NEAUVIA

INTENSE MAN

Intense Man is a biodegradable Hyaluronic Acid hydrogel crosslinked with PEG.
It is resorbed over time and intended to restore lost volume of the soft tissue.[1]

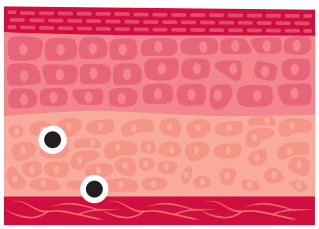
- ***Crosslinking:*** PEG
- ***HA concentration:*** 28 mg/ml
- ***Contains:*** Glycine and L-Proline

- ***Extrusion Force:*** High

- ***Syringe:*** 1x1ml
- ***Needle/Cannula guide:*** 21G/22G (included in the box)

- ***Duration:*** 6 months degradation average time[1]
- ***Area of injection:*** Face
- ***Injection plane:*** Subcutis and/or over the periosteum

1. Data on file.



SCT
SMART COMBINATION THERAPY

Discover Smart Combination Therapy:
Nlift mid-face synergistic protocol.

INTENSE MAN
and its unique composition

Intense Man is based on a unique patented Smart Crosslinking Technology S.X.T which is an innovative and advanced technology that combines Hyaluronic Acid and PEGDE in one network. Intense Man is enriched with **Glycine** and **L-Proline**.

PIONEER with PEG

PEG is a well-known polymer in the pharmaceutical market, due to its **uniqueness, versatility** and **safety profile**.[1,2] **Neauvia chose PEG**, as a crosslinker, differentiating itself in the market and presenting the following main features:

HIGH-SAFETY PROFILE:

1. **No pathologic inflammatory reactions***[3]
2. **No citotoxicity activity** detected[4]
3. **No crosslinker residuals remain** and **no changes in the surrounding tissues** can be observed after complete degradation[3]
4. **Reversible filling**[3,5]

DISTINCTIVE CHARACTERISTICS:

1. **Mechanical properties** that mimic those of natural skin tissues[1,6]
2. **High cohesivity** and balanced viscoelasticity[3,7]
3. **High resistance to heat** and **high thermodynamic stability**[6] to allow combined protocols
4. **Temporary filling** decreasing at 6 months[3]

GLYCINE and L-PROLINE

Neauvia`s fillers are enriched with Glycine and L-Proline, which are **proteinogenic amino acids** used in the biosynthesis of proteins[3]. They are added to the phosphate buffer solution to **tune the rheological properties** (viscoelastic properties) and the **swelling resistance**[3]. They ensure in Neauvia´s fillers formulation a **better control of the hydrogel swelling capacity in the postimplant phase**.[8]

This class III medical device is regulated under the EU MDR 2017/745 Regulation. Manufacturer: MATEX LAB SPA, via Carlo Urbani 2 ang. via Enrico Fermi, Brindisi, Italy. Please carefully read the instructions in the leaflets. The use of these products requires the intervention of a healthcare professional. Only to be used by physicians in accordance with local legislation, trained in the injection techniques on Hyaluronic Acid based fillers.

* None detected so far with the use of Neauvia PEG-HA Devices.

1. Marino F, Cosentino M, Legnaro M, Luini A, Sigova J, Mocchi R, Lotti T and Zerbinati N. Immune profile of Hyaluronic Acid hydrogel Polyethylene Glycol crosslinked: an in vitro evaluation in human polymorphonuclear leukocytes. Dermatologic Therapy. 2020; e13388. https://doi.org/10.1111/dth.1338
2. Jeong CH, Kim DH, Yune JH, Kwon HC, Shin DM, Sohn H, Lee KH, Choi B, Kim ES, Kang JH, Kim EK and Han SG. In vitro toxicity assessment of crosslinking agents used in Hyaluronic Acid dermal filler. Toxicology in Vitro, Volume 70, 2021, 105034, ISSN 0887-2333. https://doi.org/10.1016/j.tiv.2020.105034
3. Clinical data on file.
4. Zerbinati N, Lotti T, Monticelli D, Rauso R, González-Isaza P, D'Este E, Calligaro A, Sommatis S, Maccario C, Mocchi R, Lotti J, Wollina U, Tchernev G and França K. In vitro evaluation of the biosafety of Hyaluronic Acid PEG cross-linked with micromolecules of Calcium Hydroxyapatite in low concentration. Open Access Maced J Med Sci. https://doi.org/10.3889/oamjms.2018.044
5. Zerbinati N, Lotti T, Monticelli D, Martina V, Cipolla G, D'Este E, Calligaro A, Mocchi R, Maccario C, Sommatis S, Lotti J, Wollina U, Tchernev G and França K. In vitro evaluation of the sensitivity of a Hyaluronic Acid PEG cross-linked to bovine testes Hyaluronidase. Open Access Maced J Med Sci. https://doi.org/10.3889/oamjms.2018.046
6. Zerbinati N, Capillo MC, Sommatis S, Maccario C, Alonci G, Rauso R, Galadari H, Guida S and Mocchi R. Rheological investigation as tool to assess physicochemical stability of a Hyaluronic Acid dermal filler cross-linked with Polyethylene Glycol Diglycidyl Ether and containing Calcium Hydroxyapatite, Glycine and L-Proline. Gels 2022, 8, 264. https://doi.org/10.3390/gels8050264
7. Zerbinati N, Sommatis S, Maccario C, Capillo MC, Grimaldi G, Alonci G, Protasoni M, Rauso R and Mocchi R. Toward physicochemical and rheological characterization of different HA dermal fillers cross-linked with Polyethylene Glycol Diglycidyl Ether. Polymers 2021, 13, 948. https://doi.org/10.3390/polym13060948
8. Martina V, Gallo A, Tarantino E, Esposito C, Zerbinati U, Mocchi R, Monticelli D, Lotti T, Tirant M, Van Thuong N, Rauso R and Zerbinati N. Viscoelastic properties and thermodynamic balance improvement of a Hyaluronic Acid hydrogel enriched with Proline and Glycyne. Journal of Biological Regulators and Homeostatic Agents. 2019 Nov-Dec;33(6):1955-1959. https://doi.org/10.23812/19-252-L

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