

LEXYAL

CE certified HA filler

 Double J Holdings



LEXYAL Introduction

1. Introduction
2. Specifications
3. Treatment Areas

Features Of LEXYAL & Technology

1. CE Certificate
2. HA Gel By PNET
3. ZERO Endotoxinfety
4. Lower MoD
5. Advanced Monophasic Filler
6. Using Water For Injection

Clinical Studies Of LEXYAL

1. Clinical Trial Summary

LEXYAL Introduction



LEXYAL is a new concept filler that shows high elastic modulus and excellent cohesion.

LEXYAL is a crosslinked hyaluronic acid filler to mid-to-deep dermal implantation intended for the correction of facial wrinkles, contour and volume



Approved



certificate









Approved

Specifications

** LEXYAL has three different lines fine, Deep, Grand which are differentiated by crosslinking degree, resulting in different viscoelasticity.

** LEXYAL Grand /Deep / Fine : Non - Lidocaine, EC Certified

LEXYAL Grand /Deep / Fine PLUS : With Lidocaine, Non - EC Certified

Name	Images	Product specification				Needle specification		Property	CE
		HA	PHASIC	BDDE	CONTENTS	GAUGE (UTW)	QUANTITY		
LEXYAL GRAND		24mg/ml	MONO	<0.2ppm	1mL*1 syringe	27G	2EA		Certified
LEXYAL DEEP		24mg/ml	MONO	<0.2ppm	1mL*1 syringe	27G	2EA		Certified
LEXYAL FINE		24mg/ml	MONO	<0.2ppm	1mL*1 syringe	27G	2EA		Certified

● LEXYAL GRAND



Molecules Size : LARGE
1.0mL 1syringe / 24 mg / mL
Duration : 12~24 month

- Deep wrinkles
- Nasolabial folds
- Lips prosthesis
- Zygoma, chin, forehead augmentation
- Nose ridge
- Breast augmentation

● LEXYAL DEEP



Molecules Size : MEDIUM
1.0mL 1syringe / 24 mg / mL
Duration : 9~18 month

- Middle wrinkles / Augmentation
- Nasolabial folds
- Deep glabellar lines
- Deep worry lines
- Perioral lines
- Zygoma, chin, forehead augmentation
- Lips ptosthesis, contouring
- Nose ridge

● LEXYAL FINE



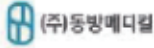


Molecules Size : SMALL
1.0mL 1syringe / 24 mg / mL
Duration : 6~9 month

- Superficial wrinkles
- Periorbital lines
- Glabellar lines
- Worry lines
- Lobule
- Perioral lines



FEATURES OF LEXYAL & TECHNOLOGY

1. CE Certificate
2. HA Gel By Pnet
3. Zero Endotoxin
4. Lower MoD
5. Advanced Monophasic Filler
6. Using Water For Injection

	
<h2>EC Declaration of Conformity</h2>	
<p>We herewith declare that the undermentioned products meet the provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.</p>	
Product Name	Sterile Absorbable Intradermal Viscoelastic Dermal Filler
Brand Name	LEXYAL GRAND, LEXYAL DEEP, LEXYAL FINE
Model Name	D24P, P0G, P0GF, P0D, P0DF, P0F, P0FF
Classification	Class III (Council Directive 93/42/EEC as amended by Directive 2007/47/EC, Annex IX, Rule 8)
Conformity Assessment Route	Annex II, Including Section 4, Council Directive 93/42/EEC as amended by Directive 2007/47/EC
Notified Body	Szrtest Uygunluk Deęerlendirme A.Ş. [Notified body No.: 2195] Tatissu Mahallesi, Akif Inan Sk. No:1, 34774 Ümraniye / ISTANBUL / Turkey
Standards applied	EN ISO 13485:2016, EN ISO 14971:2012, EN 14155:2011, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-3:2014, EN ISO 10993-4:2009, EN ISO 10993-5:2009, EN ISO 10993-6:2009, EN ISO 10993-9:2009, EN ISO 10993-10:2013, EN ISO 10993-11:2009, EN ISO 17665-1:2006, EN ISO 17665-2:2009, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-1:2006/AC:2009, EN ISO 11737-2:2009, EN ISO 20594-1:1993, EN 62366:2008, EN 1041:2008, EN ISO 15223-1:2016, ISO 11040-4:2015, ISO 11040-5:2012, ISO 14644-1:2015, ISO 14644-2:2015, ASTM F 1980-07(2011), ASTM F89/F89M-09, ASTM F 1929-12, ISTA 2017 Procedure 2A, MEDDEV 2.7/1 (Rev.4), MEDDEV 2.12/1 (Rev.8), MEDDEV 2.12/2 (Rev.2), EN ISO 14630:2009, EP, KP, USP, NF
EC Representative	Meridius Medical Europe Ltd. Unit 3D, North Point House, North Point Business Park, Old Mallow Road, Cork, T23 AT2P, Ireland /Tel: +353 212066448/ Email: isabel@meridiusedical.com
GMDN Code	59131 [Dermal tissue reconstructive material, microbe-derived]
EC Certificate	2195-MED-1834101
EC Certificate Expiry Date	2023-12-06
	
Place of Issue	Gyeonggi-do, Korea
Date of Issue	Starting Date of CE Marking
Signature	 Keun Sik, Kim Chief Executive Officer DongBANG Medical Co., Ltd. Part of 2nd floor and Part of 3rd floor, EHO Building 16-9, Dongbaekjungang-ro 160eon-gil Giheung-gu, Yongin-si, Gyeonggi-do, Korea
	Y1-DOC-001 (Rev.4), 2022.12.07

LEXYAL Filler

is a approved safe HA filler with

CE Certification.

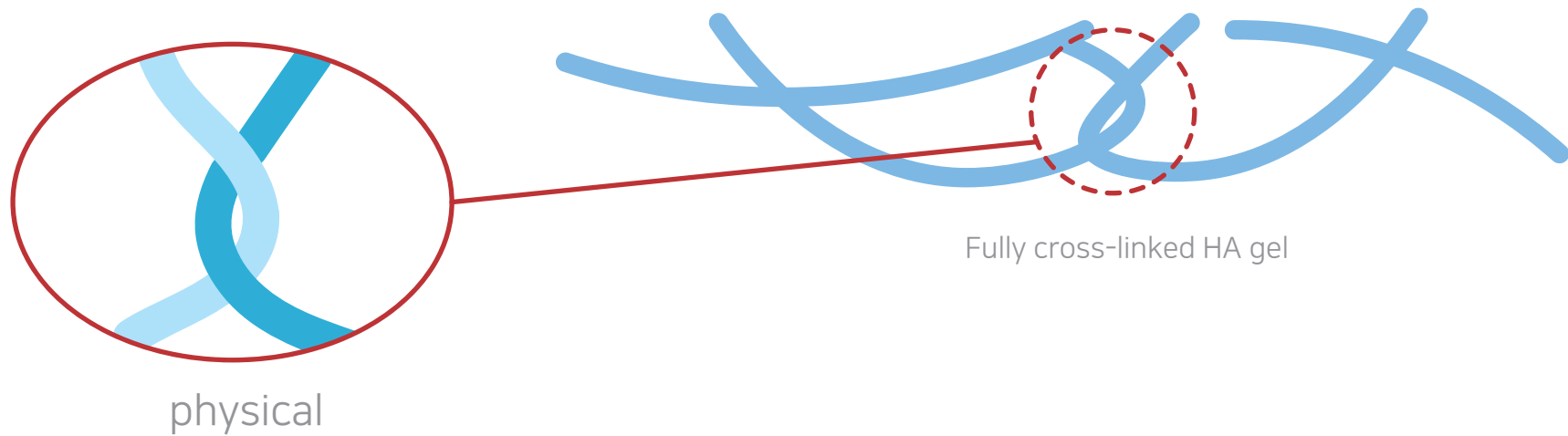
The CE mark on a product indicates that the manufacturer or Lorem ipsum importer affirms the goods' conformity with European health, safety, and environmental protection standards.

The CE mark is mandatory for certain product groups intended for sale within the European Union, the European Free Trade Association (EFTA), and Turkey.

The manufacturers of products made within these countries, and the importers of goods made in other countries, affirm that CE-marked goods conform to EU standards.

** Source : https://en.wikipedia.org/wiki/CE_marking

Preserved **Natural Cross-Linked** technology



The unique and patented stabilization technique ensures that **Natural Cross-linked**

Entangled HA network is kept in place
by introducing a limited number of synthetic cross-links,

i.e. ***minimal modification***

3. ZERO endotoxin

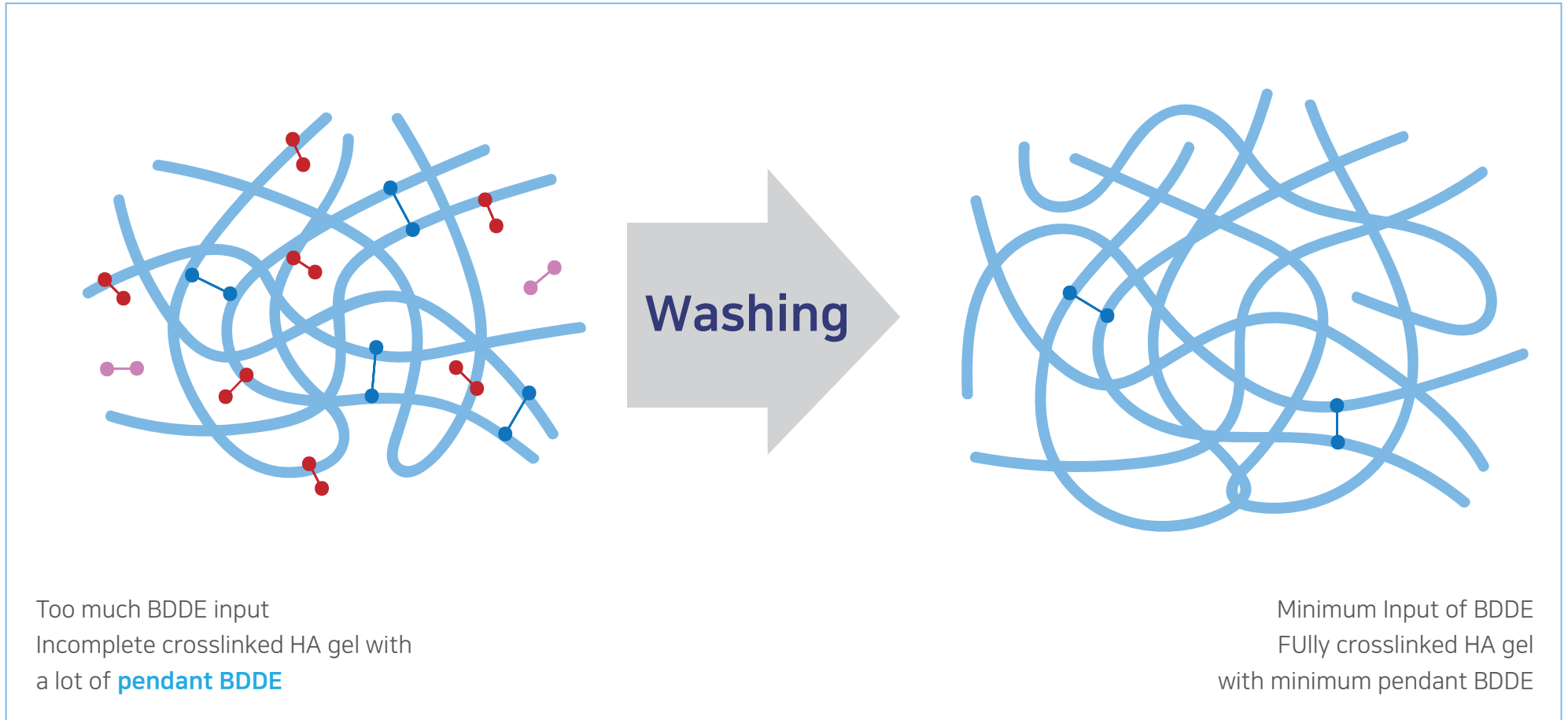
Endotoxin Level

- Control criteria 0.25 EU/ml
- Other company products criteria 0.5 EU/ml
- Actual experimental results Less than **0.005 EU/ml** (non-detected)

Sample Name: P1D3G05A1					Associated Standard Set: STD9:STD12					
Sample ID: N/A					Sample Comments: N/A					
Sample Lot Number: N/A					Endotoxin Value: <0.0050 EU/mL					
Dilution/Concentration: 1:1 mL/mL					Endotoxin Limit: N/A		Status: N/A			
EU Criteria: <					Sample CV Limit: 10.00%		Status: VALID			
Alert Limit: N/A					Spike CV Limit: 10.00%		Status: VALID			
Spike Concentration: 0.5 EU/mL					Spike Recovery Range: 50-200%		Status: VALID			
SAMPLE DATA					SPIKE DATA					
Well	Reaction Time (Sec.)	CV%	Endotoxin Value	Average Value	Well	Reaction Time (Sec.)	CV%	Spike Value	Average Value	Spike Recovery %
E5	>2490.00	0.00%	<0.0050 EU/mL	<0.0050 EU/mL	E7	806.25	4.12%	0.3297 EU/mL	0.3871 EU/mL	76%
E6	>2490.00		<0.0050 EU/mL		E8	742.50		0.4575 EU/mL		

Sample Name: P1D3G05A2					Associated Standard Set: STD9:STD12					
Sample ID: N/A					Sample Comments: N/A					
Sample Lot Number: N/A					Endotoxin Value: <0.0050 EU/mL					
Dilution/Concentration: 1:1 mL/mL					Endotoxin Limit: N/A		Status: N/A			
EU Criteria: <					Sample CV Limit: 10.00%		Status: VALID			
Alert Limit: N/A					Spike CV Limit: 10.00%		Status: VALID			
Spike Concentration: 0.5 EU/mL					Spike Recovery Range: 50-200%		Status: VALID			
SAMPLE DATA					SPIKE DATA					
Well	Reaction Time (Sec.)	CV%	Endotoxin Value	Average Value	Well	Reaction Time (Sec.)	CV%	Spike Value	Average Value	Spike Recovery %
F5	>2490.00	0.00%	<0.0050 EU/mL	<0.0050 EU/mL	F7	787.50	0.08%	0.3620 EU/mL	0.3609 EU/mL	71%
F6	>2490.00		<0.0050 EU/mL		F8	788.75		0.3598 EU/mL		

LEXYAL FILLER's endotoxin level is **98%** Less than standard



●—● Fully crosslinked BDDE
 ●—● Pendant BDDE
 ●—● Unreacted BDDE

[Reference]

1 Kenne, Lennart, et al. "Modification and cross-linking parameters in hyaluronic acid hydrogels hydrogels-Definitions and analytical methods." Carbohydrate polymers 91.1(2023):410-418.



LEXYAL	Monophasic LEXYAL		
	FINE	DEEP	GRAND
MoD(%)	1.62	2.13	3.31

Controlled	Monophasic			
	Juve***	Neu***	Yvo***	Teos***
	Voluma ²	Voluma ³	Intensive Plus ⁴	RHA 4 ⁵
MoD(%)	7.68	11.23	8.07	4

The degree of modification (MoD) reflects the deviation from the baseline **HA**.

A lower MoD value means it is more similar to natural HA and preserves biocompatibility.

In conclusion, lower MoD values prove to be safer product.

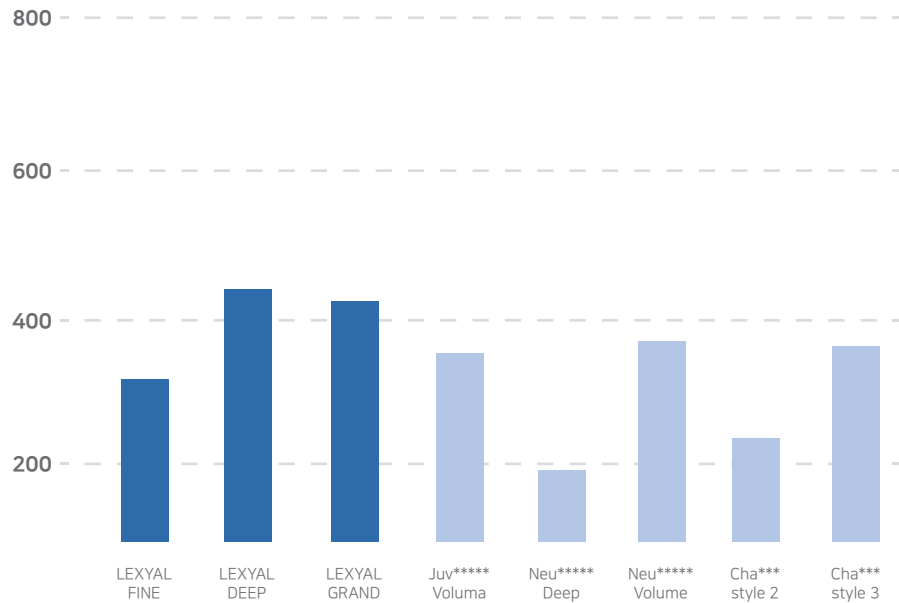
LEXYAL has the lowest modification of hyaluronic acid molecules by **BDDE**

[Reference]

1- 4 Collge of Medicine Chung Ang University, "Comparative analysis of rheological features of fillers" 2017-2018.

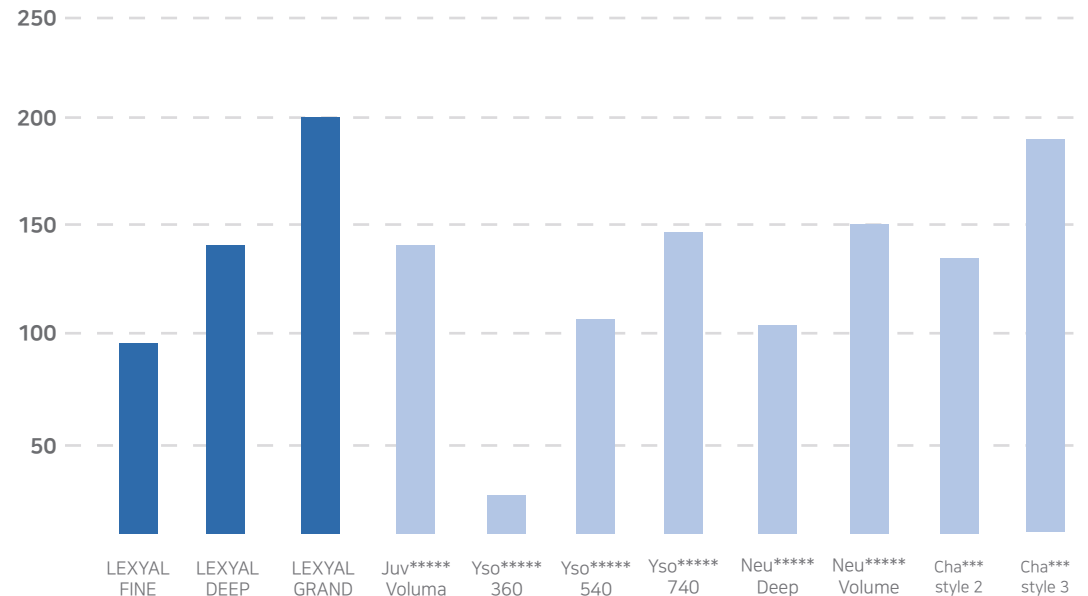
5 Teoxane Laboratories. Data on file, measurement by an independent laboratory of the HA Degree of Modification by 1H NMR.

Resistance to deformation
G* (Pa)



* Storage modulus, G', Pa :
The higher the elastic value , the better the feeling of **volume**.
The force that lift the skin tissue

Shear viscosity
(Pa*s)



* Shear viscosity(Pa * s):
The higher the shear viscosity, the higher the cohesion.
The power to keep the **volume shape** (the force that the gels try to stick together)

LEXYAL is highest level of storage modulus

6. Using Water For Injection (WFI)

| "Purified Water" (PW) when produced for oral or external use and "Water for Injection" (WFI) when produced for parenteral (injectable) use.

| WFI is more safety than PW Reducing side effects

MONOGRAPH	PWRIFIED WATER (PW)		WATER FOR INJECTION (WFI)	
	USP 31 <1231>	PhEur 9.1 <0169>	USP 31 <1231>	PhEur 9.1 <0169
PROCESS*	Distillation, RO and any other suitable process	Distillation, ion exchange, RO & other suitable process	Distillation or RO	Distillation or a Purification
CONDUC TIVITY	< 1.3 μS/cm ² @25°C	< 4.3 μS/cm ² @20°C	< 1.3 μS/cm ² @21oC	< 1.1 μS/cm ² @20oC
BAC TERIA	100 cfu/ml (suggestsd)	< 100 cfu/ml	< 10 cfu/ 100 ml (suggestsd)	< 10 cfu/100ml
ENDOTOXIN	N/A	< 0.25 IU/ml (bulk water for diaysis	< 0.25 EU / ml	< 0.25 IU / ml
TOC	500 ppb	< 0.5 mg/l	500 ppb	< 0.5 mg/l
PT	N/A	5.0 - 7.0	5.0 - 7.0	5.0 - 7.0
NITRATES	N/A	< 0.2 ppm	N/A	< 0.2 ppm
HEAVY METALS	N/A	< 0.1 ppm	N/A	< 0.1 ppm
ALUMINUM	N/A	< 10 ppb (dialysis solutions)	N/A	< 10 ppb (dialysis solutions)

*The water source used for treatment / production must be obtaion must be obtained from potable must be obtained from potable waters complying with the "U.S. Environmental Protection Agency National Primary Drinking Water Regulations" or equivalent regulations of the Euroean Union Union or Japan.

LEXYAL is made using **Water For Injection technology**

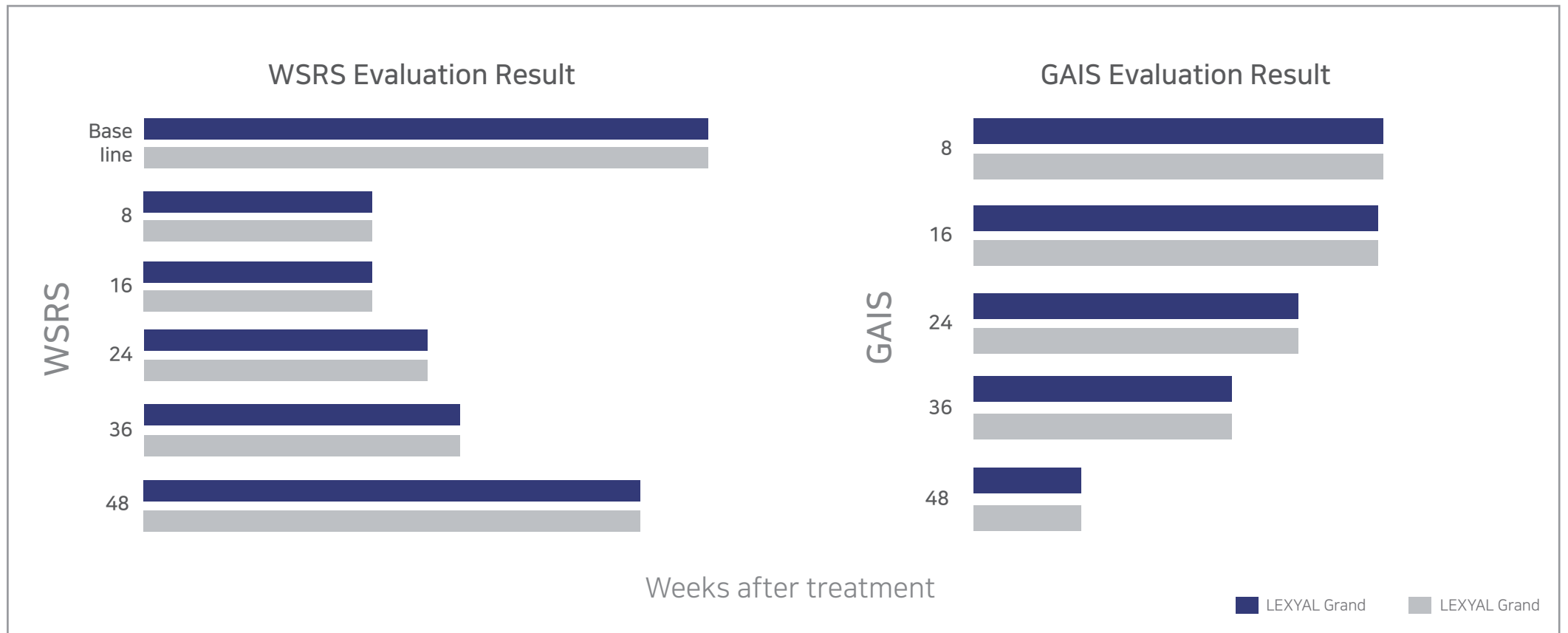
"FOR SAFE"

Clinical Trial Summary

Reference : LEXYAL

WSRS : Wrinkle Severity Rating Scale, 1~5

GAIS : Global Aesthetic Improvement Scale, 1~3



In the 48 weeks clinical study after injection, **LEXAL Grand** demonstrates **comparable efficacy** described by WSRA & GAIS vs Rest SubQ as a reference.



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