

| | | |
|--|---|------------|
| MASTELLI Officina Bio-Farmaceutica Sanremo | Codice: MC612X Revisione: 02 Del: 09/2020 | PAG. 01/01 |
| Descrizione: FOGLI ILL DEFINISSE LIGHTENING PEEL | | |
| Materiale: CARTA | | |
| Dimensioni: 440 X 200 mm | Dimensioni piegato: 27,5 X 200 mm | |
| Piega: SUL LATO LUNGO | Grammatura: 50 g/m ² | |
| n° colori: 1 | Pantoni: 296 C X X X X | |
| Altri Effetti: | X X | |



Menarini group

Definisse™ lightening peel

EN Chemical peeling solution, 50 ml bottle

PRODUCT DESCRIPTION

Definisse lightening peel, which is designed to carry out exfoliation (or peeling) of the superficial layers of the epidermis in order to obtain a lightening action, consists of a special mix of ingredients.

Definisse lightening peel allows for performing a superficial chemical peeling which is effective at several levels, in order to favor progressive reduction of skin spots from hyperpigmentation, to reduce damage to the skin structures. It has also reduced the possible side effects during the peeling and post-peeling phases.

The product consists of the following active substances: salicylic acid and pyruvic acid. Salicylic acid carries out an effective keratolytic effect on the superficial layers of the epidermis, allowing for greater penetration of the pyruvic acid. This product acts synergically with its components that made it possible to obtain a better concentration of the components themselves and consequently to limit damage to the skin structures.

The product also consists of two ingredients that combine to lighten the skin spots to reveal hyperpigmentation: salicylic acid and undecylenic pyruvate.

DEFINISSE LIGHTENING PEEL is a medical device used to promote exfoliation and favor the progressive reduction of superficial dyschromia of the skin in the face and body. For this reason, the medical device can be used to improve skin appearance and functionality of the skin:

- melanosis;
- pigmentation melasma;
- pigmentary changes;
- photoaging spots;

INGREDIENTS

Acido saliclico, acido pyruvico, diacetil boldina - triglicerido caprylic/capric, undecylenic phenylalanine, trans-retinoic acid, citric acid.

HOW TO USE AND CARE

The applications must be carried out by expert personnel who know the procedures of the various peeling phases, in accordance with local legislation.

Before treatment, carefully assess the topical treatment carried out by the patient at home, if it is advisable to suspend all procedures until the treatment is completed at least 15 days before performing the treatment.

It is recommended to protect the patient's eyes with gaze or cotton pads soaked in physiological solution and to protect cutaneous nevi and/or sensitive skin areas or skin lesions with barrier products.

Avoid applying the product in the sensitive areas described above.

1. Remove all makeup.

2. Cleanse and adapt the pH of the skin, for example with Definisse dry skin prep and/or Definisse oily skin prep.

3. Pour the necessary quantity of product for the treatment into a cotton pad (3 to 5 ml).

4. Apply the product onto the skin using a fan brush, spreading it evenly over the area to be treated, taking care not to allow the device to drop onto areas where treatment is not planned, and avoiding contact with the buccal mucosa, eyes and sensitive areas. The patient must report a brief and transient burning sensation.

5. After approximately 1-2 minutes after the application a yellowish gel will appear. The patient can remove a thin layer of salicylic acid crystals precipitated due to evaporation of the solvent.

6. Depending on the condition of the patient's skin and the desired effect, the doctor decides whether to enhance the peeling action by applying it several times.

7. At the end of the treatment or between one application and the next, carry out neutralization, for example with Definisse neutralizing buffer.

8. Following it is possible to apply a soothing cream without rinsing the patient's skin with water.

Immediately after treatment, there may be the onset of erythema, edema, oedema, inflammation, and pigmentation changes. Advise the patient to expose the skin to the sun without adequate solar protection and not to remove it or try to remove it manually pull off any peeling or skin scars.

Post-peel phase

As exfoliation causes thinning of the superficial layers of the epidermis, it is also important to take adequate precautions to prevent the onset of erythema, edema, oedema, inflammation, changes in pigmentation.

The patient must report the application of any topical exfoliating and treatment products, until the complete restoration of the skin barrier, as well as avoid the use of products on their own without first consulting the doctor.

SIDE EFFECTS

These are generally mild and disappear rapidly. They consist of erythema, edema, desquamation, changes in pigmentation. The patient may report a transient burning sensation of the skin at the site of application of the product, which appears a few minutes after application and generally diminishes spontaneously after neutralization. However, the risk of hyperpigmentation in the treated areas cannot be ruled out after the peeling treatment.

As with peeling, it is recommended not to perform the exfoliating treatment:

- in the presence of herpes simplex in the area to be treated;
- in case of the development of hypertrophic scars and post-inflammatory hyperpigmentation;
- in case of recent surgical, laser, or dermatras operations in the area to be treated;

• in case of previous radiation therapy in the area to be treated that could compromise the physiological cell regeneration;

• in case of pregnancy, breastfeeding;

• in case of known hypersensitivity to the components;

• in case of current treatment with tretinoin or retinoids;

• in case of retinoid use to carry out subsequent phototherapy.

It must be noted that the darkest phototypes may be subject to greater risks of hyperpigmentation in the treated areas.

It is recommended to avoid exfoliating treatment in the hottest season, because solar radiation can give rise to the onset of hyperpigmentation.

WARNINGS

The expiry date refers to the intact product, properly stored. Do not use the product if the package appears damaged.

Keep off reach of children.

Do not swallow; in case of swallowing consult a doctor.

Do not ingest; in case of ingestion consult a doctor.

Definisse lightening contains active substances and has an extremely short DPL; for this reason, follow the fast-aid instructions below in case of accidental contact with the device.

• In case of accidental contact with the skin, neutralize either with Definisse neutralizing buffer or a 20% sodium bicarbonate solution and wash abundantly with water for at least 15 minutes. Remove any residue.

• In case of accidental contact with the eyes, rinse thoroughly with water for at least 15 minutes.

In case of accidental spilling, wash either with Definisse neutralizing buffer or with a 20% sodium bicarbonate solution then rinse thoroughly with water.

The manufacturer cannot be held liable for any damage to objects or people caused by incorrect or improper use of the device.

For the exclusive use by medical personnel or qualified healthcare personnel.

STORAGE INSTRUCTIONS

Store the tightly sealed container away from light and heat.

DATE OF LAST REVISION
09/2020

MANUFACTURER
Mastelli srl, Via Bussana Vecchia 32, 18038 Sanremo (IM) - Italia
www.mastellit.it

MEDICAL DEVICE CE

CE

Mastelli srl, Via Bussana Vecchia 32,
18038 Sanremo, Italy

IT Soluzione per peeling chimico. Flacone da 50 ml

DESCRIZIONE DEL PRODOTTO

Definisse lightening peel, prodotto pensato per l'esfoliazione (o il peeling) delle superfici della pelle e delle struttura cutanee a sostegno di uno o più effetti di ingiallimento.

Questo dispositivo consente di eseguire un peeling chimico superficiale efficace su vari livelli, per favorire la progressiva riduzione delle macchie cutanee da iperpigmentazione e limitare i danni a carico delle strutture cutanee. Di conseguenza, contribuisce a ridurre i possibili effetti indesiderati dovuti alle fasi di peeling e post-peeling.

Il prodotto contiene le seguenti sostanze esfolianti: acido saliclico e acido pyruvico.

Il prodotto contiene due ingredienti che concorrono a schiarire le macchie cutanee causate dall'iperpigmentazione melanica: diacetil boldina e undecylenic phenylalanine.

Definisse lightening peel è un dispositivo medico utilizzato per favorire l'esfoliazione e la progressiva riduzione delle macchie della pelle a viso e corpo. Per questo motivo, il dispositivo medico può essere utilizzato per migliorare l'aspetto e la salute delle pelli.

• melanosis;

• pigmentazione melasma;

• pigmentazione changes;

• photoaging spots;

• melanomas;

• melasma;

• pigmentary changes;

• photoaging spots;

• melasma;

• pigmentary changes;