 mg/l), test performed with water accommodated fractions (rainbow trout), LD₅₀ (96 h) > 100 mg/l (nominal concentration), NOEC (96 h) 100 mg/l (nominal concentration), (OECD No. 203, semi-static) *1.

Barely toxic for fish (nominal concentration = 100 mg/l), no chronic toxic effects have been observed at or above solubility limit (rainbow trout), NOEC (28 d) 100 mg/l (nominal concentration), (OECD No. 215, Fish Juvenile Growth Test)

No adverse influence on substrate biodegradation (activated sludge) concentration (28 d) 100 mg/l (nominal concentration) (Manometric Respirometry Test, OECD No. 301 F) *1

Air Pollution: Observe local/national regulations

*1 referring to: d-α-Tocopheryl Acetate

SECTION XIII - DISPOSAL CONSIDERATIONS

Waste from Residues: Observe local/national regulations regarding waste disposal

SECTION XIV - TRANSPORT INFORMATION

Note: Not classified by transport regulations

SECTION XV - REGULATORY INFORMATION

Note: No classification and labelling according to EU directives. Water hazard class (Germany) 1: weakly hazardous for water (according to annex 1 or 2 of directive VwVwS of 17.05.1999)

SECTION XVI - OTHER INFORMATION

Use: For the enrichment of foods, Ingredient in pharmaceutical preparations
For various cosmetic products

Biological activity: 1 I.U. (International Unit) of vitamin E corresponds to the activity of 1.0 mg

pure dl-α-tocopheryl acetate

Safety-lab number: BS-1762, BS-1765, BS-4527, BS-7412

Edition documentation: Changes from previous version in sections 1, 2, 4, 7, 8, 13, 16

PRODUCT FOR PROFESSIONAL USE ONLY.

IMPORTANT NOTICE: DSM N.V., headquartered in Heerlen, The Netherlands, has acquired the vitamins, carotenoids, enzymes, food and feed ingredients, cosmetics ingredients and fine chemicals business (VFC Business) of the Roche group of companies, headquartered in Basel, Switzerland. Within the United States, DSM Nutritional Products, Inc. has purchased certain assets and assumed certain liabilities of the VFC Business formally conducted by Roche Vitamins Inc. Please note that corporate names, trade names, trade and service marks and domain names containing the word "Roche" and the "Roche" logo will continue to appear on our business documentation during our transition. We appreciate your understanding and cooperation as we complete our rebranding program. Should you have any questions, or if DSM can be of further assistance to you, please do not hesitate to contact your Account Manager or our Account Management Center at: +41-62 866 2314.

centrix

Making Dentistry Easier.SM

10°C -25°C / 50°F -50°F



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