



CROSSLINKED HA GEL · 0.3% LIDOCAINE

REVOLAX™

Fine · Deep · Sub-Q with Lidocaine

Three crosslinked hyaluronic acid grades from Across Co., Ltd. (Hugel group), Republic of Korea, for the temporary improvement of facial wrinkles.

Professional use only · Global product factsheet 2026



Made by Across. Marketed by Hugel.

Manufacturer

Across Co., Ltd., Chuncheon, Gangwon-do, Republic of Korea. KGMP facility, medical-device manufacturing licence No. 3393.

Marketer & export sponsor

Hugel Inc. markets REVOLAX™ as an export brand. In Australia the sponsor is Hugel Australia Pty Ltd.

Korean status

“Medical device for export”: a biomaterial graft and prosthesis for the temporary improvement of facial wrinkles.

Jul 2011

Export manufacturing approval for Dermalax / Revolax (Korea)

Jun 2013

REVOLAX™ trademark registered, No. 40-0975203

Sep 2015

Hugel Inc. becomes Across's largest shareholder

Jul 2023

Thailand TFDA product approval (27 Jul; announced 17 Aug)

Aug 2025

Australia TGA ARTG listing, Class III (15 Aug)

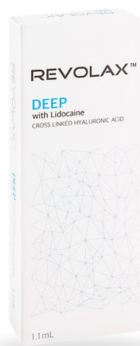
Three grades, one platform



FINE with Lidocaine

Superficial dermis

1.1 mL × 1 syringe · 2 × 30G needles



DEEP with Lidocaine

Mid/deep dermis – subcutaneous

1.1 mL × 1 syringe · 2 × 27G needles



SUB-Q with Lidocaine

Deep subcutaneous

1.1 mL × 1 syringe · 2 × 25G needles

EVERY PACK

One prefilled 1.1 mL syringe and two needles. Lidocaine 0.3% in all three grades.

No non-lidocaine REVOLAX™ grade appears on the current Across table, the TGA ARTG or the 2021 safety notice.

Sodium hyaluronate, 24 mg/mL

24 mg/mL

Crosslinked HA, Deep and Sub-Q;
Fine per the current Across table

0.3%

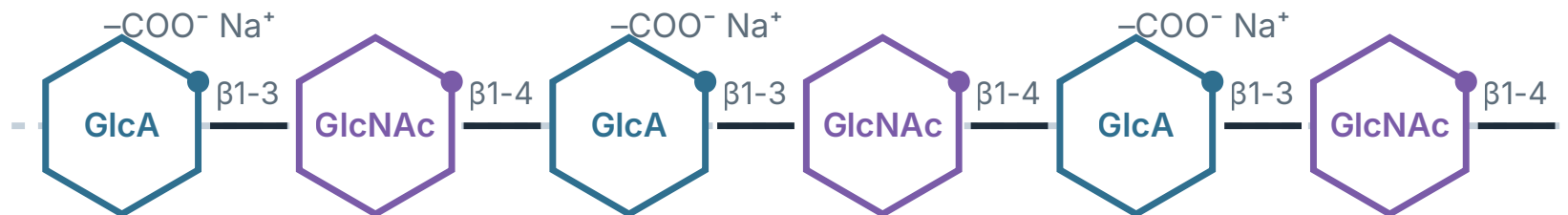
Lidocaine in every grade

1.1 mL

Prefilled syringe per pack

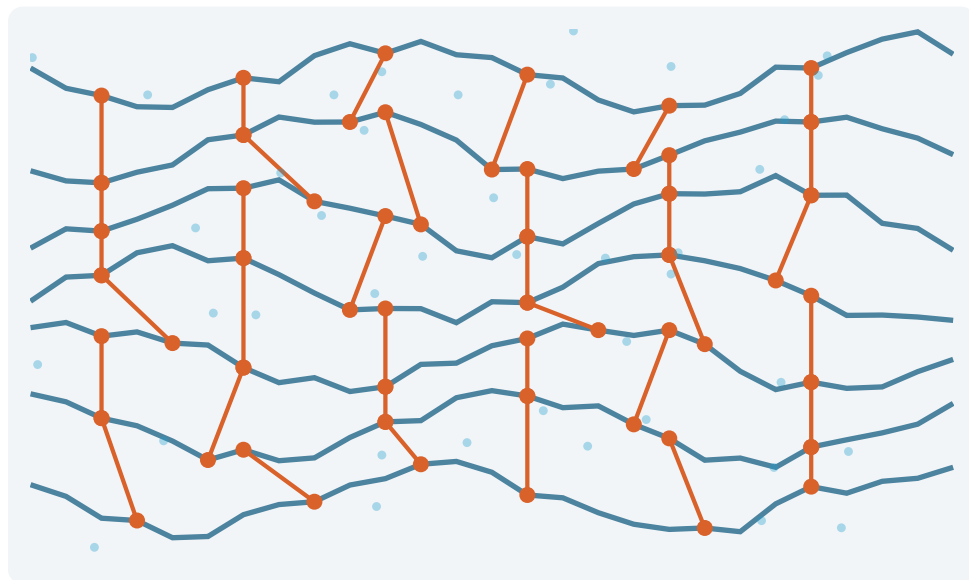
Fine grade: check the carton

The live Across table prints the Fine value with a unit typo; an older Across profile lists a different Fine value. Confirm on the carton or IFU.



Repeating disaccharide unit of sodium hyaluronate: glucuronic acid (GlcA) + N-acetylglucosamine (GlcNAc)

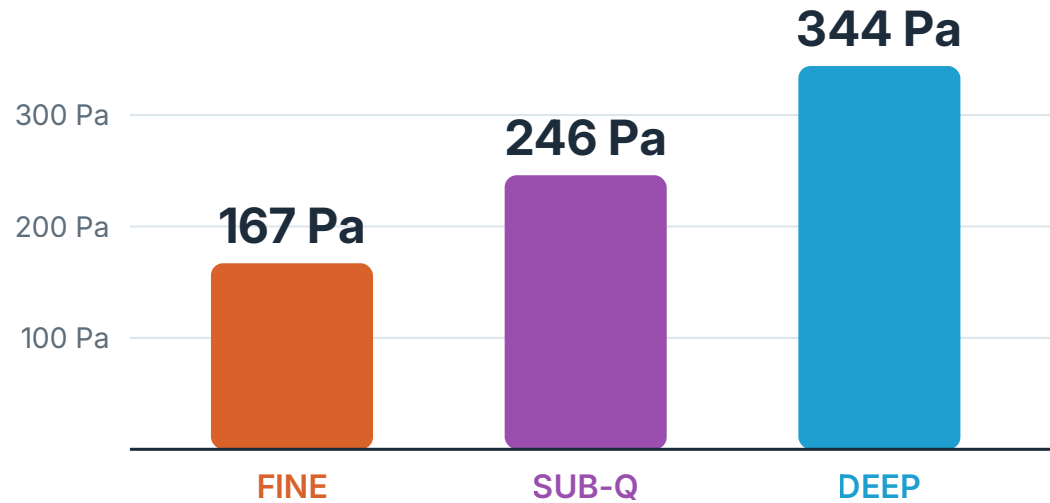
A monophasic, non-animal HA gel



— HA chains ●—● crosslink bridges ● physiological buffer ·
conceptual diagram

Property	Manufacturer-stated
Appearance	Colourless, transparent, viscoelastic gel
Material	Crosslinked sodium hyaluronate from bio-fermentation (non-animal)
Phase	Monophasic
Buffer	Physiological buffer, pH 6.8–7.5
Status	Sterile, non-pyrogenic, biodegradable
Crosslinker	Not named on the REVOLAX™ page; BDDE is the Across/Hugel franchise crosslinker, not verified for this carton
Residual crosslinker	Not published

Gel firmness, measured independently



Storage modulus G' at 10 rad/s · Wongprasert P, Dreiss CA, Murray G. Dermatol Ther 2022;35(6):e15453 · PMID 35293660

Deep is firmer than Sub-Q

At 10 rad/s Deep (344 Pa) exceeds Sub-Q (246 Pa), so the grade names do not track G' .

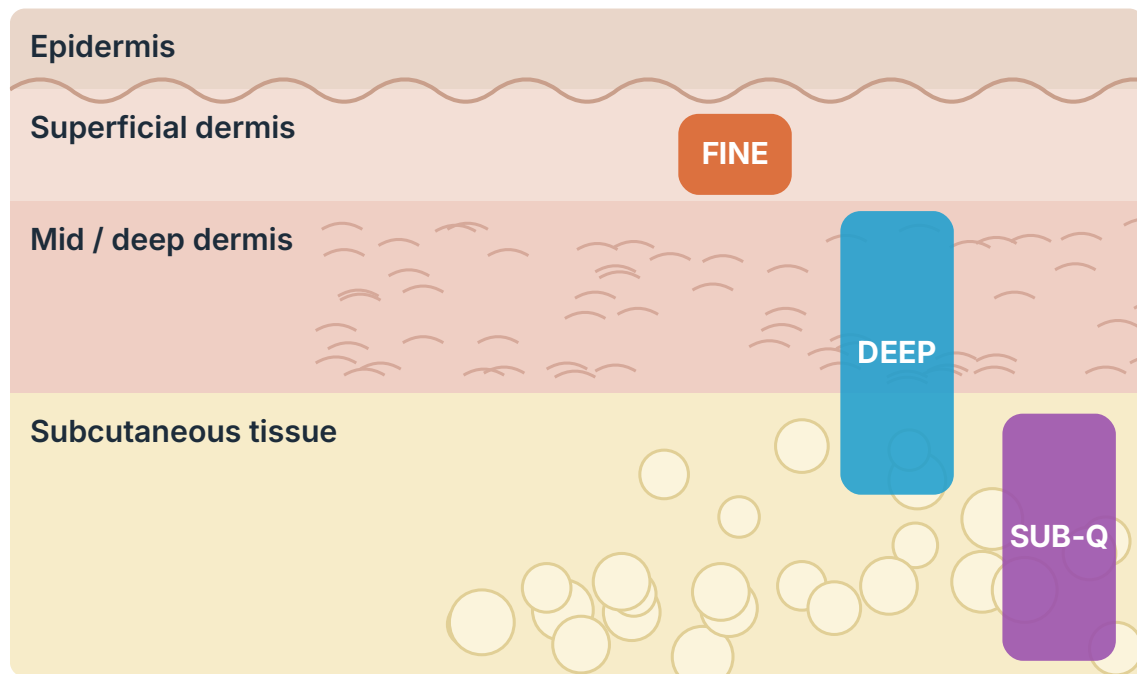
At 0.1 Hz

Fine 93 Pa · Sub-Q 281 Pa (authors' unpublished data).

Not IFU data

One UK laboratory; not manufacturer specification.

Each grade has a target layer



Grade	Across-stated layer
FINE · 30G	Superficial dermis
DEEP · 27G	Mid/deep dermis – subcutaneous
SUB-Q · 25G	Deep subcutaneous

Labelled use for all three grades: **temporary improvement of facial wrinkles**, at the depths above with the packed needle. Dose per area and retreatment interval are not independently verified; the carton IFU prevails.

By market and grade

Market	FINE	DEEP	SUB-Q
Australia · TGA Class III, 2025	ARTG 509128	ARTG 509127	ARTG 509129
Thailand · TFDA, 27 Jul 2023	Approved, brand level	Approved, brand level	Approved, brand level
Korea · MFDS	Export licensed	Export licensed	Export licensed
EU · CE marking	Current not verified	Current not verified	Current not verified
USA · FDA	Not FDA-approved	Not FDA-approved	Not FDA-approved
China · NMPA	Not registered as REVOLAX™	Not registered as REVOLAX™	Not registered as REVOLAX™

Previous CE certificate withdrawn 29 Nov 2018; no CE number or seal is shown.

Verified record

Export licence only

Not verified

Not approved

CE history, stated plainly

29 Nov 2018	Previous CE certificate (ITC notified body) withdrawn
2018 – 2020	Sold in the UK and Denmark without a valid CE certificate until 20 Oct 2020
15 Feb 2021	Across Field Safety Notice AC-FSN-03; 324,932 syringes recalled
Apr 2022	UK MHRA FOI 21/1044: no record under the manufacturer name
Today	Current CE number and MDR status not verified

324,932

syringes recalled in the 2021 regulatory recall (CE lapse). Across rated patient risk “improbable” and reported no product-performance risk.

Across states a new CE certificate was obtained. Hugel/Across cite CE at franchise level; no certificate or EUDAMED entry is on file, so no CE number or seal is shown.

Market by market

Australia · strongest record

ARTG 509127 Deep, 509128 Fine, 509129 Sub-Q, all with lidocaine. Class III, "Synthetic-fluid tissue reconstructive material, anaesthetic". Listed 15 Aug 2025.

Thailand

TFDA product approval for REVOLAX™ on 27 Jul 2023, announced by Hugel on 17 Aug 2023 and listed in Hugel annual reports 2024/2025.

Korea

Export manufacturing approval July 2011. The domestic MFDS item permit is The Chaeum, not REVOLAX™; REVOLAX™ item digits not verified.

China

The NMPA product is Persnica / Dermalax Deep (Apr 2022), not REVOLAX™.

United States

No PMA, P-number or 510(k). Hugel's 2024 FDA approval is Letybo, a botulinum toxin. "FDA approved Revolax" reseller copy is false.

What clinics should keep in view

Lidocaine allergy

Contains 0.3% lidocaine. Lidocaine allergy is a class stop.

Vascular occlusion

A class risk of HA fillers. Keep hyaluronidase on hand (clinic protocol).

Expected class reactions

Swelling, redness, bruising and tenderness: clinic protocol, not a REVOLAX™ IFU quote.

Carton IFU prevails

No English IFU PDF was found; contraindications are not independently verified.

No product-defect recall

The only recall found is the 2018–2020 regulatory CE-lapse recall.

Counterfeit awareness

A UK distributor reports hologram packaging and grey-market concerns.

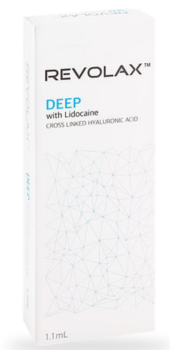
Lot traceability

Buy through traceable channels and keep lot numbers on file.

Prefilled gel

Reconstitution is not applicable.

Storage and pack details



2-25 °C

storage range · 24-month shelf life

Item	All three grades
Storage	2-25 °C
Shelf life	24 months
Fill	1.1 mL × 1 luer-lock disposable syringe, in a blister
Needles	2 per pack: Fine 30G · Deep 27G · Sub-Q 25G
Lidocaine	0.3%
HA	24 mg/mL (Fine: confirm on carton)
Gel	Sterile, non-pyrogenic, pH 6.8-7.5
Preparation	Prefilled; no reconstitution

Names, classes and sister brands

Item	Value
Brand	REVOLAX™, trademark No. 40-0975203 (June 2013)
Korean description	Biomaterial graft and prosthesis, for export
ARTG category	Synthetic-fluid tissue reconstructive material, anaesthetic · Class III
FSN clinical purpose	"Implantation of volume loss for facial morphological asymmetry"
Not a toxin	A medical device; not botulinum toxin

SEPARATE PRODUCTS, NEVER MERGED

THE CHAEUM · Korean domestic name in Hugel press; a different SKU grid (1.1 mL dual syringe, 24/20 mg/mL)

DERMALAX · Separate export brand with its own trials

Persnica · China name

VOLUS · Export, 10 mL

revolaxofficial.com · Ownership unverified; not used here

What the literature contains

Zero

PubMed hits for “revolax” (checked 14 Oct 2026). No REVOLAX™-named RCT or NCT record.

Independent rheology

Wongprasert 2022, Dermatol Ther, PMID 35293660 (PMC9285697): G' for all three grades. The paper also notes no REVOLAX™ publications.

Sister brand only

Dermalax Deep vs Restylane (J Dermatol Treat 2021, PMID 31689127) and Dermalax Implant Plus (NCT02179606) are not REVOLAX™ evidence.

Not cited for REVOLAX™

Lee 2019/2020 Dermatol Surg rheology (PMID 30883477) covers Chaeum No.1–4 only. Encapsulation-type marketing wording rests on a patent, not on measurement, and is not used here.

Claims you will see online

Claim seen online	Record
"FDA approved REVOLAX"	False No PMA or 510(k)
"MFDS / KFDA approved REVOLAX"	Export licensed Domestic permit is The Chaeum
REVOLAX™ without lidocaine	Not verified Not on Across, TGA or FSN lists
Lips, nose, chin, tear trough zones	Not labelled Labelled use: facial wrinkles
Duration in months	Not labelled No labelled duration published
"Class III CE-marked" on distributor pages	Not verified Distributor statement only

What the carton confirms

Open item	Where to confirm
Fine HA concentration (Across documents differ)	Carton / IFU
Crosslinker named on the pack	Carton print
Contraindications, dose per area, retreatment interval	Carton IFU
Current CE certificate, notified body, MDR status	EU declaration of conformity
MFDS item number for REVOLAX™	MFDS records
TGA ARTG summary documents	TGA website, retrieved manually



ABOUT YAKSU MEDI

Yaksu Medi is a Korea-based B2B wholesale supplier of Korean medical aesthetic products. Clinics and distributors worldwide buy REVOLAX™ wholesale from Korea through us, with Fine, Deep and Sub-Q with Lidocaine available alongside Korean HA fillers, skin boosters and toxins.



Genuine REVOLAX™
Across / Hugel cartons from authorised Korean channels, lot numbers kept.



All three grades
Fine, Deep and Sub-Q for clinics and distributors worldwide.



Careful shipping
Temperature-aware packing within 2–25 °C and DDP delivery options.



Documentation support
Product and shipping documents to support import.

Looking for a Korean aesthetic wholesale supplier for REVOLAX™ filler?
Ask for current Revolax wholesale pricing and lead times for Fine, Deep and Sub-Q with Lidocaine.

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