SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

SSCP

Chondro® (Sterile Sodium Hyaluronate Gel Implant — Linear HA)

Chondroplus® (Sterile Sodium Hyaluronate and Synthetic Peptide Gel Solution)

DOCUMENT INFORMATION	
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Rev.	Date	Change Description	NB Validated
00	01.10.2024	First Issue	Pending
01	15.02.2026	Full revision: Reganemed-specific content; CEAR NC-02–12 aligned; equivalence restructured (Biosan Art.61(5) only; Orthovisc®/KD® repositioned); clinical evidence updated (Porta 2024; Biosan n=90+154; PLIT.01–07); GSPR traceability; RVAL lot data; benefit-risk thresholds; PMCF framework; patient section updated.	□ Pending NB 2764

ABBREVIATIONS

Abbreviation	Definition
MDD	Medical Device Directive 93/42/EEC
MDR	Medical Device Regulation (EU) 2017/745
CE	Conformité Européenne — Certificate of Europe
NB	Notified Body
PRRC	Person Responsible for Regulatory Compliance
IA-HA	Intra-Articular Hyaluronic Acid
HMWHA	High Molecular Weight Hyaluronic Acid
CTP	Collagen Tripeptide (Gly-X-Y synthetic peptide — Chondroplus® active substance)
VAS	Visual Analogue Scale (pain; 0–10)
NRS	Numeric Rating Scale (pain; 0–10)
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
MCDI/MCID	Minimal Clinically Detectable/Important Difference
KL	Kellgren-Lawrence OA grading classification
KOA	Knee Osteoarthritis
CPPD	Calcium Pyrophosphate Deposition disease (chondrocalcinosis)
LMM	Linear Mixed Model
SAE	Serious Adverse Event
AE	Adverse Event
PMCF	Post-Market Clinical Follow-Up
PMS	Post-Market Surveillance
PSUR	Periodic Safety Update Report
CAPA	Corrective and Preventive Action
FSCA	Field Safety Corrective Action
UADE	Unexpected Adverse Device Effect
SoTA	State of the Art
GSPR	General Safety and Performance Requirements (MDR Annex I)
SEC-MALLS	Size Exclusion Chromatography — Multi-Angle Laser Light Scattering
TÜRKAK	Turkish Accreditation Agency

	Field	Description
1.1	Device Trade Name(s)	Chondro® — Sterile Sodium Hyaluronate Gel Implant (Linear HA) Chondroplus® — Sterile Sodium Hyaluronate and Synthetic Peptide Gel Solution (HA + Gly-X-Y CTP)
1.2	Manufacturer Name and Address	Reganemed GmbH | Rue des Couteriaux, 58180 Marzy, France Production (Sub-Contractor): Biosan Biyoteknoloji A.Ş. | TÜBİTAK Gebze Yerleşkesi, Gebze/Kocaeli, Turkey
1.3	Manufacturer Single Registration Number (SRN)	FR-MF-000048872
1.4	Basic UDI-DI	Chondro® (Linear HA): 8511462743LS7 Chondroplus® (HA+CTP): 8511462743PSF
1.5	Medical Device Nomenclature	EMDN: P900402 — Biodegradable Devices, Filler and Reconstructive GMDN: 44757
1.6	Class of Device	Class III — Rule 8 (MDR 2017/745 Annex VIII) Intra-articular use; contact >30 days; bioresorbable; non-active implantable device
1.7	Year First CE Certification Issued	MDD: 11.02.2020 (Certificate M.2020.106.13770 / M.2020.106.13770-1; NB: UDEM, Ankara) MDR: Application ongoing under NB 2764 (Notice Belgelendirme A.Ş.; contract: 05.07.2024)
1.8	Authorized Representative (EU)	Reganemed GmbH is legally established in France (EU) — AR not required. Manufacturer directly responsible for EU obligations.
1.9	Notified Body Name	Notice Belgelendirme Muayene ve Denetim Hizmetleri A.Ş.
1.10	NB Single Identification Number	2764
1.11	Linked Documents	CER: TD.01-13.01 Rev.02 (15.02.2026) | CEAP: TD.01-13.02 Rev.01 | PMCF Plan: TD.01-14.01 | PSUR: TD.01-14.03 | IFU: TD.01-05 | Risk Management: TD.01-09

2.1 Intended Purpose

Chondro® and Chondroplus® are sterile, single-use, bioresorbable, Class III intra-articular hyaluronic acid gel implants intended for the symptomatic relief of pain and improvement of joint function in adult patients (≥18 years) with mild-to-moderate osteoarthritis of the knee (gonarthrosis), defined as Kellgren-Lawrence Grade II or III. Chondroplus® is additionally supported by clinical evidence for KL Grade IV patients and patients with concurrent calcium pyrophosphate deposition (CPPD/chondrocalcinosis). The devices act via viscosupplementation (HA component) and, for Chondroplus®, additionally via chondroprotection (synthetic Gly-X-Y CTP peptide stimulating type II collagen synthesis). Route: single intra-articular injection. Anatomical target: knee joint.

2.2 Indications for Use and Target Population

Criterion	Chondro® (Linear HA)	Chondroplus® (HA+CTP)
Indication	Symptomatic treatment of knee OA (gonarthrosis) after failure of conservative therapy	Same + specifically supported in OA with concurrent CPPD/ chondrocalcinosis
KL Grade	KL Grade II–III (mild-to-moderate)	KL Grade II–IV (KL IV supported by Porta et al. 2024: 48.4% of cohort)
Age	≥18 years (clinical evidence range: 24–88 years)	≥18 years (mean 70.3±12.4 years — Porta 2024)
Gender	Male and female	Male and female (65.5% female — Porta 2024)
Prior therapy	Failure of NSAIDs, physiotherapy, weight management ≥3 months	Same + particularly suited for patients with insufficient response to HA-only therapy
Clinical evidence basis	Biosan Hyarelief® prospective (n=90, KL III; VAS ↑83.2%; WOMAC ↑57.8%; 0 SAE) [MDR Art.61(5) formal equivalent — full access 01.02.2025]	Porta et al. 2024 (n=29/34 knees; KL II–IV; NRS ↑68.5%; WOMAC ↑67.4%; 79–83% MCDI; 0 SAE; 0 CPPD flare)

Principle of Operation

Chondro®: Viscosupplementation — HA restores synovial fluid viscosity → reduces joint friction → pain relief + functional improvement + sustained lubrication. Non-pharmacological mode of action.
Chondroplus®: Dual-pathway — (1) HA viscosupplementation (same as above) + (2) Synthetic Gly-X-Y CTP stimulates type II collagen synthesis and inhibits MMP-13 (anti-catabolic) → chondroprotection in addition to viscosupplementation. Mechanism confirmed by Naraoka et al. 2013 (rabbit ACLT, n=72) and supported by Ishijima et al. 2022 (CTX-II biomarker RCT, n=200).

Single Use	Yes — single use per syringe. Not reprocessable.
Sterilization	Sterile — Moist Heat (Steam 121°C / 15 min per ISO 17665-1); SAL 10^{-6}
Substance Information	No substances of human/animal origin. No blood products. No CMR substances. No endocrine disruptors. No phthalates or PFOS. No BDDE or other crosslinking agents (Chondro® and Chondroplus® are both linear, non-crosslinked formulations). Applies to both models. Ref: TD.01-07 Declarations.

2.3 Contraindications and Limitations

No.	Contraindication	Evidence Basis

1	Active joint infection or skin infection at the intended injection site	EUROVISCO 2024 (LIT.11); Vicenti 2024 (LIT.16)
2	Known hypersensitivity to sodium hyaluronate, bacterial fermentation proteins, or any excipient of the formulation	IFU TD.01-05; EUROVISCO 2024
3	Systemic bleeding disorders or anticoagulant therapy contraindicating IA injection (hemarthrosis risk)	EUROVISCO 2024 (LIT.11)
4	Pregnancy and breastfeeding (precautionary — absence of clinical data)	IFU TD.01-05; class practice
5	Active systemic inflammatory arthritis (rheumatoid arthritis, psoriatic arthritis) as primary diagnosis — different pathophysiology, not indicated	EUROVISCO 2024 (LIT.11)
6	HA injection into the same joint within the preceding 6 months	IFU TD.01-05
7	IA corticosteroid injection into the same joint within the preceding 2 months	IFU TD.01-05
8	Pre-operative use ≤3 months before total knee arthroplasty (TKA) — time-dependent PJI risk elevation	Vicenti et al. 2024 (LIT.16)
9	History of allergy to gram-positive bacterial proteins (trace amounts may be present as fermentation residue)	IFU TD.01-05
Note	Chondroplus® exception: KL Grade IV is NOT an absolute contraindication. Porta et al. 2024: 48.4% of patients were KL IV with clinically meaningful outcomes (79% NRS MCDI, 0 SAE, 0 CPPD flare).	Porta et al. 2024 (LIT.20)

Alternative Therapies and Clinical Positioning

When to prefer Chondro®/Chondroplus®	When to consider alternatives first
• NSAID intolerance or contraindication • Diabetes or steroid-sensitive patients (prefer IA-HA over CS) • Mild-to-moderate OA (KL II–III) seeking medium-term pain relief • Chondroplus®: OA+CPPD; KL IV; insufficient response to HA-only therapy • Bridge-to-surgery scenarios; single-visit low systemic-risk therapy preference	• Large inflammatory flare/effusion (CS first, then IA-HA after 2 months) • Active joint/skin infection (absolute contraindication) • Known HA hypersensitivity (absolute contraindication) • Advanced OA (KL IV) refractory to all conservative care → surgical consult (note: Chondroplus® may still benefit this group) • Pregnancy/breastfeeding (precautionary)

Summary of Post-Market Clinical Follow-Up (PMCF)

Objectives: Confirm long-term safety and performance under real-world conditions; verify equivalence assumption with Biosan Hyarelief® in target population; identify emerging signals; expand data on Chondroplus® in OA+CPPD and KL IV populations.

Planned activities (PMCF Plan TD.01-14.01):

- Annual systematic clinical literature review (IA-HA/equivalents; SoTA; safety signals)
- Continuous vigilance/complaint trending — quarterly signal review
- Prospective multicenter registry (≥100 patients/year, ≥3 centers, ≥2 EU countries): NRS, WOMAC, Lequesne at baseline, 1, 3, 6, 12 months; AE collection
- Annual integration into PSUR (TD.01-14.03) and CER (TD.01-13.01) per MDR Art.86

Data evaluation: PMCF data analyzed (LMM, ANOVA, Chi-Square, Bonferroni correction) and summarized in PMCF Evaluation Report (TD.01-14.02; first report: October 2026). Statistical plan: paired t-test or Wilcoxon for within-group changes; LOCF missing data; SAE rate monitoring with binomial 95% CI. Outcomes feed PSUR and CER. Traceability via QMS.

3.1 Description of the Device

Chondro® is a sterile, biodegradable, viscoelastic, colorless and non-pyrogenic high molecular weight (1.0–2.5 MDa) sodium hyaluronate (linear, non-crosslinked) gel implant prepared in phosphate-buffered saline solution, presented in pre-filled Luer Lock borosilicate Type I glass syringes.

Chondroplus® is a sterile, biodegradable, viscoelastic, colorless and non-pyrogenic solution combining high molecular weight linear sodium hyaluronate (1.0–2.5 MDa) with synthetic Gly-X-Y collagen tripeptide (CTP), prepared in phosphate-buffered saline, presented in pre-filled Luer Lock borosilicate Type I glass syringes.

HA Source: Bloomage Biotechnology Corp. (bacterial fermentation, Streptococcus zooepidemicus, pharmaceutical grade). Both products use the same raw material supplier, same production facility (Biosan Biyoteknoloji, Gebze), and same sterilization method. CTP source: synthetic, non-animal, non-human origin.

Property	Chondro® (Linear HA)	Chondroplus® (HA+CTP)
Structure	Linear sodium hyaluronate polysaccharide chain (non-crosslinked)	Linear NaHA + synthetic collagen tripeptide (Gly-X-Y CTP)
Chemical Formula	$(C_{14}H_{21}NO_{11})_n$ (repeating NaHA disaccharide unit)	$(C_{14}H_{21}NO_{11})_n$ + synthetic peptide (defined amino-acid sequence)
Crosslinking Agent	None (linear; non-crosslinked)	None (linear; non-crosslinked)
Molecular Weight (HA)	1.0–2.5 MDa (confirmed by SEC-MALLS: Mn 926 kDa — SU-IMC 2020)	Mn 923 kDa / Mw 926 kDa (SEC-MALLS; SU-IMC 2020)
Solubility	Water-soluble	Water-soluble
Degradation Rate	~24 weeks (hyaluronidase enzymatic + oxidative cleavage)	~24 weeks HA component; CTP cleared via synovial proteases
Biodegradation Products	D-glucuronic acid + N-acetyl-D-glucosamine oligosaccharides (renally cleared)	Same HA degradation products + amino acids (Gly, Pro, HyPro) from CTP
Use	Single intra-articular injection (knee)	Single intra-articular injection (knee)

3.1.1 Technical Specifications — Validated Lot Data (RVAL-1, RVAL-2, CoA 250618-01)

Test / Parameter	Specification	Chondroplus® (RVAL-1/2)	Chondro® (CoA 250618-01)
Appearance	Colorless, clear, viscous gel	Conform ✓	Conform ✓
Turbidity	<1 NTU	RVAL-1: 0.55 | RVAL-2: 0.56 ✓	0.55 NTU ✓
pH	Chondroplus: 6.8–7.4 | Chondro: 5.0–8.5	RVAL-1: 7.2 | RVAL-2: 7.1 ✓	6.96 ✓
Viscosity	Chondroplus: 20,000–500,000 Cp Chondro: 5–500,000 Cp	RVAL-1: 42,768 Cp | RVAL-2: 42,748 Cp ✓	21,107 Cp ✓

Osmolality	Chondroplus: 270–400 mOsm/kg Chondro: 200–350 mOsm/kg	RVAL-1: 325 | RVAL-2: 321 mOsm/kg ✓	343 mOsm/kg ✓
Density	1.010–1.030 g/cm³	RVAL-1: 1.010 | RVAL-2: 1.012 ✓	1.013 ✓
Particle Size	≤0.22 µm	<0.22 µm ✓	<0.22 µm ✓
NaHA Assay	27–33 mg/mL (±10%)	RVAL-1: 29.85 | RVAL-2: 30.19 mg/mL ✓	30.67 mg/mL ✓
CTP Assay (Chondroplus®)	9–11 mg/mL (±10%)	RVAL-1: 10.23 | RVAL-2: 10.26 mg/mL ✓	N/A
Sterility	SAL 10^{-6} (steam 121°C/15min)	Sterile ✓	Sterile ✓
Aerobic Microbial Count	≤50 cfu/g	RVAL-1: 2 | RVAL-2: 3 cfu/g ✓	3 cfu/g ✓
Bacterial Endotoxin	≤0.2 EU/mg (Chondroplus) / ≤6.66 EU/mL (Chondro)	<0.015 EU/mg ✓ (13×+ below limit)	<0.015 EU/mL ✓ (>400× below limit)
Overall Evaluation	All within specification	UYGUN / CONFORM ✓	UYGUN / CONFORM ✓

Ref: FR.TM.14.02.07 Rev.00 (Chondroplus® — RVAL-1 17.10.2025, RVAL-2 20.10.2025); FR.TM.14.01.07 Rev.04 (Chondro® — Lot 250618-01, 04.07.2025). Analysts: Arzu Şen / Okan Zeytin. Approved: Sadık Güner (Sub-Contractor PRRC).

3.2 Description of Variants and Configurations

Ref.	Product	Volume	HA (mg)	CTP (mg)	Pack. (mm)
Chondro® — Intra-Articular Linear HA					
H1	Chondro® — Linear HA 2.5%	1.0 mL	25 mg	—	156×29×15
H2	Chondro® — Linear HA 2.5%	2.0 mL	50 mg	—	156×29×15
H3	Chondro® — Linear HA 2.5%	3.0 mL	75 mg	—	156×29×15
H4	Chondro® — Linear HA 2.5%	4.0 mL	80 mg	—	195×15×33
H5	Chondro® — Linear HA 2.5%	5.0 mL	100 mg	—	195×15×33
Chondroplus® — Intra-Articular HA+CTP Peptide					
P3	Chondroplus® — HA+CTP 2%	3.0 mL	60 mg	30 mg	156×29×15
P5	Chondroplus® — HA+CTP 2%	5.0 mL	100 mg	50 mg	195×15×33
P.1.3	Chondroplus® — HA+CTP 3%	3.0 mL	90 mg	30 mg	195×15×33
P.1.5	Chondroplus® — HA+CTP 3%	5.0 mL	150 mg	50 mg	195×15×33

Primary packaging: Luer Lock 1–5 mL Borosilicate Type I Glass Syringe System. Secondary packaging: Medical Grade PET Blister with Coated Tyvek in a Carton Box. Storage: 2–25°C; do not freeze. Ref: TD.01-04 Packaging Specifications; TD.01-02 Product Information.

3.3 Accessories

The device does not contain any software. Both Chondro® and Chondroplus® are used with a standard sterile injection needle (18–22G × ½ inch, Luer-lock connection). Needles are not supplied by Reganemed

and are not considered accessories covered by this SSCP. No other accessories are supplied or required.

4.1 Residual Risks and Warnings

The following residual risks and warnings are identified in the Risk Management File (TD.01-09, ISO 14971:2019) and described in the Instructions for Use (TD.01-05):

No.	Risk / Warning
1	Re-use or reprocessing (e.g., cleaning and re-sterilization) may compromise structural integrity and/or lead to device failure resulting in patient injury, illness or death.
2	Reuse or reprocessing of single-use devices creates risk of contamination and transmission of infectious material between patients.
3	Contaminated implants must not be reprocessed. Any product contaminated by blood, tissue, or bodily fluids must be disposed of per hospital medical waste protocol.
4	Only medical professionals trained in accepted intra-articular injection techniques should administer this product.
5	Injection should be administered according to disease severity, application area volume, and physician decision. Adjust to clinical context.
6	If pain increases during injection, stop the injection and withdraw the needle immediately.
7	Patients experiencing abnormal sequelae after administration should consult their physician immediately.
8	The device should be used with 18–22G × ½ inch sterile needle (Luer-lock).
9	Syringes, needles and remaining product must be disposed of in accordance with applicable medical waste regulations.
10	Follow intra-articular injection technique with suitable angle and site of the joint space. Do not inject into glandular tissue.
11	Do not use the product if the packaging is damaged or if the expiry date has passed. Conduct visual inspection before use.
12	Patients should avoid strenuous activity or weight-bearing on the treated joint for at least 48 hours post-injection. Local rest and cold application recommended for swelling or discomfort.
13	Patients should immediately consult their physician in case of excessive joint pain (VAS ≥7), swelling, redness, persistent stiffness, or signs of infection (fever, warm joint).
14	Avoid intravascular injection. Aspiration before injection is recommended to prevent intravascular placement.
15	Chemical incompatibility with quaternary ammonium compounds (e.g., benzalkonium chloride) — may cause crystal precipitation. Do not contact with such compounds.
16	Pre-arthroplasty restriction: avoid intra-articular injection ≤3 months before total knee arthroplasty (TKA) due to time-dependent PJI risk elevation (Vicenti et al. 2024).
17	Chondroplus® in CPPD: US-guided injection recommended for patients with confirmed calcium pyrophosphate deposition for precision placement.

4.2 Adverse Reactions and Complications

Adverse Event	Observed Frequency	Data Source	Severity
Injection-site local reaction (pain/swelling/erythema)	5/90 (5.6%)	Biosan Prospective (n=90) — TD.01-13.01.03	Mild — all resolved spontaneously; no treatment required

Adverse events (all 22 IFU categories)	0/154 (0.0%)	Biosan Retrospective (n=154) — TD.01-13.01.04	None
Serious adverse events (SAE)	0/244 (0.00%) Post-market: 0/ >500,000 units	Combined clinical datasets + PMS data	None
Post-injection CPPD flare (pseudogout)	0/29 KOA+CPPD patients (0.00%)	Porta et al. 2024 (Chondroplus® direct evidence)	None — despite theoretical risk with LMW HA
Infection / septic arthritis	0% observed (class rate: 0.5–2.83% timing-related per Vicenti 2024)	All clinical datasets + literature LIT.16	Rare (class-level); 0 observed
Pre-arthroplasty PJI risk	Elevated if injection ≤3 months before TKA (time-dependent)	Vicenti et al. 2024 (LIT.16)	Addressed in contraindication and IFU warning

Full IFU adverse reaction list: Infection; Arthralgia; Arthrosis; Joint disorder; Joint swelling/effusion/ stiffness; Pain in limb; Tendonitis; Paraesthesia; Phlebitis; Pruritus; Injection site erythema/edema/pain/ reaction; Arthropathy; Baker's cyst; Bursitis; Localized/aggravated osteoarthritis; Immune response.

4.3 Residual Risk / Clinical KPI Thresholds (PMCF Plan TD.01-14.01)

Residual Risk / Clinical Scenario	KPI	Alert Threshold	Action if Exceeded
Post-injection flare / effusion	% moderate-severe pain/ swelling ≤72h	<3% per 500 injections	Risk review; lot viscosity/volume check; user training; IFU clarification
Septic arthritis / infection (30-day)	Confirmed joint infection	Any serious case OR ≥1/5,000	Immediate vigilance (MDR Art.87); FSCA assessment; CAPA
Hemarthrosis / bleeding	Clinically significant bleeding	<1% per 500 injections	Review contraindication screening; update IFU warnings; CAPA
Post-injection pseudogout (CPPD flare)	Rate of acute synovitis-like reaction ≤72h	<0.5% per 500 injections	Material/lot investigation; review HMWHA+CTP formulation; CAPA
Hypersensitivity / allergy	Immediate or delayed hypersensitivity	Any serious case OR ≥2/1,000	Vigilance + medical evaluation; update contraindications if needed
Extra-articular injection / misplacement	Documented mis-injection	<0.5% per 500 injections	Technique audit; targeted training; IFU addendum; CAPA
Persistent/worsening pain (non-responder)	% with no clinically meaningful improvement at Day 60	≤30% of followed-up cases	Benefit-risk review; verify patient selection; PMCF analysis
SAE Rate	Overall SAE rate per patient	≥1.0% → immediate reassessment	Unscheduled benefit-risk reassessment; regulatory notification
PJI risk (pre-TKA)	Pre-operative injection ≤3M before TKA	Any confirmed PJI case	Immediate vigilance; FSCA assessment; CAPA

Packaging / sterility breach	Visible particles; seal failure; sterility fail	0 critical; ≥1/10,000 trend	Quarantine/investigate lots; FSCA if sterility compromised
Unexpected AEs (UADE)	New unlisted device-related events	≥3/12 months OR any serious	PSUR + CAPA; PMCF focus; update risk file + IFU
Non-responder rate at Month 6	PMCF registry non-responder rate	>40% at Month 6	Unscheduled benefit-risk reassessment; verify patient selection criteria

5.1 Summary of Clinical Data from Own/Equivalent Device Clinical Investigations (Primary Evidence)

[Ethics — Biosan Prospective Study: Tekirdağ Namık Kemal Üniversitesi Tıp Fakültesi Ortopedi ve Travmatoloji Anabilim Dalı Ethics Committee, Decision No: 2024.53.03.17, 26.03.2024]
[Ethics — Porta et al. 2024: 2-center retrospective study; IRB approval per institutional protocols. DOI: 10.3389/fmed.2024.1437160]

Source	Design	Population	Intervention	Duration	Key Outcomes
CHONDRO® — via Biosan Hyarelief® (MDR Art.61(5) Formal Equivalent; Full Access Agreement 01.02.2025)					
Biosan Prospective Study (TD.01-13.01.03) — Karaca & Kaval 2026	Open-label, Phase IV, single-center, prospective	n=90, KL Grade III, adults (24–88y), Tekirdağ Namık Kemal U.	Single IA injection of 2% linear NaHA (2 mL / 40 mg)	6 months (BL/ D30/D60/D90/ D120/D150/ D180)	VAS ↑83.2% at D90; WOMAC ↑57.8% at D120; 0 SAE; 5/90 mild local AEs
Biosan Retrospective Multicenter Study (TD.01-13.01.04)	Retrospective, multicenter (3 centers)	n=154 (Istanbul ×2, Kocaeli ×1)	IA injection of linear NaHA per clinical practice	Retrospective (released 10.02.2025)	0/154 AEs across all 22 IFU categories; ROC AUC=1.000; KL Grade sole predictor
Post-market sales/ vigilance registry	Prospective observational (PMS registry)	>500,000 units distributed (2020–2026)	Routine IA-HA in clinical practice	2020–2026 (6 years)	SAE rate: 0.00%; 0 FSCAs; 0 vigilance notifications; 0 recalls
CHONDROPLUS® — Direct Clinical Evidence + SoTA Comparator					
Porta et al. 2024 (Front Med. 11:1437160) — PRIMARY direct evidence	Retrospective 2-center observational	n=29 patients/ 34 knees; KOA+CPPD; KL II–IV (48.4% KL IV)	Single IA injection HMWHA+CTP (Chondroplus® composition)	6 months (1M/ 3M/6M assessments)	NRS: 5.4→1.7 (↑68.5%, p<0.05); WOMAC: 86.1→28.1 (↑67.4%, p<0.05); 79% NRS MCDI; 83% WOMAC MCDI; 0 SAE; 0 CPPD flare
Stagni et al. 2021 — BMC Musculoskel 22:773 (PLIT.03) PNHA (polynucleotide+HA) vs HA alone	Randomized double-blind RCT	n=98 enrolled, 79 completed 2yr; KL 2–3; age 51–74y	3 weekly injections PNHA vs HA alone	24 months	PNHA > HA: WOMAC pain p=0.0006 at 2M; ~16% WOMAC advantage sustained 2yr; 0 AEs; validates HA+bioactive combination principle

Heisel & Förster 2012 (OUP 2012;1:459) — SoTA comparator Condrotide® (chemical equivalent to Chondroplus® per 3 TÜRKAK labs)	Prospective multicenter observational	n=110/549 injections, 11 centers	IA polynucleotide+HA gel (Condrotide®)	8 weeks	VAS ↑36–42%; 89% patients "better/much better"; 0 SAE; validates HA+bioactive safety profile
Cattarini Mastelli 2015 (US Patent 9,220,734 B2) — SoTA RCT Condrotide® vs HA alone	RCT (n=60)	n=60 knee OA patients	Condrotide® vs HA alone	T16 follow-up	KOOS superiority at T16; sport/rec scale +14.55 vs HA reversion; NSAI reduction from T1; 0 SAE

Condrotide® SoTA equivalence note: Condrotide® is NOT a formal MDR Art.61(5) equivalent device for Reganemed — no contractual access agreement has been established. It is used as a SoTA comparator for Chondroplus® only, based on: (1) 3 TÜRKAK-accredited laboratory chemical equivalence reports confirming Chondroplus® ≡ Condrotide® by SEC-MALLS, FTIR, CD, UV-VIS, SEM (SU-IMC 2020, YÜ-AGAM 2020, Niğde ÖHÜ 2020); (2) Publicly available clinical data. Ref: LIT.21/22/23/24/25.

Safety Outcomes Summary

Study	n	Serious AEs	Non-serious AEs
Biosan Prospective (Chondro® equivalent)	90	**0 (0.00%)**	5 (5.6%) mild injection-site reactions — resolved spontaneously
Biosan Retrospective (Chondro® equivalent)	154	**0 (0.00%)**	0 (0.00%) — ALL 22 IFU AE categories = ZERO
Porta et al. 2024 (Chondroplus® direct)	29 patients / 34 knees	**0 (0.00%)**	0 (0.00%) — 0 CPPD flare; 0 immune response
Heisel & Förster 2012 (Chondroplus® SoTA)	110 patients / 549 injections	**0 (0.00%)**	8/110 mild technique-related (7.3% per patient; 1.5% per injection)
Post-market PMS (Chondro®)	>500,000 units	**0 (0.00%)**	0 FSCAs; 0 vigilance; 0 recalls
COMBINED CLINICAL (controlled)	388 patients	**0 (0.00%) — Upper 95% CI: <0.95%**	≤5.6% mild local, all self-resolving

Performance Outcomes — Chondro® (Biosan Hyarelief® Prospective n=90)

Visit	Mean VAS	WOMAC (normalized 0–1)	VAS Improvement	WOMAC Improvement
Baseline	6.33±1.01	0.733±0.099	—	—
Day 30	—	0.598±0.088	—	18.4%
Day 60	—	0.489±0.081	—	33.3%
Day 90	1.06±0.90	0.418±0.073	83.2% ↑	42.8%
Day 120	—	0.309±0.066	—	57.8% ↑
Day 150	—	0.325±0.069	—	55.7%
Day 180	1.18±0.94	0.323±0.069	81.4% ↑	55.9%

Statistical significance: VAS — LMM $F(7,521.304)=263.319$, $p<0.001$. WOMAC — LMM $F(7,582.502)=1054.539$, $p<0.001$. All time-points from D30 through D180 statistically significant.

Retrospective study (n=154): Baseline WOMAC 48.44±4.76; VAS 8.57±0.60; Lequesne 13.66±1.78. KL Grade sole significant predictor (WOMAC $R^2=0.837$; VAS $R^2=0.860$). ROC AUC=1.000 (100% sensitivity/specificity). 0 AEs across all 22 IFU categories.

Performance Outcomes — Chondroplus® (Porta et al. 2024 n=29/34 knees)

Outcome	Baseline	6 Months	Result
NRS Pain Score (0–10)	5.4±1.9	1.7±2.5 ($p<0.05$)	↑68.5% — 79% achieved NRS MCDI (≥2 points) ✓
WOMAC Total Score	86.1±47.4	28.1±46.9 ($p<0.05$)	↑67.4% — 83% achieved WOMAC MCDI (≥10 points) ✓
SAE Rate	—	0/29 patients (0.00%)	EXCEEDS 0% target ✓
Post-injection CPPD flare	—	0/29 CPPD patients (0.00%)	0 pseudogout events despite theoretical risk ✓
KL IV patients (48.4% of cohort)	KL IV n=15/29	Clinically meaningful outcomes in all	First evidence of HMWHA+CTP in KL IV OA+CPPD ✓

Benefit-Risk Determination

	Chondro® (Linear HA)	Chondroplus® (HA+CTP)
BENEFITS	• VAS pain reduction: 83.2% at Day 90 ($p<0.001$) • WOMAC functional improvement: 57.8% at Day 120 ($p<0.001$) • Rescue medication: reduced from ~63% to 14.4% at Day 180 • Lequesne index: significant improvement at all time-points • Durable effect: sustained through 6-month follow-up	• NRS pain reduction: 68.5% at 6 months ($p<0.05$) • WOMAC functional improvement: 67.4% at 6 months ($p<0.05$) • MCDI: 79% NRS / 83% WOMAC • Chondroprotection via Gly-X-Y CTP (CB-5): type II collagen synthesis stimulation • Effective in KL IV (48.4% of cohort) and OA+CPPD (0 flare)
RISKS	• Mild local reactions: 5.6% (5/90, all resolved spontaneously) • No systemic or serious adverse events (0.00% SAE across n=244 + >500,000 units) • Class-level residual risk: septic arthritis (0.5–2.83% timing-related per literature) — 0% observed • Pre-TKA PJI risk addressed in contraindications and IFU	• 0 adverse events (0/29 Porta 2024: 0/34 knees) • 0 CPPD flare despite all patients having confirmed CPPD • Theoretical pseudogout risk with LMW HA — NOT observed with HMWHA+CTP • Pre-TKA PJI risk addressed in contraindications and IFU
CONCLUSION	**STRONGLY POSITIVE ✓**	**STRONGLY POSITIVE ✓**

5.2 Summary of Clinical Data from PMCF Studies

Source	Design	Population	Duration	Outcomes

Post-market PMS & vigilance registry **(TD.01-14.02 PMCF Report)**	Prospective observational (continuous PMS)	>500,000 units distributed (2020–2026)	2020–2026 (6 years)	SAE rate: 0.00%; 0 FSCAs; 0 vigilance notifications; 0 recalls. Consistent with clinical study findings.

5.3 Summary of Clinical Data Related to Equivalent Devices and SoTA Comparators

Criterion	Biosan Hyarelief® — FORMAL EQUIVALENT (Art.61(5))	Condrotide® — SoTA COMPARATOR (Chondroplus® only)
Role in CER	Formal equivalent device — full contractual access (01.02.2025). Evidence directly transferable to Chondro® and Chondroplus® HA component.	SoTA comparator for Chondroplus® peptide component only. Not formal equivalent. Public data + 3 TÜRKAK lab reports.
Access Level	FULL ACCESS — Agreement TD.01-13.01.01 (01.02.2025) Technical file, clinical data, QMS, post-market data	PUBLIC DATA ONLY Published literature + 3 TÜRKAK lab chemical characterization reports commissioned by Reganemed
Equivalence Basis (Technical)	Same active substance (linear HMWHA, 1.0–2.5 MDa, Bloomage Corp.); same route; same packaging; same sterilization; SEC-MALLS confirmed (SU-IMC 2020)	Chemical equivalence: SEC-MALLS, FTIR, CD, UV-VIS, SEM — "Chondroplus ≡ Condrotide" (SU-IMC report C03-2010-006)
Clinical Performance	Prospective n=90: VAS ↑83.2%, WOMAC ↑57.8%, 0 SAE Retrospective n=154: 0 AEs Post-market >500,000 units: SAE 0.00%	Heisel & Förster 2012 (n=110/549 injections, 11 centers): VAS ↑36–42%; 89% improvement; 0 SAE Cattarini Mastelli 2015 RCT (n=60): KOOS T16 superiority vs HA; 0 SAE
Conclusion	EQUIVALENT — full evidence transferable Chondro® ≡ Biosan Hyarelief® (all dimensions: technical, biological, clinical)	SoTA COMPARATOR ONLY — NOT formal equivalence Chondroplus® chemical structure ≡ Condrotide® (confirmed by 3 labs); clinical class evidence applicable as SoTA reference

5.4 Summary of Literature-Based Clinical Data

A systematic literature review was conducted per MEDDEV 2.7/1 Rev.4, PICO framework, and PRISMA guidelines. Databases: PubMed/MEDLINE, Cochrane CENTRAL, ClinicalTrials.gov. 2,403 records identified; 32 studies included after PRISMA-compliant screening (LIT.01–25 + PLIT.01–07). All clinical studies met NOT scoring thresholds (D1≥10, D2≥9).

Key systematic literature findings: IA-HA provides VAS reduction 30–40% and WOMAC improvement 20–30% within 3–6 months (SoTA benchmark, Baron 2018 ART-ONE 75, n=199); responder rate >86% from D60 (OMERACT-OARSI, ART-ONE 75); SAE rate not statistically different from saline (Brandt 2001, n=226); EUROVISCO 2024 consensus endorses IA-HA across ages and comorbidities; Chitnis 2019 real-world (n=29,076): NSAID −9%, CS −60%, opioid −7% use reduction. IA-HA+bioactive combinations (Stagni 2021 PNHA; Xu 2021 PRP+HA) demonstrate additional anti-inflammatory and functional benefit. HMWHA (Ishijima 2022, n=200) shows distinct cartilage-stimulating mechanism (CTX-II biomarker). Full literature synthesis in CER TD.01-13.01 Rev.02 Sections 5.47–5.51.

5.5 Clinical Data from PMCF Studies

Study Name	Post-Market Clinical Follow-Up for Chondro® and Chondroplus® (Reganemed)
Conducted Under	MDR 2017/745
CIV-ID	None (non-interventional registry)
Study Design	Prospective, multicenter, observational registry (≥100 patients/year, ≥3 centers, ≥2 EU countries)
Primary Endpoints	NRS at 1, 3, 6, 12 months (MCID ≥2 pts); WOMAC at 1, 3, 6, 12 months (MCID ≥10 pts); SAE rate; Non-responder rate at Month 6
Secondary Endpoints	PGIC; Analgesic/NSAID use change; Repeat injection rate; Chondroplus® OA+CPPD subgroup; KL Grade IV subgroup
First PMCF Report	October 2026 (TD.01-14.02)
Participating Sites (planned)	Turkey (≥3 centers); target EU countries: Germany, Austria, Netherlands, Belgium, Spain, Romania
EUDAMED Upload	Planned upon PMCF report completion — TD.01-14.02

Outcome Measure	Result	Statistical Significance	Assessment vs Target
CHONDRO® — PRIMARY PERFORMANCE AND SAFETY			
VAS Pain Reduction (Day 90)	83.2% ↓ (6.33→1.06)	p<0.001; F(7,521.304)=263.319	Exceeds ≥30–40% target ✓
WOMAC Improvement (Day 120)	57.8% ↑ (0.733→0.309)	p<0.001; F(7,582.502)=1054.539	Exceeds ≥20–30% target ✓
Lequesne Index	Significant at all time-points	p<0.001 all visits	Clinical improvement confirmed ✓
Rescue Medication (Day 90)	Reduced to 14.4% (from ~63%)	Clinically meaningful	↓ analgesic burden ✓
Duration of Effect	Sustained through 6 months (all visits significant)	p<0.001 at all time-points	Meets ≥12 week target ✓
Responder Rate	ROC AUC=1.000 (retrospective); LMM all time-points significant	p<0.001	Exceeds ≥60% threshold ✓
SAE Rate	0.00% (0/244 + >500,000 units)	Upper 95% CI: <0.95%	Well below 1% alert threshold ✓
AE Rate (retrospective)	0.00% (all 22 IFU categories)	—	Exceeds ≤5.6% benchmark ✓
CHONDROPLUS® — PRIMARY PERFORMANCE AND SAFETY			
NRS Pain Reduction (6 months)	68.5% ↓ (5.4→1.7)	p<0.05; Porta 2024	Exceeds ≥30–40% target ✓
WOMAC Improvement (6 months)	67.4% ↑ (86.1→28.1)	p<0.05; Porta 2024	Exceeds ≥20–30% target ✓
NRS MCDI (≥2 pts)	79% of patients	—	Exceeds ≥60% threshold ✓
WOMAC MCDI (≥10 pts)	83% of patients	—	Exceeds ≥60% threshold ✓
SAE Rate	0.00% (0/34 knees + 0/110 Heisel)	—	Meets 0% target ✓
AE Rate (Porta 2024)	0.00% (0/29 patients)	—	Exceeds ≤5.6% benchmark ✓
CPPD flare rate	0.00% (0/29 CPPD patients)	—	0 pseudogout despite CPPD diagnosis ✓
KL IV evidence	48.4% of cohort — clinically meaningful outcomes	—	First HMWHA+CTP evidence in KL IV OA+CPPD ✓

Overall Benefit-Risk Conclusion

BENEFIT-RISK ASSESSMENT — OVERALL CONCLUSION

Chondro® (Linear HA): Based on the totality of evidence — Biosan Hyarelief® prospective (n=90, VAS ↑83.2%, WOMAC ↑57.8%, 0 SAE), retrospective (n=154, 0 AE), post-market (>500,000 units, SAE 0.00%), 32 literature sources, full technical file access (01.02.2025), and validated lot data (RVAL/CoA) — the benefit-risk profile is STRONGLY POSITIVE. Benefits substantially exceed risks. All predefined acceptance criteria met.

Chondroplus® (HA+CTP Peptide): Based on direct clinical evidence (Porta 2024: n=29/34 knees, NRS ↑68.5%, WOMAC ↑67.4%, 79–83% MCDI, 0 SAE, 0 CPPD flare including KL IV), SoTA comparator evidence (Condrotide® n=110 0 SAE; n=60 RCT KOOS superiority), pre-clinical mechanism (Naraoka 2013 dual-pathway), and 3-laboratory chemical equivalence — the benefit-risk profile is STRONGLY POSITIVE. Chondroplus® demonstrates a unique clinical profile extending HA-alone viscosupplementation into OA+CPPD and KL IV populations.

Neither Chondro® nor Chondroplus® has any discrepancies between the SSCP, CER (TD.01-13.01 Rev.02), and CEAP (TD.01-13.02 Rev.01).

Intended User	Orthopedic surgeons, rheumatologists, or physicians specifically trained and qualified in intra-articular injection techniques for synovial joint spaces.
Training Requirement	Competence required in: (a) IA joint anatomy; (b) Aseptic injection technique; (c) Effusion aspiration; (d) Identification of contraindications. Ref: IFU TD.01-05 §5.21; EUROVISCO 2024.
Setting	Outpatient clinic or hospital with appropriate sterile conditions.
Contact Points	Synovial fluid (direct); Synovial membrane (direct, >30d); Articular cartilage (direct, >30d); Joint cavity (intra-articular space); Surrounding connective tissues (non-vascularized). No contact with bloodstream, mucosa, or CNS.
Contact Category	Long-term implant (>30 days) per ISO 10993-1

7.1 Planned Markets and SSCP Languages

Planned EU Markets (initial)	Germany (DE) | Austria (AT) | Netherlands (NL) | Belgium (BE) | Spain (ES) | Romania (RO)
SSCP Language Availability	EN (master/reference) | DE | NL | ES | RO — controlled translations per TL.01.01 Translation Instruction (ISO-17100 supplier; PRRC technical verification; document coding; revision control; EUDAMED upload logging)
Document Coding & Traceability	TD.01-13.07-EN (Master) | TD.01-13.07-DE | TD.01-13.07-NL | TD.01-13.07-ES | TD.01-13.07-RO
Upload Records	Translator declarations retained in QMS; public versions uploaded to EUDAMED upon NB validation
Statement for Auditors	The SSCP is provided in the official languages of all EU Member States where the device is marketed, with EN as the master. All translations controlled under TL.01.01 and uploaded to EUDAMED.

Common Specifications: There is currently NO applicable Common Specification (CS) published under MDR 2017/745 for sterile intra-articular hyaluronic acid gel implants (EMDN P900402; Class III Rule 8). This is confirmed as of 15.02.2026. Therefore, no CS applies to Chondro® or Chondroplus®.

Group	Document No.	Document Name
Management Systems		
Management Systems	EN ISO 13485:2016	Medical Devices — Quality Management Systems
Management Systems	EN ISO 14971:2019	Medical Devices — Application of Risk Management
Management Systems	ISO/TR 24971:2020	Guidance on the Application of ISO 14971
Biocompatibility		
Biocompatibility	EN ISO 10993-1:2018	Biological Evaluation — Part 1: Evaluation and Testing
Biocompatibility	EN ISO 10993-5:2009	Part 5: Tests for In Vitro Cytotoxicity
Biocompatibility	EN ISO 10993-10:2023	Part 10: Tests for Irritation and Skin Sensitization
Biocompatibility	EN ISO 10993-11:2017	Part 11: Tests for Systemic Toxicity
Biocompatibility	EN ISO 10993-17:2023	Part 17: Toxicological Risk Assessment
Biocompatibility	EN ISO 10993-18:2020	Part 18: Chemical Characterization (incl. YÜ-AGAM report, SU-IMC report)
Sterilization & Microbiology		
Sterilization	ISO 17665-1:2024 / EN ISO 17665-1:2006	Sterilization — Moist Heat — Part 1 (SAL 10^{-6})
Sterilization	EN 556-1:2009	Sterilization — Requirements for "Sterile" Designation
Microbiology	EN ISO 11737-1:2018/A1:2021	Sterilization — Microbiological Methods — Part 1 (Bioburden)
Microbiology	ISO 11737-2:2019	Part 2: Tests of Sterility
Packaging & Shelf Life		
Packaging	EN ISO 11607-1:2020	Packaging for Terminally Sterilized Medical Devices — Part 1
Packaging	EN ISO 11607-2:2020	Packaging for Terminally Sterilized Medical Devices — Part 2
Stability	ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems
Seal Testing	ASTM F88M-23	Standard Test Method for Seal Strength of Flexible Barrier Materials
Cleanrooms		
Cleanrooms	EN ISO 14644-1:2015	Cleanrooms — Part 1: Classification of Air Cleanliness

Cleanrooms	EN ISO 14644-2:2015	Part 2: Specifications for Testing and Monitoring
Cleanrooms	BS EN 17141:2020	Cleanrooms — Biocontamination Control
Labelling & IFU		
Labelling	EN ISO 15223-1:2021	Medical Devices — Symbols to be Used with Medical Device Labels
IFU	EN ISO 20417:2021	Medical Devices — Information to be Supplied by the Manufacturer
Clinical Evaluation & PMS Guidance		
Clinical	MEDDEV 2.7/1 Rev.4	Clinical Evaluation: A Guide for Manufacturers and Notified Bodies
PMS	MEDDEV 2.12/1 Rev.8	Medical Devices Vigilance System
PMCF	MEDDEV 2.12/2 Rev.2	Post-Market Clinical Follow-up Studies
MDCG	MDCG 2019-9 Rev.1	SSCP — A Guide for Manufacturers and Notified Bodies
MDCG	MDCG 2020-5	Clinical Evaluation — Equivalence
MDCG	MDCG 2020-6	Sufficient Clinical Evidence for Legacy Devices
MDCG	MDCG 2020-7	PMCF Plan Template
MDCG	MDCG 2020-8	PMCF Evaluation Report Template
MDCG	MDCG 2021-24	Guidance on Classification of Medical Devices
MDCG	MDCG 2023-3	Q&A on Vigilance Terms and Concepts under MDR

Rev.	Date	Change Description	NB Validated
00	01.10.2024	First Issue	□ Pending
01	15.02.2026	Full Rev.01 — Reganemed-specific content replacing placeholder data. CEAR NC-02–12 all addressed. Equivalence: Biosan Hyarelief® Art.61(5) only; Condrotide® repositioned as SoTA comparator only; Orthovisc®/KD® removed from equivalence claims. Clinical evidence: Biosan n=90+154 + Porta 2024 (Chondroplus® direct) + PLIT.01–07 (32 total sources). RVAL-1/2/CoA lot data integrated. GSPR traceability matrix. Benefit-risk with predefined thresholds. PMCF framework with statistical plan.	□ Pending NB 2764

IMPORTANT: This Summary of Safety and Clinical Performance (SSCP) provides public access to an updated summary of the main aspects of the safety and clinical performance of the device. This patient section is intended for patients or lay persons. A more comprehensive summary for healthcare professionals is found in the first part of this document. This SSCP is NOT intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional if you have questions about your medical condition or the use of this device. This SSCP does not replace the Implant Card or the Instructions For Use.

What are Chondro® and Chondroplus®?

Chondro® and Chondroplus® are sterile gel implants injected directly into your knee joint. They contain hyaluronic acid (HA) — a substance that naturally occurs in your joints — which acts as a lubricant and shock absorber, helping to reduce pain and improve knee movement.

Chondroplus® contains an additional synthetic ingredient called collagen tripeptide (CTP), which may also help protect your cartilage by stimulating its natural repair processes.

Both products are manufactured by Reganemed GmbH (France) and produced by Biosan Biyoteknoloji (Turkey), are single-use (one injection per syringe), and are supplied in a pre-filled syringe.

Who are these products for?

Chondro® and Chondroplus® are intended for adults (≥18 years) with mild to moderate knee osteoarthritis (Grade II or III on the Kellgren-Lawrence scale) who have not had sufficient relief from standard treatments such as painkillers or physiotherapy. Chondroplus® may also be suitable for patients with more advanced OA (Grade IV) or with a condition called calcium pyrophosphate deposition (CPPD), based on clinical study evidence.

How are they used?

Both products are injected directly into the knee joint by a trained orthopedic doctor or physician qualified in joint injection technique. The injection takes only a few minutes. Each syringe is for single use only.

What are the expected benefits?

- Significant reduction in knee pain — in clinical studies, patients reported an average 83% reduction in pain scores (Chondro®) and 69% reduction (Chondroplus®) after 3–6 months.
- Improved knee function — patients showed approximately 58% (Chondro®) and 67% (Chondroplus®) improvement in physical function scores.
- The benefit typically lasts 3–6 months or longer.
- Reduces the need for pain-relief medications (e.g., NSAIDs).
- Chondroplus®: effective even in patients with calcium pyrophosphate crystal deposits in the knee — no flare-ups observed in 29 patients in the clinical study.

What are the possible risks and side effects?

Both products have been shown to be safe in clinical studies:

- Chondro® (via equivalent device Biosan Hyarelief®, n=90): 5 patients (5.6%) experienced mild, temporary pain or swelling at the injection site — all resolved on their own without treatment. No serious side effects in any patient.
- Chondroplus® (Porta et al. 2024, n=29 patients): 0 adverse events of any kind. 0 serious side effects. 0 pseudogout flares even in patients with CPPD.
- In a larger real-world study of 154 patients across 3 hospitals (Chondro® equivalent): no adverse events of any kind (0 events in all 22 safety categories).

Possible side effects listed in the product instructions include: injection-site pain, swelling, redness, stiffness, joint discomfort, and — very rarely — infection. Contact your doctor immediately if you experience fever, severe pain, or signs of infection.

Who should NOT use these products?

Do NOT use if you have:

- An active knee or skin infection

- An allergy to hyaluronic acid or bacterial proteins
- A bleeding disorder
- If you are pregnant or breastfeeding
- An active inflammatory joint disease (e.g., rheumatoid arthritis flare)
- Received a corticosteroid (steroid) injection in the same knee within the last 2 months, or another HA injection within the last 6 months
- A planned knee replacement surgery within the next 3 months

Always inform your doctor of all allergies and health conditions before treatment.

Further Information

Manufacturer	Reganemed GmbH | Rue des Couteriaux, 58180 Marzy, France
Sub-Contractor (Production)	Biosan Biyoteknoloji A.Ş. | TÜBİTAK Gebze Yerleşkesi, Gebze/Kocaeli, Turkey
Phone / E-mail	+90 533 439 38 56 | info@reganemed.com.tr
Website	https://reganemed.com.tr/
Document	SSCP TD.01-13.07 Rev.01 | 15.02.2026
Linked CER	Clinical Evaluation Report TD.01-13.01 Rev.02 | 15.02.2026
EUDAMED	Document will be available on EUDAMED upon NB 2764 validation