This Technical Data Sheet (TDS) is enclosed inside the product carton box. Clinicians, pharmacists, and patients are advised to retain this sheet for reference during the course of use. For detailed prescribing, monitoring, and clinical guidance, refer to the full TDS included with every unit of Keto Nephron™ SS and DS.

Esta Ficha Técnica del Producto (TDS) está incluida dentro de la caja del producto. Se recomienda conservarla como referencia durante el tratamiento. Para orientación clínica detallada, consulte la ficha técnica completa incluida en cada unidad de Keto Nephron™ SS y DS.

1 PRODUCT CLASSIFICATION

Keto Nephron™ is classified as a **Medical Food** as defined under **21 U.S.C. §360ee(b)(3)**. It is a specially formulated and processed product — not a naturally occurring foodstuff — intended for oral administration only, under active physician supervision.

No NDC number. No "Rx only" designation. No disease treatment claims.

2 REGULATORY STATUS

Medical Food per 21 U.S.C. §360ee(b)(3) & FDA Medical Food Guidance (3rd Ed., 2023). Manufactured in a cGMP-compliant facility (21 CFR Part 111). FSMA Preventive Controls compliant (21 CFR Part 117). FDA Food Facility Registered. Halal Certified. Free from major food allergens as defined by the U.S. FDA (FALCPA).

Product Variants — Single Strength (SS) vs. Double Strength (DS)

FEATURE	SS — SINGLE STRENGTH	DS — DOUBLE STRENGTH
Strength per tablet	Standard (1×) — equivalent to reference formulation	Double (2×)
Dosing basis	**1 tablet / 11 lb IBW/day**	**1 tablet / 22 lb IBW/day**
Tablets/day (70 kg)	**14 tablets/day**	**7 tablets/day**
Calcium per tablet	~50 mg (1.25 mmol)	~100 mg (2.50 mmol)
Nitrogen per tablet	36 mg	72 mg
Target patient	Standard initiation; titration flexibility	Established dose; high tablet burden; compliance challenges

Both strengths deliver identical total daily active ingredient dose when dosed per body weight. Equivalent safety and efficacy profiles.

3 INTENDED USE

"A specially formulated and processed Medical Food for the dietary management of Chronic Kidney Disease (CKD, Stages 3–5) in adults on protein-restricted diets — a condition whose distinctive nutritional requirements cannot be met by modification of the normal diet alone, as determined by medical evaluation. For use under active physician supervision. 21 U.S.C. §360ee(b)(3)· 21 CFR 101.9(j)(8)."

4 DISTINCTIVE NUTRITIONAL REQUIREMENTS

CKD Stages 3–5 patients exhibit medically established nutritional needs that cannot be met by normal diet: impaired protein/nitrogen metabolism → ↑BUN; protein-energy wasting (PEW); intolerance to standard dietary protein; metabolic acidosis → muscle catabolism; hyperphosphatemia → secondary hyperparathyroidism (CKD-MBD); insufficient EAA availability on VLPD.

(KDIGO 2024 Practice Point 3.3.1.2 · KDOQI 2020)

5 COMPOSITION — ACTIVE INGREDIENTS PER TABLET (DESCENDING ORDER BY WEIGHT)

ACTIVE INGREDIENT (COMMON NAME)	CHEMICAL / IUPAC NAME	SS / TABLET	DS / TABLET
L-Lysine acetate	Free amino acid (≡ L-Lysine 75 mg SS / 150 mg DS)	**105 mg**	**210 mg**
α-Ketoanalogue of Leucine (Ca-salt)	Calcium (R)-4-methyl-2-oxovalerate	**101 mg**	**202 mg**
α-Ketoanalogue of Valine (Ca-salt)	Calcium 3-methyl-2-oxobutyrate	**86 mg**	**172 mg**
α-Ketoanalogue of Phenylalanine (Ca-salt)	Calcium 2-oxo-3-phenylpropionate	**68 mg**	**136 mg**
α-Ketoanalogue of Isoleucine (Ca-salt)	Calcium (RS)-3-methyl-2-oxovalerate	**67 mg**	**134 mg**
α-Hydroxyanalogue of Methionine (Ca-salt)	Calcium DL-2-hydroxy-4-(methylthio)butyrate	**59 mg**	**118 mg**
L-Threonine	Free amino acid	53 mg	106 mg
L-Histidine	Free amino acid	38 mg	76 mg
L-Tyrosine	Free amino acid	30 mg	60 mg
L-Tryptophan	Free amino acid	23 mg	46 mg
Total Calcium (via keto-analogue Ca-salts)		**1.25 mmol (50 mg)**	**2.50 mmol (100 mg)**

Both strengths are phosphorus-free and potassium-free. Inactive excipients: Microcrystalline cellulose, croscarmellose sodium, PVP, magnesium stearate, colloidal SiO2. Enteric coat (Eudragit L 30D-55), Triethyl Citrate, Talc, Titanium Dioxide (TiO2)."

6 MECHANISM OF ACTION

Keto-analogues are **nitrogen-free precursors** of essential amino acids (EAA). They undergo **transamination** — accepting amino ($-NH_2$) groups from circulating branched-chain amino acids — to form the corresponding EAA without introducing new dietary nitrogen, thereby: (1) reducing urea and BUN via **endogenous nitrogen recycling**; (2) meeting EAA needs on LPD/VLPD; (3) exerting a **phosphate-modulating effect** via calcium salt forms, correcting hyperphosphatemia and secondary hyperparathyroidism; (4) supporting metabolic acidosis correction. L-Lysine, L-Threonine, L-Histidine, L-Tyrosine, and L-Tryptophan are provided directly as free amino acids.

7 GUIDELINE ALIGNMENT

KDIGO 2024 Practice Point 3.3.1.2: Consider VLPD (0.3–0.4 g/kg/day) + EAA or keto-acid analogues for CKD patients at risk of kidney failure, under close supervision.

KDOQI 2020: Supports keto-analogue supplementation with LPD/VLPD in non-dialysis CKD (Stages 3–5) under dietitian-guided supervision.

FDA Medical Food Guidance (3rd Ed. 2023): Medical Food framework supports specialized nutritional products for diseases with distinctive, medically-determined nutritional requirements not met by normal diet modification.

8 DOSAGE & ADMINISTRATION

STRENGTH	DIET	DOSE
SS	LPD (0.6 g/kg/day)	**1 tab / 11 lb IBW / day**
DS	LPD or VLPD	**1 tab / 22lb IBW / day**

"Swallow whole — do NOT crush, chew, or split. Crushing or breaking the tablet destroys the enteric coating and allows premature gastric release, potentially reducing efficacy and increasing GI irritation."

BODY WT.	SS / DAY	DS / DAY
40 kg	8 tablets	4 tablets
50 kg	10 tablets	5 tablets
60 kg	12 tablets	6 tablets
70 kg	14 tablets	7 tablets
80 kg	16 tablets	8 tablets
90 kg	18 tablets	9 tablets
100 kg	20 tablets	10 tablets

9 CONTRAINDICATIONS

Do NOT use in: **Hypercalcemia** (without physician clearance); **Acute kidney injury (AKI)**; Metabolically unstable patients; Known hypersensitivity to any ingredient; **Patients on dialysis** (without specialist guidance); Pediatric patients under 18 years (without specialist oversight).

DS-specific: ~100 mg Ca/tablet — use with heightened caution in patients receiving active vitamin D analogs or with pre-existing hypercalcemia.

10 WARNINGS & PRECAUTIONS

Use under strict, active, ongoing medical supervision only. Ensure adequate caloric intake (≥30–35 kcal/kg/day). Monitor serum calcium regularly — SS: ~50 mg Ca/tablet (standard risk); DS: ~100 mg Ca/tablet (elevated risk, more frequent monitoring). Use caution in adynamic bone disease or concurrent active vitamin D analog therapy. Renal dietitian involvement strongly recommended (KDIGO 2024, KDOQI 2020). Not a sole source of nutrition. Not a replacement for CKD medical management. Both strengths have equivalent safety/efficacy when dosed per body weight.

11 MONITORING PARAMETERS

PARAMETER	FREQUENCY (SS)	FREQUENCY (DS)	RATIONALE
eGFR / Serum Creatinine	Every 1–3 months	Every 1–3 months	Primary marker of kidney function response
Serum Calcium ⚠	Every 1–3 months	**Every 1 month**	Hypercalcemia risk; elevated for DS (~100 mg/tab)
Serum Phosphorus	Every 1–3 months	Every 1–3 months	Phosphate-correcting benefit assessment
PTH (Parathyroid Hormone)	Every 3–6 months	Every 3–6 months	CKD-MBD and secondary hyperparathyroidism
BUN / Blood Urea Nitrogen	Every 1–3 months	Every 1–3 months	Nitrogen balance and urea reduction efficacy
Serum Bicarbonate	Every 1–3 months	Every 1–3 months	Metabolic acidosis correction
Serum Albumin / Prealbumin	Every 3 months	Every 3 months	Nutritional status (PEW surveillance)
Body weight & dietary intake	Every visit	Every visit	Caloric adequacy and protein restriction compliance

12 CLINICAL EVIDENCE SUMMARY

STUDY	KEY FINDING
Garneata et al., JASN 2016	VLPD+KA/EAA delayed dialysis vs. LPD alone (CKD 4–5)
Li A et al., NDT 2024 (Meta)	KA-supplemented LPD significantly delayed CKD progression
NDT 2025; 40(12):2372	KA-VLPD dominant strategy — better outcomes, lower costs
KDIGO 2024 PP 3.3.1.2	VLPD+EAA/KA for motivated supervised CKD patients

13 ADVERSE EFFECTS

EFFECT	FREQUENCY	MANAGEMENT
Hypercalcemia	Most reported; higher with DS	Reduce vit-D first; if persists, reduce dose or switch to SS
Nausea / GI discomfort	Occasional, transient	Take with food; temporarily reduce dose
Constipation	Occasional	Increase dietary fiber and fluid intake

14 FOR CLINICIANS & RENAL DIETITIANS

Prescribe SS for initiation and titration flexibility. Prescribe DS for established-dose patients with compliance challenges. Dietitian involvement is essential for dietary prescription, caloric adequacy (≥30–35 kcal/kg/day), and PEW surveillance. DS hypercalcemia protocol: monitor Ca monthly; prefer SS until calcium stability confirmed; reassess DS suitability. Upon dialysis transition, reassess use and dose. For reference to equivalent DS formulation globally approved under respective national regulatory frameworks.

15 REGULATORY COMPLIANCE

Medical Food Class:	✓ 21 U.S.C. §360ee(b)(3)	**Dietary Mgmt Claim:**	✓ 21 CFR 101.9(j)(8)
cGMP Compliance:	✓ 21 CFR Part 111	**FSMA Compliance:**	✓ 21 CFR Part 117
No NDC Number:	✓ Confirmed	**No Rx Designation:**	✓ Confirmed
Allergen Statement:	✓ FALCPA compliant	**Bilingual Labeling:**	✓ 21 CFR 101.15(c)(2)

Dissolution Test (USP <711> two-stage):
Stage 1 — intact after 2 hrs in 0.1N HCl; Stage 2 — ≥75% dissolved in 45 min in phosphate buffer pH 6.8

16 STORAGE & MANUFACTURING

Store below **25°C (77°F)** in a cool, dry place. Protect from direct sunlight and moisture. Keep container tightly closed after use. Do not use after expiry date on label. Keep out of reach of children.

17 MANUFACTURER INFORMATION

Manufactured by :
CLAPS Industries Pvt. Ltd. B-1202, Infinity Tower, Beside Hotel Ramada 60 Feet Road, Prahladnagar,Ahmedabad-Pin 380015,Gujarat,India.
Manufactured under cGMP in accordance with 21 CFR Part 111 and FSMA (21 CFR Part117).

Country of Origin: India

Imported by:
Quantum LifeSciences Inc.,USA.Claremont, CA 91711, USA.

Toll Free (USA & Canada) : 1-877-NEPHLON

www.NephLong.com/Keto-Nephron-DS/

Lot No.: CT263991 | Mfg. Date : 01 /2026 | Exp. Date :12/ 2027

18 KEY REFERENCES

1. FDA. Frequently Asked Questions About Medical Foods. 3rd Ed. 2023. 2. KDIGO 2024 CKD Clinical Practice Guideline. Kidney Int. 2024. PP 3.3.1.2. 3. KDOQI 2020 Nutrition in CKD Guideline. Am J Kidney Dis. 2020;76(3)Suppl 1. 4. Garneata L, et al. KA-supplemented VLPD and CKD progression. JASN. 2016;27(7):2164–76. 5. Li A, et al. Meta-analysis: KA+LPD and CKD progression. NDT. 2024. 6. Cost-effectiveness KA-VLPD. NDT. 2025;40(12):2372. 7. Fresenius Kabi. Ketosteril® SPC. 2009. [SS composition reference] 8. Alniche Lifesciences. Ketoalfa-DS CDSCO approval. Clinical evidence summary. 2024.

" For more detailed information, please refer to the enclosed product technical data sheet (TDS)."
www.NephLong.com/Keto-Nephron-DS/

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