

MTM30

PROFESSIONAL REVITALIZING PEEL
(15% mandelic acid/15% lactic acid)

MTM45

PROFESSIONAL REVITALIZING PEEL
(22.5% mandelic acid/22.5% lactic acid)

MTM60

PROFESSIONAL REVITALIZING PEEL
(30% mandelic acid/30% lactic acid)

MTM70

PROFESSIONAL REVITALIZING PEEL
(30% mandelic acid/40% lactic acid)

MTM

PROFESSIONAL
REVITALIZING PEEL

Neutralizing Solution

INSTRUCTIONS FOR HEALTHCARE PROFESSIONALS

M™ Professional Revitalizing Peel is a superficial peeling agent containing nature's fruit acids to help reduce the visible signs of aging. The unique combination of mandelic acid and lactic acid in the **M™** Professional Revitalizing Peel smoothes away fine lines and wrinkles.

The **M™** Professional Revitalizing Peel is offered in a variety of strengths designed for treatment flexibility and a variety of skin types. The peel can be used as a series of treatments to achieve the optimal outcomes. The **M™** Professional Peel is accompanied by the **M™** Professional Neutralizer. The neutralizer is applied to the face to inactivate the peel.

FOR EXTERNAL USE BY TRAINED HEALTH CARE PROFESSIONALS ONLY. The **M™** Revitalizing Peel should not be applied on patients who are sensitive to mandelic or lactic acids.



PROFESSIONAL
REVITALIZING PEEL

Instructions for Healthcare Professionals

Pre-Peel Discussion with the Patient

Approximately two weeks prior to scheduling a peel procedure, a consultation is recommended to discuss the following:

1. Patient/Healthcare Professional Expectations

Establish patient expectations in advance of the procedure (Table 1).

Discussion points:

A. What does the patient want to achieve?

- softening of the skin

- improvement in the appearance of fine lines due to accumulated sun damage
 - softening of shallow acne scars
 - evening of pigmentation irregularities
 - improved skin brilliance or skin tone
 - diminution of pore size
- B. Has the patient reviewed post-procedure photographs of other patients with his/her skin type (pigmentation, condition, sensitivity) to evaluate the type and degree of improvement that may be possible?
- C. What are the areas of the face or body that the patient would like to improve? (e.g., face, neck, chest, shoulders, back, hands)
- D. How rapidly does the patient expect to see improvements?
- E. How does the patient want to look immediately after the peel? Are visual signs of peeling and healing acceptable to the patient? The deeper the peel, the longer the healing time.
- F. Discuss the patient's medical history and demonstrated tolerability to alpha hydroxy acids (AHA). The patient's tolerance to alpha hydroxy acids should be determined prior to use of a revitalizing peel.

Following a thorough skin and health assessment, including a discussion of patient and health care professional expectations, the initial superficial peel procedure is scheduled after the pre-peel discussion with the patient.

Table 1: General Expectations from Superficial Peels

| Conditions | Potential Changes |
|-------------------------|----------------------------------|
| Fine lines and wrinkles | Softening in appearance |
| Hyperpigmentation | Evening of skin tone |
| Mild acne scars | Softening of scars |
| Pore size | Some diminution in size |
| Uneven/rough texture | Increased smoothness |
| Dull skin tone | Improved natural glow & radiance |

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2. Medical History

Review the patient's medical history with particular regard to the following:

- Skin type/color: Some skin types require special attention. Patients with sensitive skin may be unable to tolerate the higher strength peel solutions due to discomfort. Darker complected patients have an increased risk of hyper- or hypopigmentation. Use a gradual treatment approach including low concentration peels and short exposures for any individual at risk for pigmentary disorders and healing concerns.
- Allergies: A history of allergies may indicate that the patient's skin will be reactive to the peel procedure. In addition, a specific allergy to any of the ingredients in the peel solutions should be reviewed.
- History of atopic skin reactions, eczema, seborrheic dermatitis, rosacea, or other sensitivities: Use a gradual treatment approach including low concentration peels and short exposures for patients with a history of these conditions.
- History of collagen disease, autoimmune disease, or diabetes: Peel procedures are not recommended in these patients.
- Viral infections: Peel procedures can induce a herpes breakout in patients who have had them previously. Patients with a history of herpes simplex should be placed on an appropriate oral antiviral medication for prophylaxis. If the patient has warts on the targeted area, peel procedures are not recommended due to the potential of spreading the wart virus.
- Prior photosensitivity: After a peel procedure the treated skin should be protected from sun exposure and other sources of UV radiation and heat (including heat lamps and artificial tanning booths). Any prior photosensitivity could be exacerbated. Use sunscreen and avoid sun exposure until skin is fully healed.
- Current medications: Anticoagulant users may heal more slowly. If a peel inducing epidermolysis is inadvertently performed, the risk of bleeding may be increased. In addition, any immune suppressing agents can affect post-peel healing times. Patients using isotretinoin (e.g., Accutane[®]) should not use chemical peels due to unpredictable responses. Use of topical retinoids within four weeks prior to a peel can enhance skin sensitivity and reactivity.
- Use of tobacco: Smokers may heal more slowly.

- Pregnancy: While alpha hydroxy acids are generally considered safe cosmetic ingredients, they have not been tested in a pregnant population. It is not recommended to perform peels during pregnancy or while nursing.

3. *Concurrent Product/Treatment Use*

Due to the potential for some products/treatments to increase the reactivity of the skin to a peel, allow for healing time after the following procedures before a peel is performed.

- Electrolysis
- Waxing
- Depilatories
- Masks/facials
- Prior peels, dermabrasion, microdermabrasion, non-ablative laser, light therapy, and ablative laser (*See Section 4. Combination Use of Superficial Peels and Cosmetic Procedures.*)
- Retin-A[®] (tretinoin) and other exfoliative/keratolytic drugs
- Hair dying treatments
- Permanent wave or straightening treatments
- Topical/systemic retinoids and other exfoliative/keratolytic drugs
- Loofah or other types of exfoliating sponges

4. *Combination Use of Superficial Peels and Cosmetic Procedures*

Superficial peels may be combined with other cosmetic procedures to optimize skin benefits.

- **Microdermabrasion-** light microdermabrasion performed immediately prior to the peel will increase the skin's reactivity to a peeling solution. Heavy microdermabrasion should not be performed within the same week as a peel.
- **Non-ablative laser/Intense Pulse Light (IPL) and Ablative laser-** Peels are not recommended with these techniques until the skin has fully healed.

5. *Exclusions to Peels*

Specific exclusions to AHA peels include:

- Active herpes simplex
- Warts

- Isotretinoin (e.g., Accutane®) use within six (6) months
- Topical actinic keratosis treatments within the past six (6) months
- Recent surgery (healing wounds)
- Recent radiation treatment
- Insufficient solar protection/sunburn
- History of hypertrophic or keloidal scarring
- Cryotherapy/cryosurgery within the past six (6) months
- Pregnancy or while nursing

Caution should be observed in patients having a history of hyper- or hypopigmentation. These patients require the use of lower strength peels with short exposures in order to minimize inflammation and the risk of dyspigmentation.

Selection of Peel Concentration and Timing

1. Begin at the lowest (M30™) concentration. The exposure time depends on the skin's responsiveness to the product. When the first signs of redness appear and/or patient discomfort occurs, the peel should be neutralized with the recommended neutralizing agent. The first peel usually lasts for 1 to 3 minutes.
2. To achieve a successful peel, it is important to monitor carefully the condition of the patient's skin during the procedure. Note: cold or dry weather may enhance skin reactivity. A peel may need to be terminated more quickly in the winter months compared to summer months in the same patient.
3. Observe the outcome of the peel. Ask the patient to monitor the effect of the peel on the skin during the post-peel healing time.
4. For all subsequent peels, discuss the outcome of the previous peel.
 - If a good response was observed (e.g., slight redness, light peeling, minimal discomfort, and complete healing in 3 to 5 days), then the patient will most likely tolerate a peel with the same concentration and time. Based on the response, the time of exposure or concentration may be increased.
 - If no response was observed, then the patient may tolerate an increased time of exposure or concentration compared to the previous peel.
 - If a poor response was observed (e.g. extreme redness, heavy peeling, blistering, scabbing, pigmentation changes, and long healing times) after complete healing

has occurred, the patient should be peeled with a decreased time of exposure and concentration.

5. Maintain any given concentration until the skin can safely tolerate application for 5 minutes. For the next peel, use either the same concentration for up to 5 minutes or move to the next higher concentration with a decreased time of exposure.

Other Materials Needed

- Petrolatum
- Cotton-tipped applicators (small and large)
- Sponges (small) or cotton balls
- Dispensing cups (small)
- Examination gloves
- 40" X 60" paper drape sheet
- 4" X 4" non-woven gauze
- 2" X 2" non-woven gauze or eye pads
- Surgical bonnet or hair clips
- Bowl for ice water
- Ice water
- Timer or stop-watch
- Eye rinse solution
- Large Hair clips
- Waterproof "beauty" bib
- Hand mirror
- Fan (positioned about four feet from, and aimed toward, the targeted area)

Side Effects of a Superficial Peel

Patients may experience the following sensations and conditions following a peel procedure: redness (erythema), stinging, itching, burning, tightness, minor swelling, and peeling of the superficial layer of the skin. These sensations gradually diminish over the course of a week.

Superficial peels may also cause peri-oral dermatitis, an acne flare, or a herpes simplex flare (particularly if no prophylactic antiviral treatment is initiated).

Some patients may experience hyper- or hypo-pigmentation after a superficial peel. If left untreated, these conditions generally resolve with time. However, hypopigmentation responses may take longer to resolve and may be permanent. Peeling should not be repeated on patients having unresolved changes in pigmentation.

WARNING: If the peel is left on the skin for longer than the recommended treatment time or goes too deep, potential side effects may include:

- Moderate to severe erythema
- Epidermolysis
- Post inflammatory hyper- or hypo-pigmentation
- Blistering and peeling
- Scarring
- Sun sensitivity

Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase the skin's sensitivity to the sun and particularly the possibility of sunburn. Patients should use a sunscreen, wear protective clothing, and limit sun exposure while using this product and for a week afterwards.

I. Pre-Peel Procedure: Prepare The Skin

- Hair should be secured off the face.
- **Remove contact lenses.**
- Thoroughly cleanse the skin using a mild facial cleanser to remove any residual skin debris, make-up, and surface oils.
- Using a small cotton-tipped applicator, apply petrolatum lightly to any cuts or abrasions and other areas in which the peel solution may pool to protect these areas during the procedure.
- Place a fan about four feet from the patient's face to help keep the skin cool and reduce discomfort during the peel procedure.

II. Peel Procedure

- **Apply** an adequate amount (approx. 2 cc) of the selected strength of the **M™** Professional Revitalizing Peel with a non-woven gauze pad, cotton ball, or large cotton-tipped applicator. Application should be completed within 30 seconds to one minute. Note the time of application. Additional applications (or layering) of the peel solution may be performed, although this may increase the intensity of the peel.
- **Monitor** the progress of the peel and the time of exposure.
- **Terminate** the procedure using the neutralizer solution when one or more of the following occurs. (Note the time of termination. The first peel usually remains on the skin 1 to 3 minutes.)
 - The first signs of redness: Erythema (redness) indicates early dyscohesion of the stratum corneum.
 - Patient discomfort: The patient can verbally communicate their discomfort level on a range from 1 to 10 with 1 being low and 10 being high. Neutralize immediately for scores over 7.
 - Blanching (whitening or frosting), which indicates epidermolysis and medium depth.
 - Desquamation, which indicates epidermal detachment and medium depth.

NOTE: Blanching and desquamation are signs that the peel solution has penetrated too deeply, causing a medium depth peel to occur. This will lead to a longer healing time and potential side effects such as post-inflammatory hyperpigmentation.

- **Neutralize:** Cover the eye area with cotton pads. Spray a neutralizer solution such as **M™** Professional Neutralizer over the entire peeled area. The **M™** Professional Neutralizer generates effervescent foaming, due to the release of carbon dioxide during the neutralization process. This is an indication that the **M™** Professional Peel is being neutralized. Reapply the neutralizer solution after ten to fifteen seconds of the initial application. Neutralization is complete once the foaming stops.
- **Covering** the treated area with iced 4" x 4" gauze pads will provide some relief from sensations of burning or stinging.

III. Post-Peel Procedure

After a peel, the skin may experience some stinging, burning, redness, tightness and sensitivity. There may also be some light swelling, superficial scabbing and peeling.

These effects will gradually diminish over the course of a week. Occasionally, there is temporary dyspigmentation of skin. If your patient experiences unusual discomfort or change in skin color, they should be directed to contact your office immediately.

Directions

- **Apply** moisturizing cream (a non-steroid, non-AHA, emollient), immediately following the peel and then twice a day until the skin is fully healed.

To **promote the healing process**, patients should be advised to:

- Avoid products containing AHAs, salicylic acid, retinoids, or other potentially irritating topicals until the skin returns to its normal condition.
- Delay application of make-up on the peeled area if the skin is sensitive.
- Avoid the use of abrasive or exfoliating sponges on the area.
- **Avoid sun exposure, artificial tanning devices, and direct heat sources** until the skin is fully healed.
- Use a broad-spectrum sunscreen as tolerated.

Do not:

- Peel the skin
 - Pick the skin
 - Scrape the skin
 - Scratch the skin
 - Use a mask on the skin
 - Wear tight headbands, hats, etc.
 - Expose the skin to sun or sun lamps
- **Maintain** newly peeled skin using a mild facial cleanser and moisturizing creams, lotions or gels, after the skin returns to near-normal appearance. Protect during the daytime by using a non-AHA moisturizer with sunscreen. Following a peel, skin may become sensitive to AHA products.

Warnings: FOR EXTERNAL USE ONLY BY TRAINED HEALTH CARE PROFESSIONALS. Avoid contact with eyes, lips, and mucous membranes. Do not apply to broken or inflamed skin. If contact occurs, rinse well with water. If ingested, drink a glass of water and contact a Poison Control Center. Not recommended for use

during pregnancy or while nursing. Use sunscreen and avoid sun exposure until skin is fully healed. **Keep out of reach of children.**

Ingredients: Water, Lactic Acid, Mandelic Acid, Methyl Pyrrolidone, Ammonia Solution, Nonoxynol-9.

Store at room temperature.

NO ANIMAL TESTING

Manufactured for Dermik Laboratories, A business of sanofi-aventis U.S. LLC,
Bridgewater, NJ 08807

U.S. Patents 5,091,171; 5,571,841; 5,674,899

If you have any comments concerning this product please contact Dermik Laboratories at 1-800-633-1610.

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Appendix 1

Peel Procedure Informed Consent (Example)

I, _____, consent to the treatment known as a superficial chemical peel. The treatment has been explained to me and I have had the opportunity to ask questions. I understand that the procedure may cause swelling or puffiness of my face or _____(body site treated) that may be uncomfortable. The procedure may cause my skin to appear red and peel like a sunburn. During and after the procedure, the following may be experienced: redness, stinging, itching, burning, mild pain, tightness, peeling, and scabbing of the superficial layers of the skin. These sensations will gradually diminish over the course of a week as the skin returns to normal. Some patients may react differently. In severe cases the skin may turn very red, blister, swell, and later scab and crust. The skin may be uncomfortable and look like a very bad sunburn. The peeling usually lasts about three to seven days, although it may last longer.

Sunburn Alert: This product contains an alpha hydroxy acid (AHA) that may increase your skin's sensitivity to the sun and particularly the possibility of sunburn. Use a sunscreen, wear protective clothing, and limit sun exposure while using this product and for a week afterwards.

I understand that there is a risk of developing a temporary or permanent pigment (color) change in the skin. There is a small incidence of the reactivation of 'cold sores' (herpes infections) in patients with a prior history of herpes. There is also a small incidence of a flare of acne-like lesions after the peel. There is a rare incidence of scarring and infection. I have been given a copy of the post-peel instructions and have reviewed them.

Patient's Signature (or Guardian)

Date

Patient's Name (please print)

Witness

Date