

YAKSU MEDICAL RESEARCHER — ENGLISH FACT SHEET (INJECTABLES ONLY)

REJURAN PN intradermal medical-device family — PharmaResearch Co., Ltd. (Republic of Korea)

Cut-off: 24 September 2026 (KST). Companion to rejuran.md. Not an IFU. Cosmetics / topicals / SYNERGE vial kits EXCLUDED.

1. Identity

Manufacturer: PharmaResearch Co., Ltd. Domestic IFU manufacturing address: **77-19, Gwahakdanji-ro, Gangneung-si, Gangwon-do, Korea.** EN: <https://pharmaresearch.com/en/> — authenticity: <https://rejuran.co.kr/>

Class: Polynucleotide sodium (PN) intradermal tissue-restoration medical device. Not cross-linked HA volumising filler; not FDA-approved drug. Manufacturer distinguishes injectable PN from pharmaceutical/cosmetic PDRN / c-PDRN.

Exclude: REJURAN Cosmetics, Healing Cream, Scalp Ampule, SYNERGE Skin/Tone-up/Hair Booster kits.

2. Official injectable SKUs

SKU	Pack	Composition	Label / storage
REJURAN (Healer)	2 cc x 2 syringes/pack (EN). IFU model M2-001: 2 syr/box	PN	Temporary facial wrinkle improvement (adults). 1-30 C shade; 24 months (IFU)
REJURAN i	1 cc x 1 (EN). IFU model M2-002: 1 syr/box	PN	EN card: eye/perioral/neck/decollete/hands. Same IFU family. 1-30 C
REJURAN s	1 cc x 1 (EN). IFU model M2-003: 1 syr/box	PN	Temporary facial wrinkle improvement (EN). Marketing scars/viscosity = claim. 1-30 C
Rejuran HB plus	1 mL x 1 (EN). TH brand: +33G needle, 1 blister/box	PN + HA + Lidocaine HCl	Crow's feet temporary improvement (KR/TH narrative). Store 2-8 C

MFDS: Rejuran / i / s IFU licence **Jeoheo 14-825** (Dec 2024 IFU DB0229(02)). HB Plus: MFDS approval 2021 (Korea Biomedical Review 3 Aug 2021); English licence number not independently verified.

Concentration: Peer-reviewed Rejuran PN often cited at **20 mg/mL** (Lee PMID 32248707; systematic-review tables). Manufacturer EN HTML cards do not print mg/mL. HB Plus (rejuranth.com): PN **10** + HA **10** + lidocaine HCl hydrate **3** mg/mL. Do not invent G'.

3. Technology (claims)

DOT (DNA Optimizing Technology): patented salmon-germ-cell DNA fragment optimisation — manufacturer claim. Regenerative / collagen marketing language = claims, not IFU indication substitute.

4. Regulatory

Korea: Medical device Jeoheo 14-825 (Rejuran/i/s). HB Plus approved 2021.

EU CE MDR: Korea Biomedical Review 27 Dec 2024 — CE MDR for Rejuran, Rejuran i, Rejuran s. VIVACY EN: Class III CE marking (NB digit CE 2265). DoC/serial/EUDAMED Basic UDI-DI: not independently verified. HB Plus CE in same announcement: not independently verified.

USA FDA: Injectable not approved/cleared. Company device-pathway intent; media ~2031-2032 (Edaily 27 Aug 2026). MoCRA cosmetics ≠ injectable clearance. Flag false FDA-approved Rejuran injectable reseller claims.

5. Clinical evidence (PMID)

- Pak et al. JKMS 2014 PMID **25473210** PMC4248006 — n=72 crow's feet — RETRACTED 2016 (funding/COI). Do not use efficacy for marketing.
- Lee et al. J Dermatolog Treat 2022 PMID **32248707** — RCT split-face n=27; Rejuran PN 20 mg/mL vs HA; 3x q2wk periorcular; mild AEs ~3.7% each erythema/pruritus/irritation (sysreview table).
- Kim et al. Aesthetic Plast Surg 2022 PMID **35357558** — PN 20 mg/mL crow's feet n=30 (28 completed); 4x q2wk.
- Park et al. Dermatol Ther 2016 PMID **26814448** — long-chain PN case series n=5.
- Jeong et al. J Cosmet Dermatol 2020 PMID **31680395** — PCL vs PN crow's feet RCT n=29.
- Lampridou et al. J Cosmet Dermatol 2025 PMID **39645667** PMC11845969 — sysreview 9 studies n=219; notes Pak retracted. PROSPERO CRD42024588712.

Duration months (distributor "6-12 months"): not independently verified from IFU — do not print as labelled duration.

6. Safety (IFU Rejuran/i/s)

C/I: non-absorbable/recent filler sites; NSAID/anticoagulant/immunosuppressant users; allergic/autoimmune/sarcoid/Osler endocarditis; no intravascular injection; hypersensitivity to polynucleotide sodium; pregnancy/lactation; minors; inflamed/infected skin. AEs: local inflammation up to ~1 week; nodules; discoloration; lack of effect. Post-care: no makeup 12 h; avoid prolonged sun/UV/cold/heat ~2 weeks. Vascular caution. Lips S/E not established. HB Plus: also lidocaine/amide LA and mannitol allergy C/I (TH brand page).

7. POSTER-SAFE ONLY

- PharmaResearch Korea — PN injectable medical-device skin booster (not HA filler; not toxin)
- SKUs: REJURAN 2x2 cc; REJURAN i 1x1 cc; REJURAN s 1x1 cc; Rejuran HB plus 1x1 mL (PN+HA+lidocaine)
- MFDS Jeoheo 14-825 — temporary facial wrinkle improvement in adults (Rejuran/i/s IFU)
- CE MDR for Rejuran / i / s (company/KBR Dec 2024) — print CE MDR; do not invent certificate serial
- Storage: Rejuran/i/s 1-30 C; HB Plus 2-8 C; shelf life 24 months (classic IFU)
- Classic line PN often cited 20 mg/mL in peer-reviewed papers; HB Plus 10+10+3 mg/mL (TH brand site)

8. DO NOT PRINT

FDA-approved injectable / PMA / 510(k); MoCRA as injectable clearance; invented CE serials; G'/Pascal/BDDE; duration months without IFU/trial cite; RETRACTED Pak efficacy numbers; injectable as PDRN drug; cosmetics as injectable; grey-market leaflets; local-market-only distributor brands outside GLOBAL English scope.

9. Key URLs

<https://pharmaresearch.com/en/product/list.html?code=2>
<https://rejuran.co.kr/manual/RJR.pdf>
<https://www.koreabiomed.com/news/articleView.html?idxno=26154>
<https://www.koreabiomed.com/news/articleView.html?idxno=11811>
<https://vivacy.com/en/rejuran-korea-leading-skin-booster>
https://rejuranth.com/product_rejuran/rejuran-hb-plus/

<https://en.edaily.co.kr/news/eda202608275176/>
<https://pubmed.ncbi.nlm.nih.gov/25473210/> (RETRACTED)
<https://pubmed.ncbi.nlm.nih.gov/32248707/>
<https://pubmed.ncbi.nlm.nih.gov/35357558/>
<https://pubmed.ncbi.nlm.nih.gov/39645667/>

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