

ULTRA PLLA **Filler**

(PLLA : Poly-L-Lactic Acid)

PLLA Filler
for Collagen Booster



ULTRA PLLA filler

ULTRA-PLLA is a new generation of collagen stimulators in aesthetics that provides immediate and sustained correction by volumization through biostimulation, with long-lasting effects for 1 year more and high degree of patient satisfaction. Sub-dermal implantation of ULTRA-PLLA in the face is indicated for lasting correction of facial wrinkles and ageing signs or any facial age-related conditions.

ULTRA-PLLA is made of carboxymethyl cellulose, the component which provides the immediate effect, and of PLLA which provides the sustained effect.

- Composition : PLLA : Gel carrier with Na-CMC = 30% : 70%

PLLA is a form of nanoparticles with smooth and regular surface, spherical shape, size of 30-50 µm contribute to the product biocompatibility.



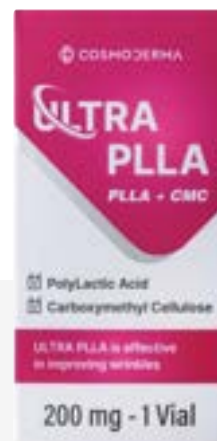
Tissue tightening and rejuvenation & collagen regeneration

1. Diminishes facial wrinkles by restoring the underlying structure of the skin.
2. Stimulate a patient's own collagen growth to restore natural volume.
3. Longlasting the effectiveness more than 1 year.



**Collagen Booster
[ULTRA-PLLA]**

Ultra PLLA Filler



Ultra PLLA is a new generation of collagen stimulators in aesthetics that provides immediate and sustained correction by volumization through biostimulation, with long-lasting and natural beauty.

● Product

Ultra PLLA Filler 2ml vial

● Safety (PLLA)

GMP class, Elemental Impurities - conforms to ICH Q3D requirements

● Mixture

Sterile distilled water 3~5cc + Lidocaine 1cc
(dilution time : over 30sec)

● Needle Size(G)

26~27 Gauge (demis injection)

● Main Ingredients

PLLA(Poly L Lactic Acid) 200mg, 70
% aqueous CMC-based gel carrier

● Indication for Use

Ultra PLLA(dermal filler) is an injectable implant, indicated for subdermal implantation in the face for the lasting correction of wrinkles and facial aging signs or conditions.

● Cautions

These adverse events include but are not limited to infection, minimal acute inflammatory tissue reaction (redness, swelling, rash, oedema, erythema, lumps/nodules etc.), pain (which may be temporary or persistent in nature), transient haematoma or bruising.

● Shelf Life & Storage

Shelf life : 2 years from production Period after opening : Stable for 5 days in refrigerator
Storage : Store between 2°C~30°C. Protect from sunlight

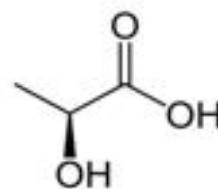
Key Feature

Contains biomaterials with well established safety and performance characteristics.

Ingredients: Biocompatible, non-toxic, non-antigenic, non-allergenic

● **PLLA (Poly-L-Lactic Acid) nano & spheripol particle** **30%**

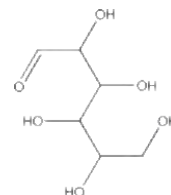
- Standard GMP manufactured soft material
- Biocompatible and Biodegradable
- Used in medical device as filler, suture, orthopedics and sustained release applications. It complies with FDA, REACH, GMP, EHS, DIN ISO 9001, MAF, DMF regulations



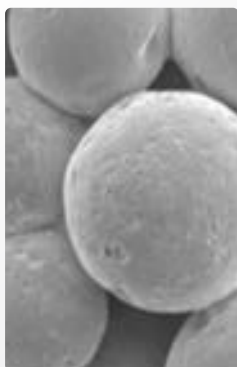
Poly-L-Lactic Acid, 51KDa

● **CMC Gel Carrier** **70%**

- pharmaceutical excipient used in the formulation of many drugs with USP grade.
- Carboxymethyl cellulose (CMC) forms the basis of the gel carrier with PBS (Phosphate Buffered Saline) and glycerin representing 70% by volume. PBS is the solvent medium and glycerin enhances CMC solubility



Carboxymethyl Cellulose



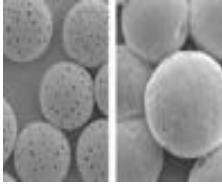
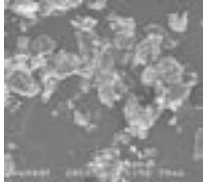
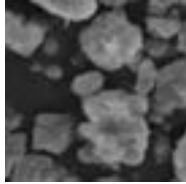
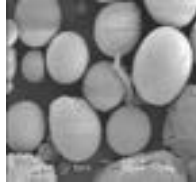

**Microscope
Magnification of PLLA**



**Lyophilized
Bead type of Filler**

- **PLLA Nano Particle**
Spheripol shape with size of 30-50 μm .
- **Lyophilized bead type of Filler**
Ultra PLLA Filler with smooth and regular surface, bead shape (D=5.5mm)

Collagen Booster of Competitor

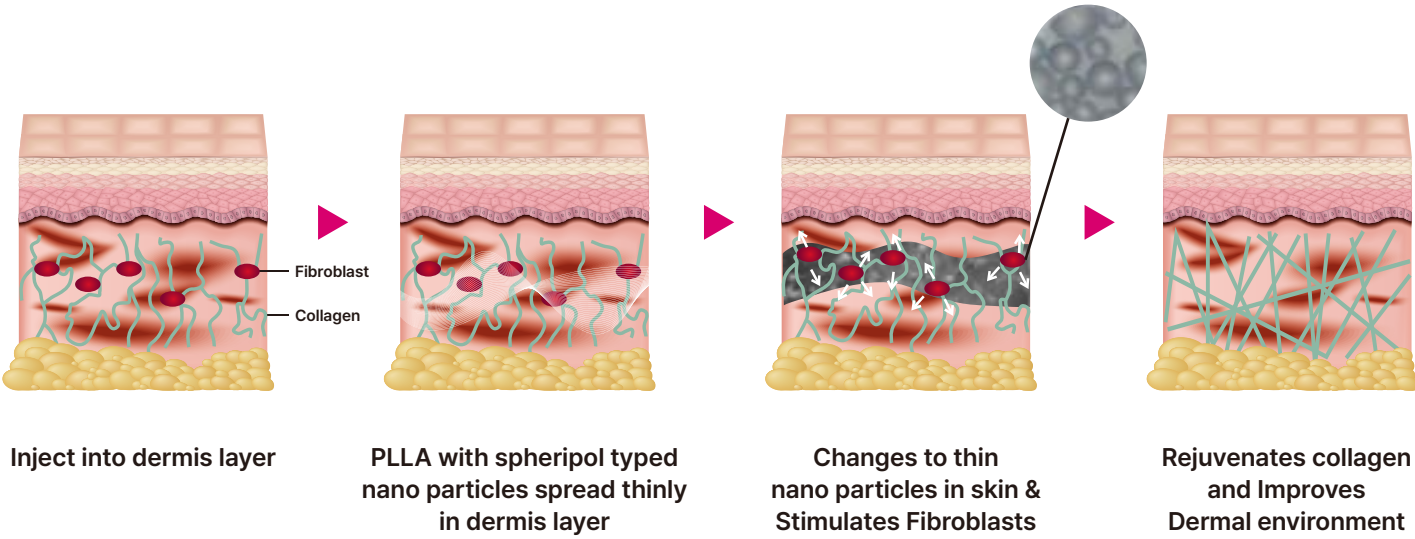
Product	Ultra PLLA	SculXXXX	JuveXXXX	AestXXXXXX	EllanXX
Ingredients	PLLA (poly-L-lactic acid)	PLLA (poly-L-lactic acid)	PDLLA hybrid filler (PDLLA+HA)	PLA (poly lactic acid)	PCL (poly caprolactone)
Features	High crystalline structure	High crystalline structure	High crystalline structure	Low crystalline structure	Low crystalline structure
Duration	Over 2 years	Over 2 years	1~1.5 years	1~2 years	Over 2 years
Procedure Convenience	Suspension & convenience of injection	Suspension & convenience of injection	Suspension & convenience of injection	Suspension & convenience of injection	Good convenience of injection
Filler particle shape					
Formation	Spheripol PLLA(200mg) + CMC+ Trehalose	Amorphous PLLA(145mg) + CMC+ Mannitol	Amorphous PDLLA(42.4mg) + HA(7.5mg)	Spherical PLA(156mg) + CMC(carboxymethyl cellulose)	Spherical PCL+ Glycerin + CMC+ Phosphate buffer

Benefit of Ultra PLLA Filler



- 1 Neo Collagensis**
Generating new collagen
- 2 Nano particles with spheripol type**
Particle size 30~50 μ m
Minimizes Side effects & Pain
- 3 Biocompatible Polymer**
Safety certified of PLLA
- 4 Long lasting Efficacy**
Improvement in initial volume and
newly generated collagen remains
for 2years
- 5 Can be applied to dermis**
Needle injection, Meso Roller, MTS

Mechanism of New Collagenesis

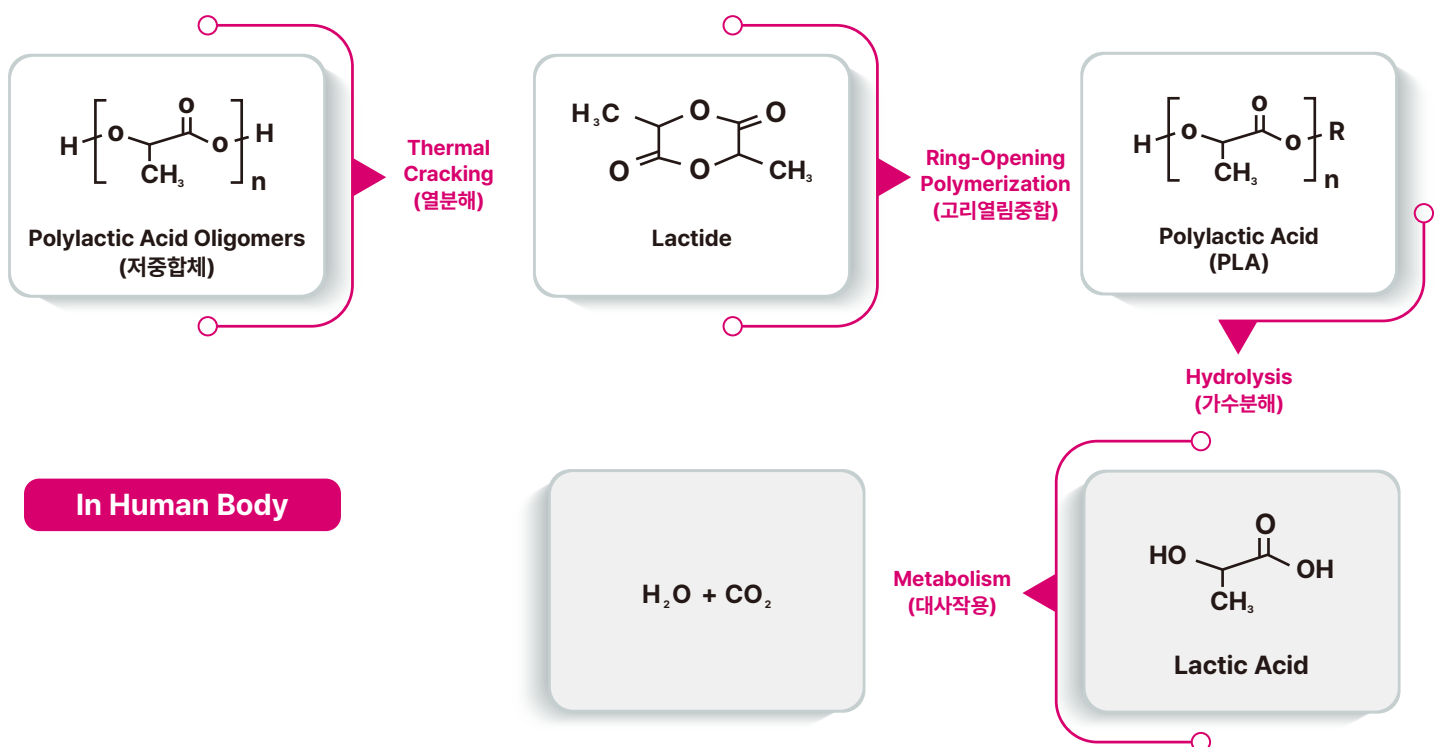


Regeneration of elastin and collagen fibers for 24weeks

	Day 0	4 weeks	8 weeks	12 weeks	24 weeks
Elastic Fiber Formation (100X)					
Collagen Fiber Formation (400X)					

Safety ; Mechanism of PLLA Bio-Degradability

PLLA is hydrolyzed in the human body with simple H₂O and CO₂ without specific enzymes and is discharged outside the body



- PLA[Poly(L-lactide)], the main ingredient of Ultra PLLA, is a biocompatible polymer extracted from fermented corn, a vegetable ingredient. It is a polymer approved by the U.S. Food and Drug Administration (FDA) and is a biopolymer that has been widely used for medical purposes for the past several decades.

PLLA is a non-toxic and very safe material because it is decomposed into lactic acid and glycogen through a hydrolysis reaction in the body and then excreted out of the body in the final form of water and carbon dioxide through in vivo metabolism.

Application Methods

Ultra PLLA can be directly applied to

DERMIS LAYER

1

Injectable to Dermis
(0.85~0.1mm depth)



2

Mesotherapy equipment
(MTS needle, Meso pen, etc)



1 time



5 cc

- With Ultra PLLA, dermal booster, only one session is needed for immediate results and long lasting correction.

Application Part

Ultra PLLA can be directly applied to **DERMIS LAYER**



● TREATMENT SITES :

1

Wrinkle improvement

- deep forehead lines
- frown lines
- brow droop
- crow's droop
- nasolabial folds
- marionette lines

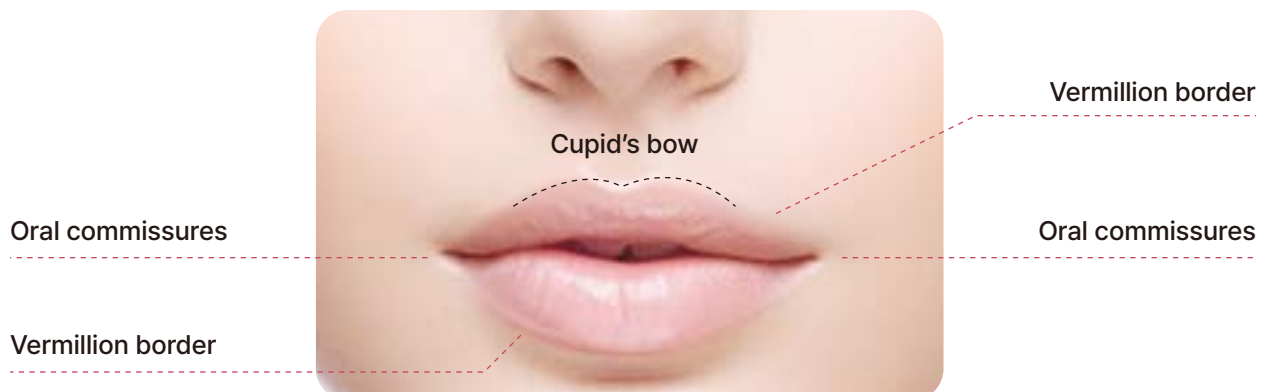
2

Volume

- temple augmentation
- cheek augmentation
- chin augmentation

3

Nose Correction



Precautions

- ① The product should be injected only to the lower layers of the dermis or the layers of the hypodermis.
- ② Like other injections, in case of the patients who have administered anticoagulants, this product may lead the risk of hematoma or local bleeding in the injection sites.
- ③ Do not inject this products shallow closer to the outer layer of the skin in order to prevent early papules or modules at the injection sites.
- ④ If this product is injected into blood vessels, it may obstruct blood vessels or flows, and cause skin embolism.
- ⑤ In order to avoid contamination, each vial packages should be used for inly one patient. Since this product is a disposable single-use material, do not re-use or re-sterilize it after opening its sealed package or reconstituting the solution.
- ⑥ If the sealed package was broken, damaged or modified in its outside, do not use the product.
- ⑦ It is strictly prohibited to use this product for other purposes except its originally intended purpose.
- ⑧ Before treatment be sure to use this product after completing the reconstitution prepared as it is indicated in the preparation guideline of the product.
- ⑨ A sterile, disposable 25G needle or cannula must be used in this injection treatment.

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