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Before use, read the instruction carefully. MDC-75 is a highly effective but corrosive solution. Follow each step described in this leaflet. Keep this leaflet, you may need to read it again.

### Intended Use

MDC-75, the medical device manufactured by R&D PHARMA is an acid solution for topical application aimed at treating a variety of superficial and benign skin lesions such as acrochordons, seborrheic keratoses, warts and condylomas, benign non-active dermic nevi and actinic keratoses by tissue denaturation.

**MDC-75 is intended to be used as supplied. Modifications or use of the product outside of the IFU may be dangerous and adversely impact the performance of the product. A correct application is important, and the application method varies depending on the size and location of the skin lesion.**

### Intended User

MDC-75 is intended to be used **exclusively by dermatologists or other doctors** experienced in the diagnosis or treatment of skin lesions or by a healthcare professional under the supervision of such a doctor.

Environment: Professional medical environment.

### APPLICATION PROCEDURE

- Before application it is recommended to clean the lesion and the skin. Dry before application of MDC-75. A new uncontaminated applicator shall be used for each withdrawal and for each patient. The vial shall be immediately recapped after each use. The product shall be discarded if contamination is suspected or if the validated in-use period is exceeded.
- If the lesion is in a sensitive area or if there is risk of product leakage outside the lesion area, apply a protective silicone cream around the lesion to protect the surrounding skin. Make sure the cream is set before applying MDC-75.
- Position the application area horizontally to minimize the risk of overflow on healthy skin.
- Depending on the size of the lesion and doctor discretion, use an acid safe micropipette tip, a glass capillary tube or a cotton bud. Try to slowly apply drops (5 µL each) of the solution to cover the full lesion. Wait until a change of color is observed, turning whitish. The surrounding skin can show slight transient hyperemia with mild redness and a slight tingling sensation. Add drops if no reaction was observed. Stop applying once the full lesion has whitened or 6 total drops were used. The applicator used to extract MDC-75 from the vial should be new and should never be reused between extractions or between different patients to avoid risk of potential contamination and discarded immediately.
- An opaque dressing can be applied 5 minutes after the last application if deemed necessary by the medical professional. Do not cover the lesion with the glue part of the plaster.
- For 2 days after application avoid wetting the treated surface with any liquids. Use an adhesive waterproof protective bandage when taking a shower.
- During the period of mummification, it is strictly prohibited to: Damage the scab (it must move away on its own). Expose the lesion to intense solar activity without wearing photoprotective clothes, bandages or sunscreen. Excessively wet the scab or apply any nourishing or protective creams, oils or other substances that affect the process of mummification and scab formation.
- After the mummified scab has detached the medical professional should choose the best course for further action depending on lesion condition. A maximum of 3 application procedures can be conducted on a lesion per month. More frequent applications have not been clinically evaluated.

### Clinical Benefit

MDC-75 enables the controlled chemical destruction of selected superficial benign skin lesions, allowing removal without surgical intervention. When used as directed, the device facilitates lesion detachment while supporting natural skin regeneration and minimizing damage to surrounding healthy tissue.

### Contraindications

#### Do not use this product:

- On patients who are allergic (hypersensitive) to any ingredients of the formulation.
  - On wounds or irritated skin areas.
  - On lesions that show inflammation or infection.
  - On lesions not clearly diagnosed as benign such as any atypical skin lesions and cancerous skin lesions.
  - On a lesion located on skin affected by a disease or condition such as but not limited to atopic dermatitis, psoriasis, or vitiligo.
  - On patients with a history of cheloids, hypertrophic or abnormal scarring without exercising additional care.
  - On pregnant or breastfeeding patients as the device has not been specifically evaluated in these populations.
  - On patients with diabetes mellitus, poor blood circulation, or peripheral neuropathy without doctor approval. This product was not specifically studied on patients with these conditions, and the healthcare professional should balance the benefits of this procedure with the risks of poor cicatrization and wound closure in this population.
  - On areas that have undergone cryotherapy, laser or surgery, until the skin has fully healed. Or where a scab or a crust is still present.
  - On lesions that are restricted according to local national protocols and treatment standards.
  - On lesions requiring post-treatment biopsy, histopathological evaluation is not feasible following MDC-75 application, as the induced mummification process renders the lesion unsuitable for sampling.
  - On mucous membranes and eyes.
- Stop treatment if excessive pain, burning, blistering or irritation develops.
  - Protect surrounding healthy skin with silicon-based cream before applying the product.
  - Do not wet the area for at least 2 days after treatment and possibly cover it with a protective bandage if recommended by a medical professional.
  - Do not damage the scab, it must fall off on its own.
  - Avoid exposure to sunlight or UV light on treated area for at least 15 days after product application and until normal skin color returns to prevent hyper- or hypopigmentation.

### Precautions

- MDC-75 is for external use only.
- Apply in a well-ventilated area and avoid inhalation.
- Avoid contact with healthy skin surrounding the treated lesion, eyes, and mucous membranes.
- If unwanted contact with healthy skin or contact with mucous membranes, or eyes occurs, rinse immediately with plenty of water.
- Do not repeat the application if the lesion presents a white color or if hyperemia appears around the treated lesion. Do not apply product on a remaining scab or crust.

### Side Effects

Not all users will experience side effects when using MDC-75.

Possible side effects that may occur include:

- Skin irritation at the application site
- Burning or stinging sensations
- Redness of the skin
- Increased skin sensitivity or hypersensitivity reactions
- Hyper- or hypopigmentation

If any of these side effects become severe, persist, or if you notice any side effects not listed in these instructions for use, consult a qualified healthcare professional.

### Disposal













Used products must be treated as biological hazards and required to be disposed of according to the country's waste regulations, hospital policies and procedures.

### Product Complaints

Any complaint or dissatisfaction with the quality, identification, reliability, safety, efficacy and/or performance of MDC-75™ must be communicated either to the manufacturer (R&D Pharma S.A.M.) or distributor. If there is a serious incident or a risk of a serious incident occurring in relation to the device, the manufacturer (or distributor) must be informed immediately by appropriate means. Any serious incident occurring in relation to the device should also be reported to the competent authority of the Member State in which the user or patient is established.

All complaints must be accompanied by the product name, reference number and lot/batch number. The person formulating the complaint should state their name and address, and describe the nature of the complaint, providing as many details as possible.

#### Explanation of Symbols related to MDC-75

 Manufacturer R&D Pharma S.A.M. 5, rue du Gabian 98000 Monaco	 Caution: Only for Topical Application	 Caution: Corrosive Substance	 Distributor R&D Pharma S.A.M. 5, rue du Gabian 98000 Monaco
 Do not use if packaging is damaged	 Keep away from direct sunlight	 Batch Code	 Medical Device
 Device CE Marking and Notified Body Number 1282	 Date of Manufacture	 Use-by date	 EU Authorized Representative International Associates Auditing & Certification Limited The Black Church St Mary's Place Dublin 7, Dublin, D07 P4AX Ireland



Access the eIFU using this link, Accédez à l'eIFU via ce lien

[www.rd-pharma.mc/products/MDC-75/documents/ifu](http://www.rd-pharma.mc/products/MDC-75/documents/ifu)

### Storage Instructions

Store MDC-75 in its original packaging in a room at room temperature (15°C - 30°C), away from sunlight and in an upright position. **Following first opening, the product shall be used within 6 months under the same storage conditions.**

### MDC-75 Ingredients

Alpha-Chloropropionic Acid (70% v/v),  
Dimethyl Sulfoxide (DMSO), Purified Water, Luminol