Fito®

cream / gauze advance

Product Summary File

This dossier is to be reviewed only by healthcare professional members of the hospital committee

All documents contained in this dossier, including all scientific journal publications, are not intended for product detailing or promotional purposes.

All documents contained in this dossier, including all scientific journal publications, will serve as scientific evidence that is to be assessed during the hospital committee meeting.

Handling of the contained medical/scientific information in all GCC countries is the sole responsibility of the scientific affairs department.

Scientific Affairs Department
Phone +971 4 247 6400
Fax +971 4 247 6499
e-mail: mmoeg@leo-pharma.com
Web: www.leo-pharma.com

LEO Pharma A/S Representative Office
Barsha Heights, i-Rise Tower, 34th Floor, Office C1 & C2
P.O.Box 9952 & 9628, Dubai – UAE

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PIL : patient information leaflet

Composition

Fito® cream is of natural herbal origin as it's an aqueous extract of *Triticum vulgare*. It's composed of:

Rigenase® (wheat extract) as the main active ingredient, 2-phenoxyethanol, polyethylene glycol400, polyethylene glycol1500, polyethylene glycol3000, polyethylene glycol4000, liquid paraffin, cetyl alcohol, stearyl alcohol, glycerin, and purified water.

***Triticum vulgare* extract** [1]

Triticum vulgare belongs to the Poaceae family, *Triticum vulgare extract* mainly contains lipids and liposoluble vitamins. Also, it's the richest natural source of vitamin E in comparison with any other vegetable oil.

- **Lipids**

  Wheat lipids are mostly stored in the germ. The most abundant omega-3 fatty acid is linoleic acid (55%), followed by oleic and palmitic acids. Also, ceramides and glycol-ceramides can be extracted from wheat.

Table 1. Fatty acid composition of wheat germ oils (%).

Fatty acid	RI	% *
Palmitic acid (C16:0)	1286	17.4
Stearic acid (C18:0)	1565	0.9
Oleic acid (C18:1)	1592	17.1
Linoleic acid (C18:2)	1656	56.1
Linolenic acid (C18:3)	1741	6.9
Arachidonic acid (C20:0)	1843	0.2
Eicosenoic acid	1886	1.4

*Results are given as mean (n=3).

- **Lipo-soluble vitamins and Minerals**

  The oils produced from cereals germ are the main source of tocopherols (Vitamin E) and Vitamin B.

  The below table illustrates the mineral content of wheat germ:

Table 2. Mineral content of wheat germ.

Elements	Mean (ppm)
Nitrogen (N)	5.31*
Potassium (K)	11240
Phosphorus (P)	10700
Calcium (Ca)	268
Magnesium (Mg)	2950
Sodium (Na)	242
Iron (Fe)	88
Manganese (Mn)	236
Zinc (Zn)	158
Copper (Cu)	10

*Expressed as %.

Mechanism of action

- Fito® cream forms a protective barrier against the external environment, thus maintaining wound microenvironment under control. [2,3]

- Fito® fills and covers the surface of either superficial and deep wounds keeping wound microenvironment moist which creates the favorable conditions for a fast and correct wound healing and promotes optimal re-epithelialization. Moist wound microenvironment has been proved to result in:[2-6]

    a. significant reduction in the time required for re-epithelialization (faster healing)
    b. reduced intensity and duration of inflammation during healing thus reduce scar formation.
    c. less necrosis and better quality of healing (prevent dehydration, enhance angiogenesis and collagen synthesis, thus improves the aesthetics of the wound).
    d. decreased pain leading to:
        i. a reduced stress response and less fatigue in patients which helps in the healing process.
        ii. a better patient mobility, which improves circulation, oxygenation, and allows for better healing.
    e. decreased incidence of wound infection

Fito is considered as a topical bioactive dressing.[7] It does not only forms a protective barrier against the external environment; but also interacts with the wound bed components to further enhance wound healing through the following actions:

1. Protecting Keratinocytes from damage by free radicals (anti-oxidant effect) [8]
2. Increasing Keratinocytes viability (hydrating effect) [9]

The later actions are important to facilitate the proliferation and migration of keratinocytes to restore the epidermis defect after injury through “Re -epithelialization”. Complete re-epithelialization is essential for successful wound healing.

Indications

Fito® cream is a medical device consisting of water hydro-soluble non-greasy cream. It's colorless, odorless, and non-staining cream that does not leave behind any residue or stain the clothes.

Fito® cream & gauze are indicated for treatment of the following conditions: [2,3]

a) Burns

1. First-degree burns
2. Second-degree burns

b) Wounds:

Examples:

1. Contusion or bruise
2. Abrasions
3. Lacerations
4. Surgical incisions

c) Ulcers

Examples:

1. Venous ulcers
2. Neuropathic ulcers
3. Arterial ulcers
4. Pressure ulcers

Formulations

Fito® is available in two forms: [2,3]

Fito® cream

Fito® cream (32 g tube) is a medical device consisting of water hydro-soluble dermatological cream contained in an aluminium tube.

Fito® gauze advance:

Fito® gauze Advance (10×10 cm) is a dermatological medical device consisting of single dose gauze imbibed with water hydro-soluble cream.

Administration

How to use Fito® cream? [2]

- When first using the product, pierce the tube by using the small punch contained in the upper part of the cap.
- Spread the necessary amount of cream on the area and cover with sterile gauze, possibly imbibed with more cream.
- If there are no contraindications, in following applications it is possible to previously cleanse the area with sterile water as the cream is totally water hydro-soluble and leaves no residues.
- Depending on the seriousness, extension and location of the damage, application can be reduced to simple massages to let the cream be absorbed.

How to use Fito® gauze? [3]

- Apply the gauze directly on the area after cleansing and disinfecting it.
- Cover with sterile gauze and/or cotton wool (in case of very secreting sores).
- If there are no contraindications, in following applications it is possible to previously cleanse the area with sterile water as the cream is totally water hydro-soluble and leave no residues.
- Repeat application every 48 hours unless differently prescribed.

Clinical efficacy

Fito® efficacy in different indications has been proven by several evidence based clinical trials.

This section summerizes the design, patients, methods and the results of clinical studies that are supporting the use of Fito® in the following indications:

- Burn
- Ulcer
- Wound

Moreover, this section contains the pre-clinical studies that proves the effect of Fito® as a bioactive dressing and its interactions with the wound bed components to further enhance wound healing through the following effects:

- Anti-oxidant effect
- Hydrating effect

Burns

Different forms of Wheat Extracts have been widely used since decades in the treatment of cutaneous lesions in which a stimulation of tissue repairing processes (e.g. in burns) is needed, and their place in therapy is well recognized. The next section includes some clinical data on the use of Fitostimoline-based products which is another aqueous extract of Triticum vulgare.

Efficacy of wheat grass extract versus silver sulfadiazine in 1–5% second degree burns: A randomized controlled trial [10]

Abstract: The aim of this prospective randomized controlled study was to compare the rate of wound healing of 1–5% second degree burns treated with wheat grass extract versus silver sulfadiazine (SSD) cream in 60 patients aged 1-60 years. The primary outcome was completeness of wound healing at 3 weeks and the secondary outcomes were pain relief within 24 h, compliance of patient with allocated treatment, and incidence of wound infection.

Results:

A) Days of wound healing

Wheat grass promoted healing of second degree burns faster than silver sulfadiazine group. *(P =0.0001)*

Table 3 Mean days of wound healing (*P* value 0.0001)

Day of wound healing	Wheatgrass group (mean ± SD)	SSD group (mean ± SD)
Days of wound healing	8.77 ± 4.06	13.77 ± 1.43

B) Pain relief within 24 hrs

In the wheat grass group, pain relief was characteristically achieved by an hour after application and persisted for 10–12 h; minimal amount of analgesic was required for breakthrough pain. However, none of the patients in the SSD group achieved pain relief within 24 h and all required ongoing analgesia.

Table 1 Distribution of patients according to pain relief within 24 h

Pain relief within 24 h	Wheatgrass group		SSD group	
	No.	%	No.	%
Relieved	28	93.33	0	0.0
Not relieved	2	6.7	30	100.0
Total	30	100.00	30	100.00

C) VAS pain Score at the end of 24 hrs

Wheat grass achieved better pain relief than SSD in our study subjects. *(P =0.0001)*

Table 4 VAS score at the end of 24 h in both the groups (*P* value 0.0001)

VAS score	Wheatgrass group (mean ± SD)	SSD group (mean ± SD)
At the end of 24 h	1.27 ± 1.72	4.66 ± 0.88

D) Patient Compliance

Wheat grass group showed better compliance vs the silver sulfadiazine group. *(P =0.0001)*

N.B. Wheat grass is cost-effective and there were neither wound infections nor adverse effects in both groups

Efficacy and tolerability of Fitostimoline®* in two different forms (Soaked Gauzes and Cream) and Citrizan Gel in the topical treatment of second-degree superficial cutaneous burns [11]

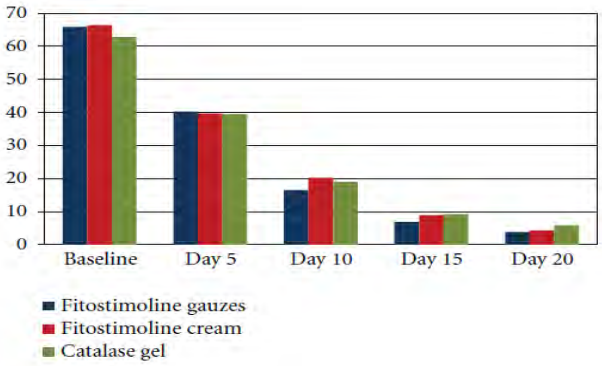
Abstract: A total of 227 patients with second-degree superficial cutaneous burns of thermal origin were randomized to receive Fitostimoline® in two forms (soaked gauzes and cream) or Catalase gel. The primary outcome was the rate of lesion healing and the secondary outcome was Total Symptoms Score (TSS) reduction.

Results:

A) Reduction in largest burn diameter

The mean largest burn diameter progressively decreased from baseline to end of study in all treatment groups. There were no statistically significant differences in the overall comparison.

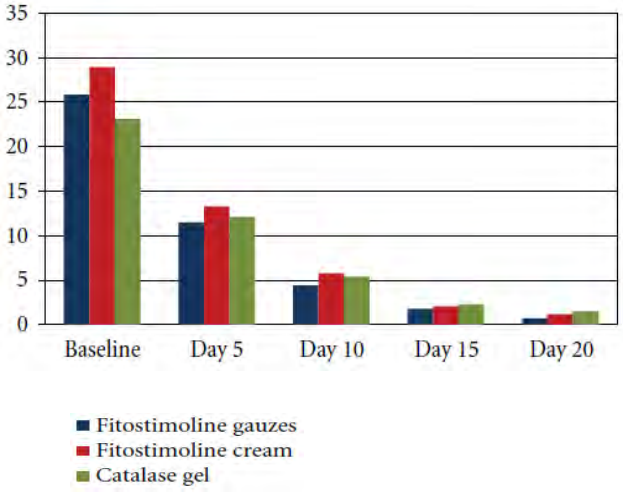
(p =0.41)



B) Reduction in lesion surface area

Mean lesion surface area progressively decreased from baseline in all treatment groups. The comparisons between groups didn't show statistically significant differences.

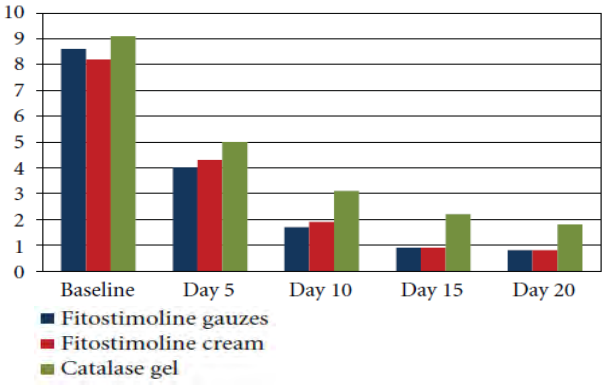
(p =0.39)



*Fitostimulin® is another form for Aqueous Extracts of Triticum Vulgare

C) Reduction of Total Symptoms Score (TSS)

Improvements in total symptoms score at end of study were significantly more marked in the pooled Fitostimoline® groups than in the catalase gel group. (*P =0.036)*



Tolerability:

Fitostimoline® is well tolerated as the rate of patients with adverse events was higher in the catalase gel group (5.2%) than in patients treated with Fitostimoline® (1.3%).

A comparative study of the wound healing action of Triticum vulgare aqueous extract soaked gauzes vs Asiaticoside-soaked gauzes in the treatment of 2nd degree burns [12]

Abstract: A prospective, randomized, comparative study was carried out on 60 patients with second-degree skin burns, with the aim of assessing the efficacy and tolerability of *Triticum vulgare* aqueous extract soaked gauzes versus Asiaticoside soaked gauzes. The primary outcome was the healing time and the secondary outcomes were wound adherence and bleeding, use of pain killers, and incidence of wound infection.

Results:

A) Reduction in healing time

Healing time in the *Triticum vulgare* group was 14.8 ± 1.4 days, while in the *Centella asiatica* group was 20 ± 1.9 days. *(P =0.0295)*

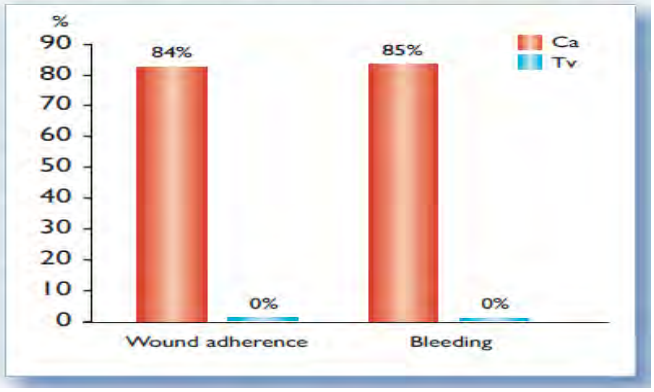
Table 2.
Skin surface (BS) with initial burns and time of healing.

	Triticum vulgare	*Centella asiatica*	
BS with burns %	11.5	11.6	
Time of healing - days	14.8 ± 1.4	20 ± 1.9	p = 0.0295

B) Wound adherence and bleeding

In the *Triticum vulgare* group, gauzes neither adhered to tissue nor was there any bleeding along the edges. In the *Centella asiatica* group, gauzes adhered to tissue in 84% of the cases and bleeding occurred in 85% of the cases. *(P =0.0001)*

Figure 1.
Clinical behavior to treatment with Tv vs Ca.



C) Use of pain-killers

Patients in the *Triticum vulgare* group did not require the use of pain killers. While in the *Centella asiatica* group, pain-killers were used in 20% of patients. *(P =0.003)*

Table 3.
Use of additional medication for pain management.

Medication group studied	*Triticum vulgare*		*Centella asiatica*		p
	Yes	No	Yes	No	
Antibiotics	6	24	6	24	Not adm.
Tranquillizers	3	27	7	23	0.041
Pain-killers	–	30	6	24	0.003

D) Infection of lesions

There was infection of the lesions in 3.4% and 6.7% of the patients in the *Triticum vulgare* and *Centella asiatica* groups respectively. *(P =0.207)*

Ulcers

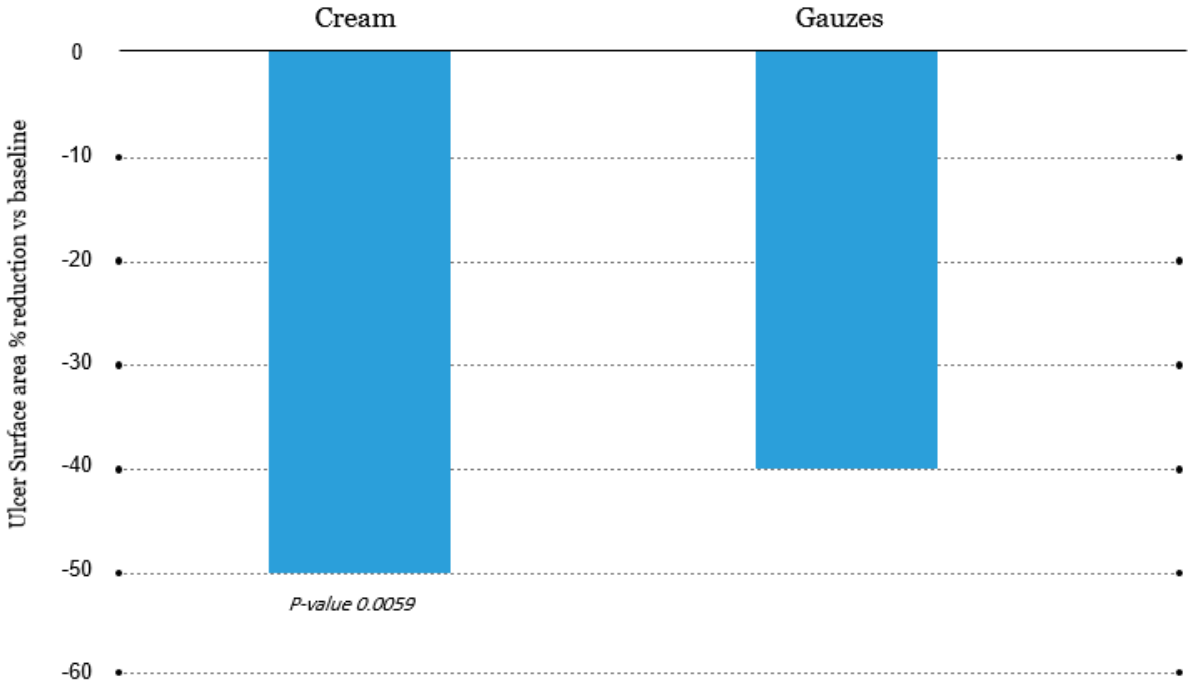
Clinical evaluation of the efficacy and safety of a medical device in various forms containing Triticum vulgare for the treatment of venous leg ulcers; A randomized pilot study [13]

Study Design: This study was carried out to assess the efficacy and tolerability of the topical application of an aqueous extract of *Triticum vulgare* in different vehicles (cream, impregnated gauzes, foam, hydrogel, and dressing gel) for the treatment of 50 patients with venous lower leg ulcers. The primary outcome was ulcer surface area reduction and the secondary outcome was Total Symptoms Score (TSS) reduction.

Results:

A) Ulcer surface area reduction

Surface area reduction has been shown in all groups. The cream showed the greatest effect on the mean reduction of lesion size. *(P-values: Student's t, 0.0095; Wilcoxon, 0.0059).*



PERCENTAGE REDUCTION (VS. BASELINE) OF THE ULCER SURFACE AREA AT THE END OF THE STUDY

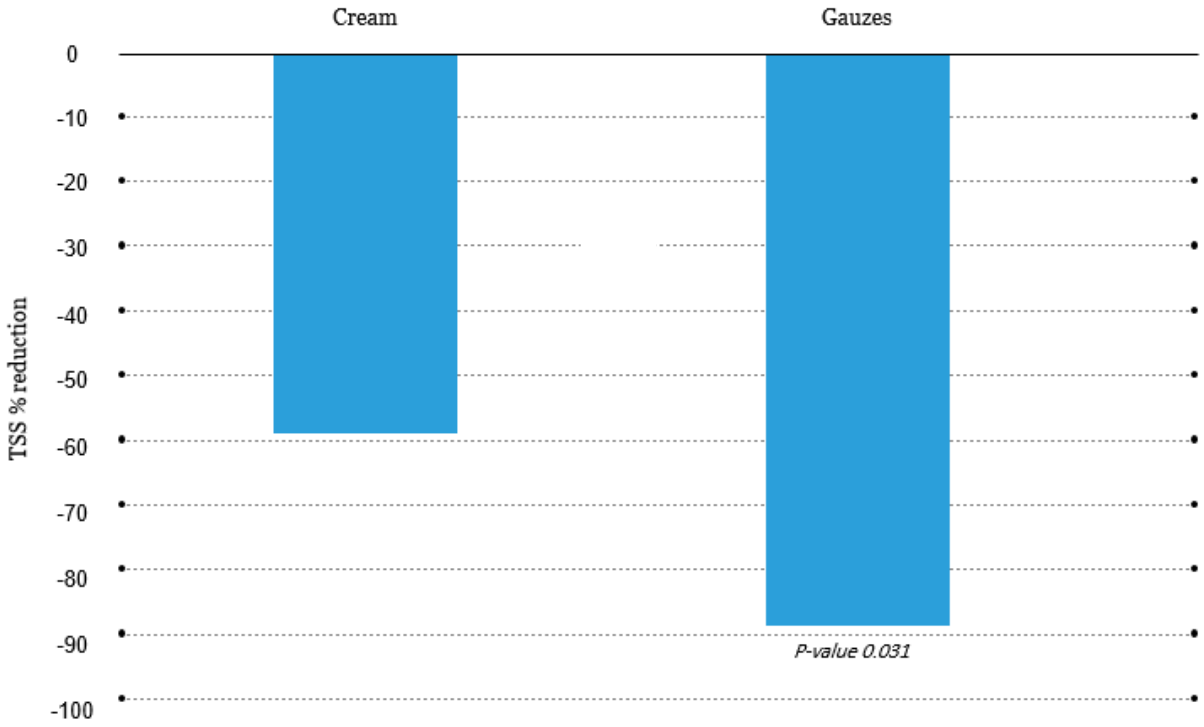
This study was carried out to assess the efficacy and tolerability of the topical application of an aqueous extract of Triticum vulgare (TV) in different vehicles (cream, impregnated gauzes, foam, hydrogel, and dressing gel) for the treatment of venous lower leg ulcers. Fifty patients were randomized to receive one of the five investigational vehicles. Treatment was performed up to complete healing or to a maximum of 29 days.

B) Total Symptoms Score (TSS) reduction

Signs measured: perilesional erythema & bleeding

Symptoms measured: burning, pain & itching

The TSS decreased in all groups throughout the study. The greatest efficacy on signs/symptoms was observed in the patients treated with the gauzes. *(P-values: Student's t, 0.031; Wilcoxon, 0.023).*



PERCENTAGE REDUCTION (VS. BASELINE) OF TOTAL SYMPTOMS SCORE (TSS) AT THE END OF THE STUDY

This study was carried out to assess the efficacy and tolerability of the topical application of an aqueous extract of Triticum vulgare (TV) in different vehicles (cream, impregnated gauzes, foam, hydrogel, and dressing gel) for the treatment of venous lower leg ulcers. Fifty patients were randomized to receive one of the five investigational vehicles. Treatment was performed up to complete healing or to a maximum of 29 days.

Signs (perilesional erythema, bleeding) and symptoms (burning, pain, itching) due to the lesion were measured using a 4-point scale (0–3: absent, mild, moderate, severe) at each visit, and in each patient the scores were added up to obtain the Total Symptoms Score (TSS).

Conclusion:

- In the patients treated with Fito® cream and gauzes, the reduction of ulcer size was 40%–50%
- Reduction in signs/symptoms of venous leg ulcer was more evident in the patients treated with Fito® gauzes

Wounds

An Indian clinical trial to assess wound healing activity and safety of Fitostimoline®* 15%+1% cream as a topical treatment of different types of wounds

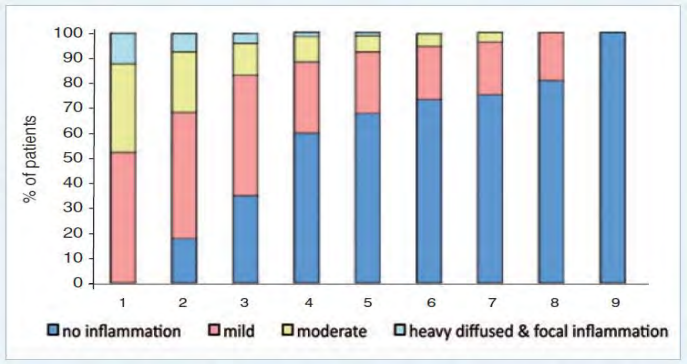
Abstract: The aim of the study was to evaluate the safety and efficacy of Fitostimoline®. This study has been conducted on 210 patients complaining skin lesions of various origin (burns, wounds, ulcers, and abrasions) and the patients were assessed at regular visits on day 0, day 2, day 4, day 6, day 9, day 22, day 15, day 18, and day 21.

Results:

A) Parameters of efficacy

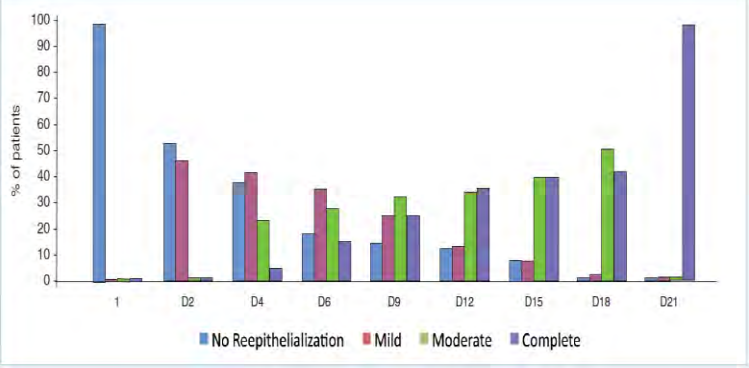
1. Inflammation

All patients with various types of wounds had inflammation which gradually reduced with the progression of treatment. *(P < 0.05)*



2. Re-epithelialization

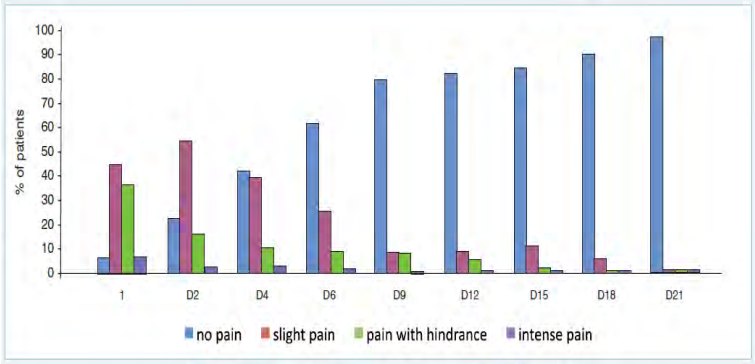
Re-epithelialization rate was gradually increased as the healing progressed.



Fitostimulin® is another form for Aqueous Extracts of Triticum Vulgare

3. Pain

The pain is significantly (P<0.05) reduced on progression of treatment with Fitostimoline®

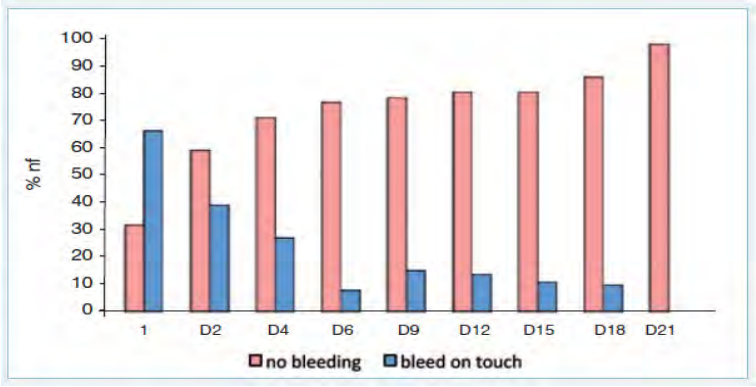


4. Scar maturation

Out of a total 204 patients, 199 (97.54%) showed healing of wounds without scar formation, 5 patients showed healing with formation of scar.

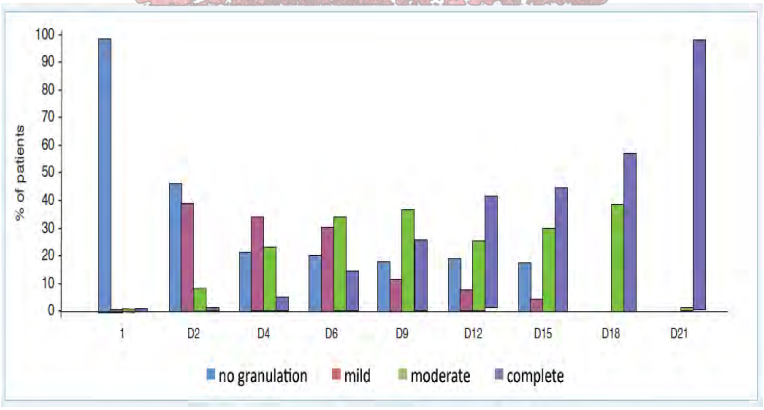
5. Bleeding of wound

Bleeding of wounds was the most common symptoms observed which ceased as the wound progressed to healing.



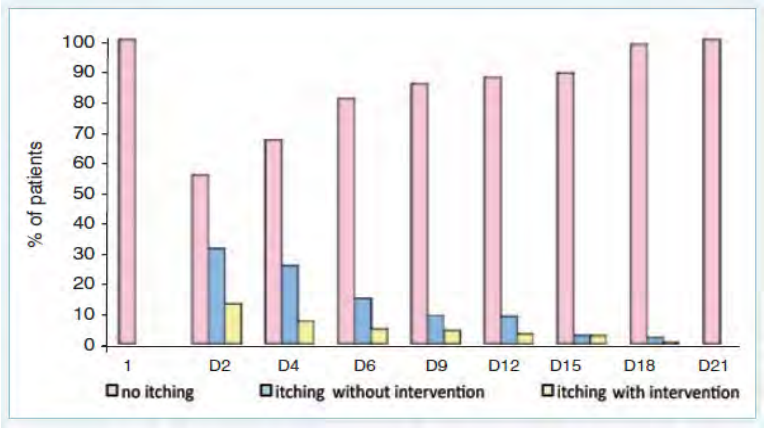
6. Granulation

In patients with smaller wounds, granulation rate was increased as the healing progressed.



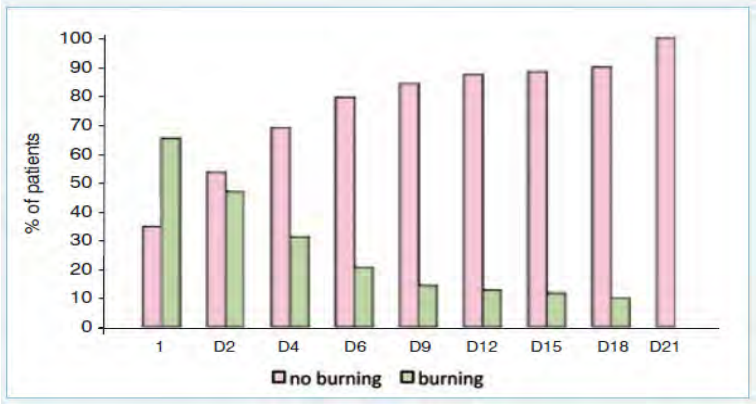
7. Itching

Itching was generally observed during the healing process and subsided as complete healing occurred.



8. Burning sensation

Burning sensation is gradually subsided with the progression of the healing process.



B) Safety analysis:

- Out of the total of 210 patients enrolled in the study, only 2 (0.98%) experienced adverse effects during the trial treatment. One patient developed skin allergic reaction and was withdrawn from the study. Another patient developed oozing of the wound and discontinued the treatment.

- Complete wound healing achieved without encountering any complications and incidence of infection.

Anti-oxidant effect

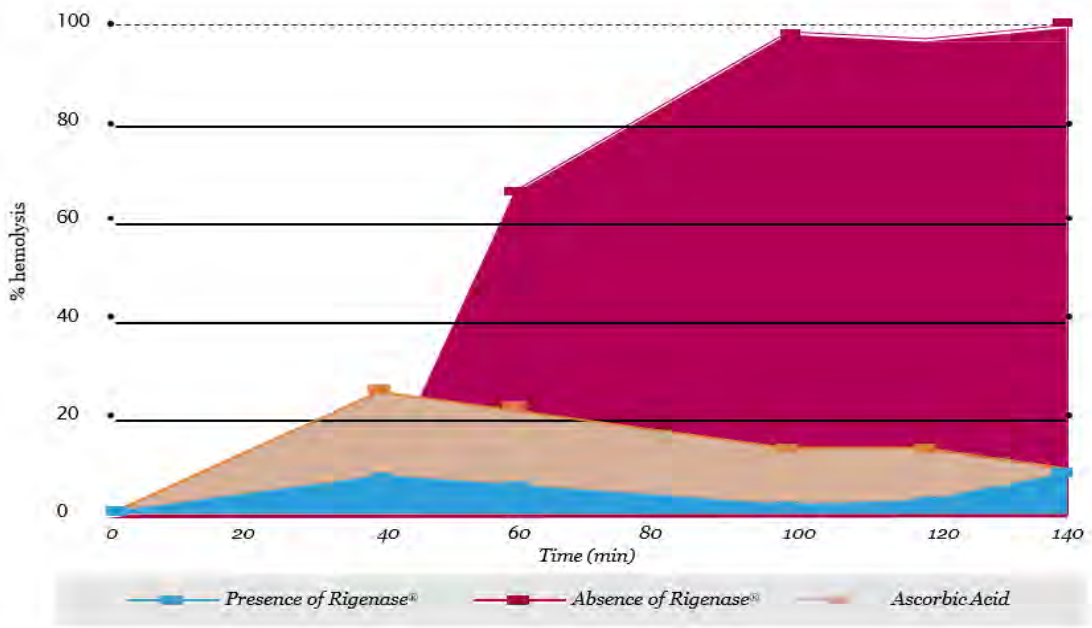
Antioxidant capacity of Rigenase®, a specific aqueous extract of Triticum vulgare [8]

Introduction: Burns and injuries such as decubitus ulcers, and sores are characterized by high concentrations of free radicals which might delay the wound healing process. The aim of this study was to show the scavenging effect of Rigenase® toward free radicals, thus pointing to its relevant antioxidant activity.

Method: The antioxidant capacity of Rigenase® has been assessed through oxidative hemolysis inhibition assay, which is based on inhibition of free radical-induced membrane damage in sheep erythrocytes by antioxidants. Erythrocytes suspension was incubated with AAPH, which induces generation of free radicals, at 37°C in the absence and in the presence of Rigenase® or ascorbic acid.

Results: The extract showed a stronger inhibition of AAPH-induced erythrocytes hemolysis than ascorbic acid, highlighting its relevant radical scavenging activity.

Conclusion: Fito® "Rigenase®" exhibits antioxidant capacity by inhibition of free radical-induced cell membrane damage (radical scavenging activity)



INHIBITION OF AAPH*-INDUCED ERYTHROCYTE HEMOLYSIS# BY FITO®

Preclinical Studies
**2,20-azobis(2-amidinopropane) dihydrochloride (AAPH): a free radical-generating azo compound*
#Erythrocytes suspension was incubated with AAPH at 37 °C in the absence and in the presence of FITO® or ascorbic acid. Each value, from which the spontaneous hemolysis was subtracted, is the mean ± SD of three separate experiments.

Hydrating effect

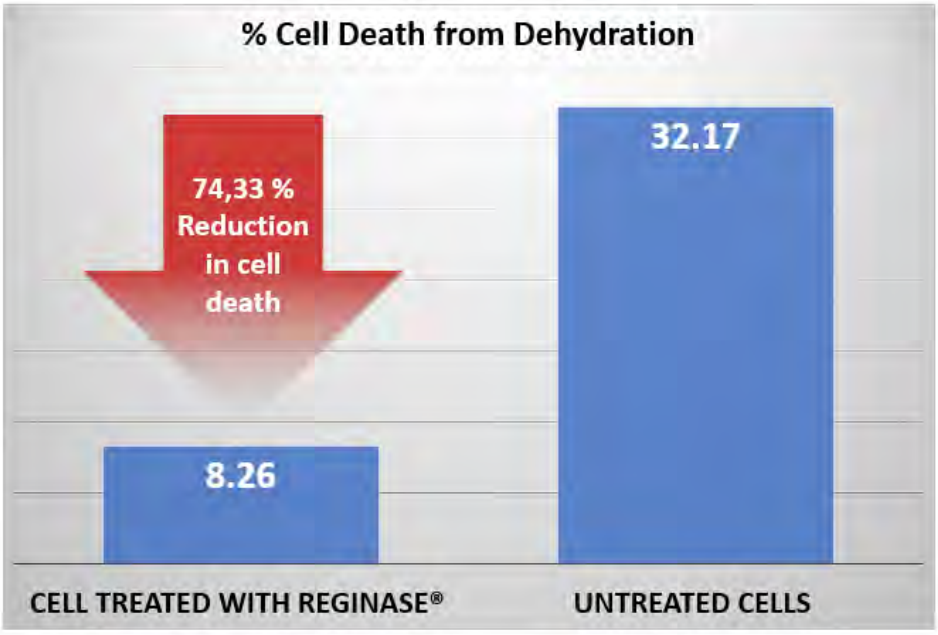
Hydrating activity on human Keratinocytes [9,15,16]

Introduction: Keratinocytes are the most abundant cell of the outermost layer of human skin "epidermis". Viable Keratinocytes are important for skin barrier maintenance, and for restoring the epidermis after injury through a process termed "Re -epithelialization". Proliferation and migration of keratinocytes are essential for re-epithelialization of the wound defect. Complete re-epithelialization is essential for successful wound closure. A wound cannot be considered healed in the absence of re-epithelialization.

Study Design: Cells are exposed to an in vitro hyper-osmotic stress by adding sodium chloride to the cell medium that causes cells death because of dehydration. We evaluate if the cells treated with Rigenase® at different concentrations show a higher viability rate in comparison with the stressed and untreated cells. Stressed cells untreated with Rigenase® (CDNT) and unstressed untreated cells have been used as controls in the experiment.

Results: it showed an in vitro dose-related protection against dehydration on human keratinocytes.

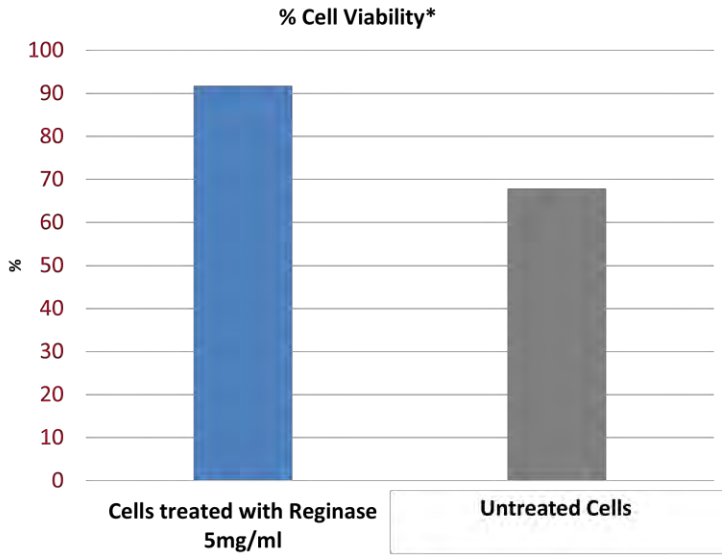
Conclusion: Fito® "Rigenase®" is effective in increasing keratinocytes capability of water retention & protecting them from the osmotic stress-induced dehydration



FITO® protects human keratinocytes from dehydration

Cells are exposed to hyper-osmotic stress by adding sodium chloride (NaCl 250 mOsm) in both arms
The highest effect is pointed out at 5 mg/ml concentration

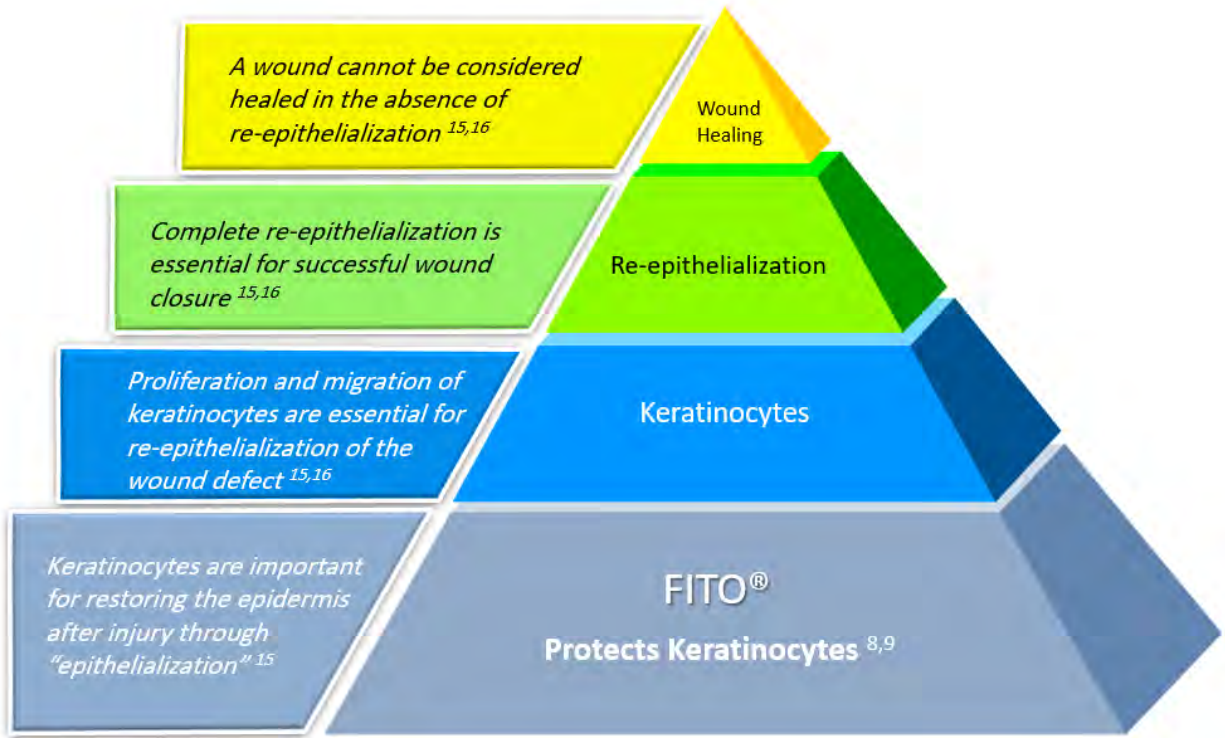
FITO® increases human keratinocytes viability by its hydrating effect [9]



Stressed Keratinocytes treated with Reginase® exhibit a higher viability rate compared to untreated cells*.

*In vitro assessment of the hydrating potential of (Reginase ®) on cultures of human skin derived keratinocytes. Cells are exposed to hyper-osmotic stress by adding sodium chloride (NaCl 250 mOsm) to the cell medium that causes suffering and cell death due to dehydration. Cells viability was tested with the Citotoxicity (MTT) assay.

Summary of the bioactive effects of Fito®



A diagram illustrating the role of Viable Keratinocytes in restoration of the epidermis after injury through "Re -epithelialization" and why Re-epithelialization is an essential component of wound healing.

Safety and tolerability [2,3]

Side effects

No side effects have been reported.

Contraindications

Known or suspected hypersensitivity to any of the ingredients.

Precautions for use

The use of all topical products, especially if continued, can cause the onset of sensitization phenomena. Should this occur, the use must be stopped and, if necessary, appropriate treatment must be administered.

Interactions

There are no known interactions or incompatibilities with other products.

Fito® Cream PIL

Fito® cream

Fito® cream is a medical device consisting of water dispersible dermatological cream contained in an aluminium tube.

INGREDIENTS: Rigenase® (wheat extract), 2-phenoxyethanol, polyethylene glycol400, polyethylene glycol1500, polyethylene glycol3000, polyethylene glycol4000, liquid paraffin, cetyl alcohol, stearyl alcohol, glycerine, purified water.

PROPERTIES: Fito® cream forms a protective barrier against the external environment, thus creating favorable conditions for a fast and correct skin re-epithelialization and contributes to keeping its microenvironment under control; consequently, the product is indicated for the treatment of ulcers, sores, wounds, abrasions and first and second degree burns. Rigenase® is a specific wheat extract.

INSTRUCTIONS FOR USE: How to apply the product: When first using the product, pierce the tube by using the small punch contained in the upper part of the cap. Spread the necessary amount of cream on the area and cover with sterile gauze, possibly imbibed with more cream. If there are no contraindications, in following applications it is possible to previously cleanse the area with sterile water as the cream is totally water dispersible and leaves no residues. Depending on the seriousness, extension and location of the damage, applications can be reduced to simple massages to let the cream be absorbed. After use, close the tube by tightly screwing the cap on it. How often to apply the product: follow medical advice. Cutaneous use.

SIDE EFFECTS: No side effects have been reported. However, it is important to report the possible onset of side effects to the doctor or the pharmacist.

CONTRAINDICATIONS: Known or suspected hypersensitivity to any of the ingredients.

PRECAUTIONS FOR USE: The use of all topical products, especially if continued, can cause the onset of sensitization phenomena. Should this occur, the use must be stopped and, if necessary, appropriate treatment must be administered.

INTERACTIONS: There are no known interactions or incompatibilities with other products.

WARNING: Carefully read the enclosed leaflet before use. Keep out of children's reach and sight. Do not swallow and avoid contact with eyes. Do not use after the expiry date shown on the package; the expiry date refers to the product properly stored in its unopened container. Do not use if the container has been damaged.

STORAGE CONDITIONS:
Do not store above 30°C. Do not freeze.

PACKAGING: 32 g tube, Free Medical sample 10 g

DISPOSE OF THE CONTAINER RESPONSIBLY AFTER USE

DISTRIBUTED BY:
LEO Pharma A/S
Ballerup, Denmark

MANUFACTURED BY:
Farmaceutici Damor S.p.A.
Via E. Scaglione, 27 - Naples - Italy
Fax: +39 0817405172
e-mail:damor@farmadamor.it

CE
0546

Date of information leaflet revision: January 2017

® Trademark

Description of the symbols used on primary and secondary packaging:

	Dispose of the container responsibly after use.
CE	Stamp of compliance with EC directives.
30°C 2°C	Limit of temperature of storage conditions.
	Carefully read the information leaflet.
	Carefully read the instructions.
LOT	Batch number.
	Expiry date.
ALU	Aluminium container.
	Manufactured by.

LEO
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Fito® Gauze PIL

Fito® gauzes
Advance

Fito® gauze Advance is a dermatological medical device consisting of single dose gauzes imbibed with water dispersible cream.

INGREDIENTS: Rigenase® (wheat extract), 2-phenoxyethanol, polyethylene glycol400, polyethylene glycol600, polyethylene glycol1500, polyethylene glycol4000, glycerine and purified water.

PROPERTIES: Fito® gauze Advance forms a protective barrier against the external environment, thus creating favorable conditions for a fast and correct skin re-ephelialization and contributes to keeping its microenvironment under control; consequently, the product is indicated for the treatment of ulcers, sores, wounds, first and second degree burns and abrasions. Rigenase® is a specific wheat extract.

INSTRUCTIONS FOR USE: How to apply the product: Apply the gauze directly on the area after cleansing and disinfecting it. Cover with sterile gauze and/or cotton wool (in case of very secreting sores).
If there are no contraindications, in following applications it is possible to previously cleanse the area with sterile water as the cream is totally water dispersible and leaves no residues. Repeat application every 48 hours unless differently prescribed. Cutaneous use.

SIDE EFFECTS: No side effects have been reported. However, it is important to report the possible onset of side effects to the doctor or the pharmacist.

CONTRAINDICATIONS: Known or suspected hypersensitivity to any of the ingredients.

PRECAUTIONS FOR USE: The use of all topical products, especially if continued, can cause the onset of sensitization phenomena. Should this occur, the use must be stopped and, if necessary, appropriate treatment must be administered.

INTERACTIONS: There are no known interactions or incompatibilities with other products.

WARNING: Carefully read the enclosed leaflet before use. Keep out of children's reach and sight. Do not swallow and avoid contact with eyes. Do not use after the expiry date shown on the package; the expiry date refers to the product properly stored in its unopened container. Do not use if the container has been damaged. Do not reuse the gauze: reuse can cause infections.

STORAGE CONDITIONS: Keep the product at a temperature below 30 °C. Do not freeze.

PACKAGING: 10 gauze box.

DISPOSE OF THE CONTAINER RESPONSIBLY AFTER USE.

DISTRIBUTED BY:
LEO Pharma A/S
Ballerup, Denmark

MANUFACTURED BY:
Farmaceutici Damor S.p.A.
Via E. Scaglione, 27 - Naples - Italy
Fax: +39 0817405172
e-mail:damor@farmadamor.it

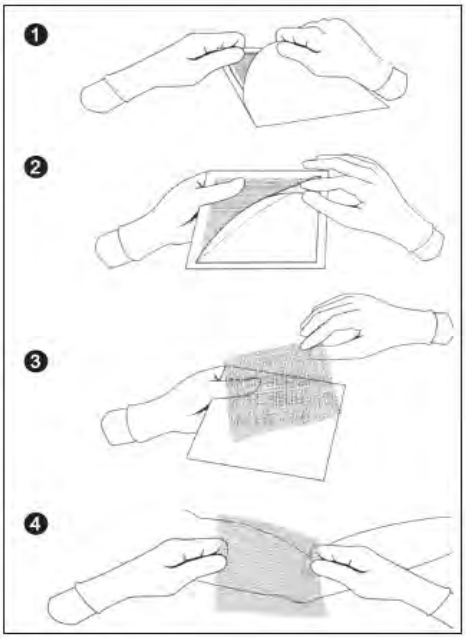
Date of information leaflet revision: January 2017

®Trademark

CE 0546

Description of the symbols used on primary and secondary packaging:

PAP/ALU/PP/LDPE	Paper/aluminium/polyethylene bag containing a 10 x 10 imbibed gauze enveloped in a film of polypropylene/ polyethylene plastic material.
	Dispose of the container responsibly after use.
CE	Stamp of compliance with EC directives.
30°C 2°C	Limit of temperature of storage conditions.
	Carefully read the information leaflet.
	Carefully read the instructions.
LOT	Batch number.
	Expiry date.
2	Use the gauze once only.
	Manufactured by.



LEO
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Approval Signatures

Name: Fito product summary_for scientific affairs use only

Id: MAT-22288

Version: 1

Status: Approved

Product: Fito®

Form:

Strength:

Region/Country: GCC+

Target Audience: Healthcare Professionals (HCPs), LEO Employees

Description: Fito product summary_for scientific affairs use only

Document Approvals	
Hatem Samir El Behairy (HMEAE)	Regulatory - 17-Jan-2019 06:31:29 GMT+0000
Mohamed Moukhtar Mohamed El Shaar (MMOEG)	Scientific/Medical Affairs - 18-Jan-2019 13:31:48 GMT+0000
Mohamed Moukhtar Mohamed El Shaar (MMOEG)	Scientific/Medical Affairs - 18-Jan-2019 13:32:59 GMT+0000