



# Complementary and Alternative Medicine Patients Are Talking About: Lycopene

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Lycopene is a carotenoid present in ripe fruit, especially tomatoes, watermelon, grapefruit, and guava. The deep red color of a ripe tomato is a result of lycopene. Other fruits that contain lycopene are apricots, cranberries, eggplants, grapes, papayas, peaches, and cloudberries. Lycopene is one of more than 600 carotenoids found in nature, is a known antioxidant, and accounts for almost 50% of the carotenoid distribution found in the blood. Lycopene has a potential role in the prevention and treatment of prostate cancer.

**Route of administration:** Lycopene is taken orally, supplied over the counter in capsules, softgels, tablets, and foods.

**Dosing and cost:** The daily recommended dose is 5–10 mg (13–75 mg per day in clinical trials) (Thomson™ Micromedex, 2005; Wolters Kluwer Health, 2004). The approximate cost is less than \$5 per month, but lycopene is not covered by most prescription plans.

**Indications:** Lycopene is marketed commercially as an antioxidant and to promote prostate health. Scientific evidence for the safe therapeutic use of lycopene during pregnancy is not available.

**Regulation:** As a dietary supplement as defined by the Dietary Supplement Health and Education Act of 1994, lycopene does not fall under postmarket regulation by the U.S. Food and Drug Administration (FDA). The FDA is responsible, however, for taking action against any unsafe products once reported.

**Efficacy:** The relationships among diet, nutrition, and prostate cancer have been and continue to be the subject of much clinical investigation. In a review, Giles and Ireland (1997) determined that the association between diet and prostate cancer is weak and inconsistent because of the quality and small sizes of the retrospective studies, as well as

poor dietary measurement instruments. Several dozen randomized, controlled trials involving lycopene and cancer have been conducted since that time, showing varying results. In a meta-analysis of 11 case-controlled and 10 cohort studies, Etminan, Takkouche, and Caamano-Isorna (2004) concluded that the preventive effect of lycopene against prostate cancer was slightly stronger for high intakes of tomato products than for high intakes of raw tomatoes. The authors supported that tomato products may play a role in the prevention of prostate cancer, but the evidence was not enough to recommend the use of lycopene supplements in the prevention of prostate cancer. Dagnelie, Schuurman, Goldbohm, and Van den Brandt (2004) summarized the evidence determining the role of selenium, vitamin E, and tomatoes or lycopene in the prevention of prostate cancer. Following a review of 37 cohort and 4 interventional studies, the authors concluded that no relationship was found between prostate cancer and consumption of meat, eggs, vegetables, fruit, coffee, tea, carotenoids, and vitamins A, C, and D. However, a protective effect existed for selenium, vitamin E, and tomatoes or lycopene.

**Interactions:** Lycopene is contraindicated in those who possess hypersensitivity to lycopene. Olestra may reduce the absorption of lycopene.

**Adverse reactions:** No adverse reactions have been reported with the recommended oral form or food doses.

**Clinical trials:** For a list of clinical trials studying the relationship between lycopene and cancer, see Figure 1.

**Future:** Overall, more research is needed to determine the type and quantity of products involved in the potential prevention of prostate cancer, specifically lycopene supplements

## Phase II Study of Lycopene in Patients With Asymptomatic Androgen-Independent Metastatic Prostate Cancer Who Have an Elevated Prostate-Specific Antigen Level

- Sponsor: National Cancer Institute
- Type of trial: treatment
- Protocol identification: NCCTG-N0351

## Phase I Study of Lycopene as Chemoprevention for Prostate Cancer in Healthy Participants

- Sponsor: National Cancer Institute
- Type of trial: prevention
- Protocol identification: UIC-2004-0040

## Phase I Study of Lycopene for the Chemoprevention of Prostate Cancer

- Sponsor: National Cancer Institute
- Type of trial: prevention
- Protocol identifications: UIC-H-99-058, UIC-N01-CN-85081, NCI-P00-0143

## Randomized Pilot Study of Isoflavones Versus Lycopene Prior to Radical Prostatectomy in Patients With Localized Prostate Cancer

- Sponsor: National Cancer Institute
- Type of trial: prevention
- Protocol identifications: MCC-0105, NCI-3811, NCI-P02-0216

## FIGURE 1. CLINICAL TRIALS STUDYING THE RELATIONSHIP BETWEEN LYCOPENE AND CANCER

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