Tri-DK Softgel

Vitamin D_3 200,000 IU +
Vitamin K_2 100mcg (As MK7)

1 SOFTGEL CAPSULE

$D_3 + K_2$
VITAMIN

1 SOFTGEL CAPSULE

ٹرائی-ڈی کے سافٹ جیل

ڈی تھری + کے ٹو وٹامن

وٹامن ڈی-۳، وٹامن کے-۲

COMPOSITION

Ingredient	Strength per Softgel Capsule	Form / Grade
Vitamin D_3 (Cholecalciferol)	200,000 IU	USP Grade
Vitamin K_2 (Menaquinone-7)	100 mcg	USP Grade (as MK7)

DESCRIPTION

Tri-DK is a combination neutraceutical softgel capsule containing two synergistic fat-soluble vitamins: Cholecalciferol (Vitamin D3)200,000 IU and Menaquinone-7 (Vitamin K2as MK7) 100 mcg. This combination has been formulated on the basis of strong scientificevidence supporting the complementary roles of Vitamin D and Vitamin K2in calcium metabolism, bone mineralisation, andcardiovascular health.

Vitamin D3(Cholecalciferol):

The naturally occurring form of Vitamin D synthesised in the skin upon exposure to UVB radiation. It is essential for intestinal calciumand phosphate absorption, bone remodelling, and immune regulation.

Vitamin K2(Menaquinone-7 / Mk7):

The long-chain, highly bioavailable form of Vitamin K2. MK7 activates osteocalcin (bone Gla protein) and matrix Gla protein (MGP),directing calcium into bones and preventing its deposition in soft tissues and arterial walls.

PHARMACOLOGY & MECHANISM OF ACTION

Synergistic Mechanism of D3+ K2:

Vitamin D3increases circulating calcium levels by enhancing intestinal absorption and promoting osteocalcin synthesis. However,without adequate Vitamin K2, elevated calcium may deposit in arteries and soft tissues. Vitamin K2(MK7) activatesecarboxylation-dependent proteins that act as calcium-routing factors, ensuring calcium is directed to bone matrix rather than vasculature-thereby combining bone-building with cardiovascular protection.

Vitamin D3Pharmacokinetics:

After oral administration, Cholecalciferol is absorbed from the gastrointestinal tract with dietary lipids. It undergoes 25-hydroxylation inthe liver to form 25-hydroxyvitamin D (25(OH)D3— the principal storage form) and subsequent 1-alpha-hydroxylation in the kidney toyield the biologically active 1,25-dihydroxyvitamin D3(Calcitriol). Calcitriol regulates calcium/phosphate homeostasis in conjunction withparathyroid hormone (PTH) and calcitonin. Elimination is primarily via bile and faecal excretion.

Vitamin K2(MK7) Pharmacokinetics:

Mk7 has the longest side chain among all menaquinones, resulting in superior bioavailability and an extended serum half-life ofapproximately 72 hours (versus less than 2 hours for Mk4). It is transported via LDL lipoproteins, reaching extra-hepatic tissuesincluding bone and vasculature. MK7 undergoes hepatic metabolism and is excreted primarily in bile.

INDICATIONS & CLINICAL USE

- Treatment and prevention of Vitamin D deficiency states: rickets, osteomalacia, osteoporosis.
- Prevention of vascular calcification and support of arterial flexibility.
- Reduction of fracture risk in post-menopausal women and the elderly.
- Adjunct therapy in hypoparathyroidism and renal osteodystrophy.
- Prevention of Vitamin D deficiency in high-risk patients: malabsorption syndromes, chronic renal/hepatic disease, patients onlong-term corticosteroids, anticonvulsants, or other drugs affecting Vitamin D metabolism.
- Dietary supplementation for immune support, muscle function, and general bone health.
- Patients with cardiovascular risk requiring calcium re-routing away from arterial walls.

DOSAGE & ADMINISTRATION

Tri-DK is for oral administration. Each softgel capsule should be swallowed whole with water, preferably with a meal containing some fatto enhance absorption of fat-soluble vitamins. Dosage is as directed by the physician. Serum 25(OH)D3levels should be checked prior to and during supplementation.

Note: Dietary and supplementary sources of Vitamin D and Vitamin K2 must be considered when determining total intake. Calcium supplementation should accompany therapy where indicated. This product is for adults; use in children only under physician supervision.

CONTRAINDICATIONS

Tri-DK must NOT be administered in the following conditions:

- Hypersensitivity to Cholecalciferol, Menaquinone-7, or any excipient of the formulation.
- Hypercalcaemia and/or hypercalciuria (elevated serum or urinary calcium).
- Hypervitaminosis D (Vitamin D toxicity).
- Patients with a history of calcium-containing kidney stones (nephrolithiasis).
- Pseudohypoparathyroidism (Vitamin D requirements may be fluctuating).
- Patients on Vitamin K antagonists (e.g., Warfarin) - Vitamin K2may antagonise anticoagulant effect (see Drug Interactions).
- Severe renal impairment or active nephrocalcinosis.

WARNINGS & PRECAUTIONS

Hypercalcaemia Monitoring: Prolonged high-dose Vitamin D therapy may lead to hypercalcaemia. Serum calcium, phosphorus,alkaline phosphatase, and renal function (serum creatinine) should be monitored before initiation and every 3–6 months during long-termtherapy. Discontinue if serum calcium exceeds 10.5 mg/dL or urinary calcium exceeds 4 mg/kg/day in adults.

Anticoagulant Therapy: Vitamin K2can reduce the efficacy of Vitamin K antagonist anticoagulants. Patients on warfarin or similaragents must have INR closely monitored if Tri-DK is co-administered.

Renal Impairment: Patients with impaired renal function are at increased risk of hypercalcaemia due to altered Vitamin D metabolism.Use with caution and under strict medical supervision.

Sarcoidosis and Granulomatous Disease: Risk of hypercalcaemia is increased due to enhanced conversion of Vitamin D to its activemetabolites. Monitor plasma and urinary calcium carefully.

Immobilised Patients: Immobilisation increases the risk of hypercalcaemia and hypercalciuria. Exercise caution.

Cardiac Glycosides: Hypercalcaemia potentiates the toxicity of digoxin and other cardiac glycosides; ECG and plasma calciummonitoring are essential.

DRUG INTERACTIONS

Hypercalcaemia Monitoring: Prolonged high-dose Vitamin D therapy may lead to hypercalcaemia. Serum calcium, phosphorus,alkaline phosphatase, and renal function (serum creatinine) should be monitored before initiation and every 3–6 months during long-termtherapy. Discontinue if serum calcium exceeds 10.5 mg/dL or urinary calcium exceeds 4 mg/kg/day in adults.

Drug / Class	Interaction & Clinical Significance
Warfarin / Vitamin K antagonists	Vitamin K_2 antagonises anticoagulant effect; monitor INR closely.
Thiazide diuretics	Reduce renal calcium excretion; increased risk of hypercalcaemia. Monitor serum calcium.
Digoxin / Cardiac glycosides	Hypercalcaemia increases glycoside toxicity. Monitor ECG and plasma calcium.
Phenytoin / Barbiturates	Induce hepatic enzymes that accelerate Vitamin D catabolism; higher doses may be required.
Glucocorticoids	Impair intestinal calcium absorption and reduce the effect of Vitamin D_3.
Cholestyramine / Colestipol	Reduce intestinal absorption of fat-soluble vitamins. Administer Tri-DK at least 4 hours apart.
Magnesium-containing antacids	Risk of hypermagnesaemia, particularly in chronic renal failure.
Orlistat	May reduce absorption of fat-soluble vitamins including D_3 and K_2.
Other Vitamin D supplements	Additive effect; risk of hypervitaminosis D. Avoid concurrent use without physician guidance.

OVERDOSAGE

Signs & Symptoms: Overdosage is primarily manifest as hypercalcaemia. Acute symptoms include nausea, vomiting, and diarrhoea.Chronic toxicity presents as constipation, anorexia, progressive weakness, headache, polyuria, polydipsia, azotaemia, soft-tissuecalcification, nephrocalcinosis, and cardiac arrhythmias. Biochemically: elevated serum 25(OH)D3, hypercalcaemia, hypercalciuria.

Management: Immediately discontinue Tri-DK. Institute calcium-restricted diet with adequate hydration. Forced diuresis with furosemidemay be considered. Glucocorticoids, calcitonin, or bisphosphonates may be administered depending on severity. Haemodialysis may berequired in severe cases. No specific antidote exists. Normalisation of hypercalcaemia may take several weeks due to the long tissuehalf-life of Vitamin D3.

USE IN SPECIAL POPULATIONS

Pregnancy: There is no conclusive evidence of teratogenicity at therapeutic doses of Vitamin D3in humans. High-dose Vitamin D3supplementation in pregnancy should only be used when clearly indicated and when the benefits outweigh potential foetal risk. VitaminK2is generally considered safe; however, the combination at 200,000 IU D3dose should be used in pregnancy only under directphysician supervision.

Lactation: Both Vitamin D3and Vitamin K2are excreted in breast milk. Monitor serum calcium in both mother and nursing infant.Physician supervision is required.

Paediatric Use: The 200,000 IU dose is a high loading dose. Use in children only under strict medical supervision with appropriatedosage adjustments based on weight and serum 25(OH)D3levels.

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STORAGE & HANDLING

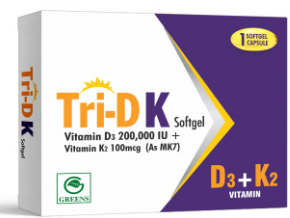
Storage Conditions:
- Store below 25°C. Refrigeration recommended in hot climates.
- Protect from heat, direct sunlight, and moisture.
- Do not freeze.
- Improper storage may deteriorate product quality.
- Keep out of the reach of children.

Handling Instructions:
- Inspect capsule before use; do not use if leaking or discoloured.
- This is a softgel capsule — do not crush or chew.
- Dispose of unused medicine responsibly; do not flush.
- Check expiry date before use.

PRESENTATION

Tri-DK is available as: 1 Softgel Capsule per blister pack.
Each capsule contains: Vitamin D3(Cholecalciferol) 200,000 IU + Vitamin K2(Menaquinone-7 / MK7) 100 mcg.

ٹرائی-ڈی کے
سافٹ جیل
وٹامن ڈی-۳، وٹامن کے-۲



خوراک: دواڈاکٹر کی ہدایت کے مطابق استعمال کیجیے۔
ہدایات: دواکو گرمی، روشنی اور نمی سے محفوظ ۲۵ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیے۔
تمام دوائیں بچوں کی پہنچ سے دور رکھیے۔

Neutraceutical: "Not for treatment of any disease"
نیوٹراسیوٹیکل: یہ پراڈکٹ کسی بیماری کے علاج کے لئے نہیں ہے

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