

10.0 ml

**DERMOCFILL<sup>®</sup>**

CROSS LINKED HYALURONIC ACID

HV

JUVANIX  
LABORATOIRES  
PARIS



# DERMOCFILL®

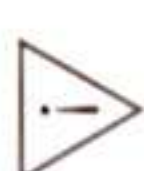
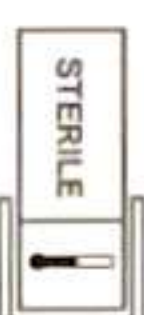
CROSS LINKED HYALURONIC ACID

HV (High Viscosity)



CE

0123



NEEDLE

SYRINGE



JUVVANIX  
LABORATOIRES  
PARIS

WWW.DERMOCFILL.COM

## GB Composition:

Hyaluronic acid 25mg/ml  
Lidocaine HCl 0.3% w/w  
Sodium chloride 6.9mg/ml  
Water for injection 10ml

## D Zusammensetzung:

Hyaluronic acid 25mg/ml  
Lidocain HCl 0.3% w/w  
Natriumchlorid 6.9mg/ml  
Wasser fuer injektion 10ml

## F Composition:

L'acide hyaluronique 25mg/ml  
L'idocain HCl 0.3% w/w  
Chlorure de sodium 6.9mg/ml  
Eau pour injection 10ml

## RU Состав:

Гиаууроновая кислота 25mg/ml  
Лидокаин HCl 0.3% w/w  
Хлорид натрия 6.9mg/ml  
Вода для инъекций 10ml

## I Composizione:

Acido ialuronico 25mg/ml  
Lidocaina HCl 0.3% w/w  
Cloruro di sodio 6.9mg/ml  
Acqua per iniezione 10ml

## E Composición:

Ácido hialurónico 25mg/ml  
Lidocaina HCl 0.3% w/w  
Cloruro de sodio 6.9mg/ml  
Agua para inyección 10ml

## P Composição:

Ácido hialurônico 25mg/ml  
Lidocaina HCl 0.3% w/w  
Cloreto de sódio 6.9mg/ml  
Água para Inieção 10ml

## NL Samenstelling:

Natriumhyaluronaat 25mg/ml  
Lidocaina HCl 0.3% w/w  
Natriumchloride 6.9mg/ml  
Water voor injectie 10ml





DERMOFILL®

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CROSS LINKED HYALURONIC ACID

● ● ● HV 10.0ml



## GB Instruction leaflet

### COMPOSITION

|                                  |            |
|----------------------------------|------------|
| Hyaluronic acid .....            | 25mg/ml    |
| Sodium chloride.....             | 6.9mg/ml   |
| Disodium hydrogen phosphate..... | 0.039mg/ml |
| Sodium dihydrogen phosphate..... | 0.555mg/ml |
| Lidocaine.....                   | 3mg/ml     |

Water for injection

[Crosslinked with Butandiol-diglycidylether (BDDE)]

### DESCRIPTION

Dermofill® HV is a high viscosity sterile, odorless, colorless and transparent aqueous gel of cross-linked hyaluronic acid with synthetic origin and non-pyrogenic property. Each package contains one 10ml disposable syringe pre-filled with Dermofill® HV gel and instruction brochure.

### INDICATIONS

Dermofill® HV is a dermal filler intended for treatment of body rhytides and lipoatrophy by injecting to the skin. On average, the implant lasts between 6-12 months, depending on the depth and location of injection.

### CONTRA-INDICATIONS

- Injection into eye Contour (eye circle, eyelids)
- Injection into the blood vessels
- Patients suffering from untreated epilepsy
- Pregnant or breastfeeding women
- Individuals under the age of 18
- Individuals prone to hypertrophic scarring
- Patients with known hypersensitivity to HA
- Patients suffering from porphyria
- Injection into inflamed and/or infected areas such as acne, herpes, etc.
- Simultaneous laser treatment, intense pulsed light, chemical peeling or dermabrasion
- Presence of considerable inflammatory response to surface peel
- Coagulation defects or under anti-coagulation therapy
- Overcorrection
- Individuals with unachievable expectations

### PRECAUTIONS

- Dermofill® HV should never be utilized for breast enlargement or for implantation into bone, tendon, ligament or muscle.
- Due to the lack of sufficient clinical data to profile the tolerance of Dermofill® HV patients with a history of past or current auto-immune disease, multiple allergies or anaphylactic shock. Physicians are strongly advised to administer this product with discretion on case-by-case basis, carefully considering the nature of the disease.
- Patients with a high risk of hematomas.
- Patients on anti-coagulant medications.
- It is possible that needle punctures could trigger break out of cold sores in patients with previous episodes of facial cold sores.
- If you are using aspirin, non-steroidal anti-inflammatory medications. St. John Wort or high doses of Vitamin E supplements prior to treatment or any similar medications be aware that these may increase bruising and bleeding at the injection site
- Using this product in patients suffering from acute rheumatoid arthritis with cardiac complication and in patients with a history of recurring streptococcal sore throats is inadvisable.
- It is strongly recommended not to use any make-up or touch the treated area within 12 hours after injection.
- Avoid any extended exposure to sunlight, UV radiation as well as extreme heat or cold until the initial swelling and redness have subsided.
- Dermofill® HV should never be injected into an area where there is permanent filler or implant.
- Presently, there are no clinical data to characterize the efficacy and tolerance of this product when injected into the area already injected with another filling product.

### SIDE EFFECTS

There are potential immediate or delayed side effects associated with the implantation of this product. Medical practitioners must inform the clients of these side effects which include but are not limited to:

- Inflammatory reactions (redness, swelling, erythema, etc) accompanied by itching, pain, pressure, discoloration or tenderness at the injection site
- Hematomas