

### Medical food definition

A food which is **formulated** to be administered **enterally** under the **supervision of a physician** and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation

### Does FDA regulate medical foods as drugs?

No. Medical foods are not drugs and, therefore, are not subject to any regulatory requirements that specifically apply to drugs.

Does FDA require that medical foods be made available by written or oral prescription?

No. The requirement for a written or oral prescription in section

# How does FDA interpret "under the supervision of a physician"?

Under the supervision of a physician to mean that the intended use of a medical food is for the dietary management of a patient receiving active and ongoing medical supervision (e.g., in a health care facility or as an outpatient) by a physician who has determined that the medical food is necessary to the patient's overall medical care. The patient should generally see the physician on a recurring basis for, among other things, instructions on the use of the medical food as part of the dietary management of a given disease or condition.



### Indication and Contraindications

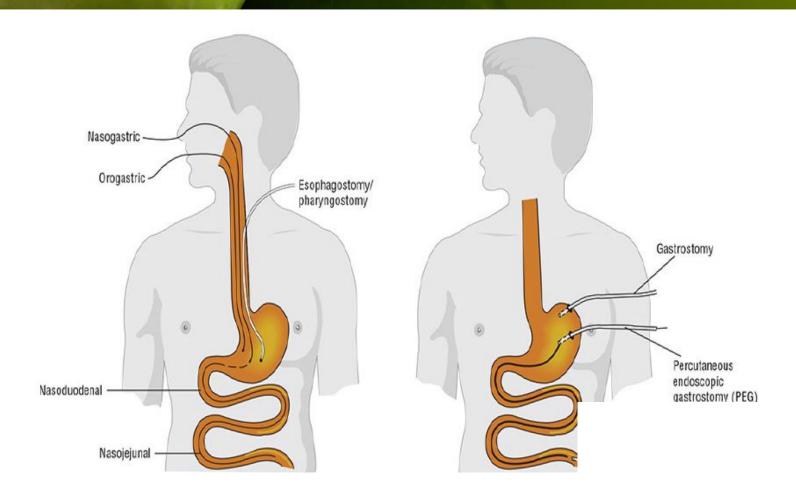
- Medical food must be intended for a patient who has a limited or impaired capacity to ingest, digest, absorb, or metabolize ordinary foodstuffs or certain nutrients, or who has other special medically determined nutrient requirements, the dietary management of which cannot be achieved by the modification of the normal diet alone.
- FDA generally considers inborn errors of metabolism to be diseases or conditions that a medical food could be used to manage

- Contraindications to EN use are distal mechanical intestinal obstruction, bowel ischemia, and necrotizing enterocolitis.
- Contraindications to tube placement include active peritonitis and uncorrectable coagulopathy

### Some examples of MFs

- Special infant formulas
- Formulations for metabolic disorders
- Oral rehydration products
- Special nutritional formulas for patients with AIDS, kidney disease, or inborn errors in metabolism

## Access sites for tube feeding



Indications	Features	Category
Designed to meet the needs of the majority of patients with functional GI tract	1-1.2 kcal/mL May contain fiber	Standard polymeric
Patients with protein requirements >1.5 g/kg/day, such as trauma patients and those with burns, pressure sores, or wounds	May contain fiber	High protein
Patients requiring fluid and/or electrolyte restriction, such as kidney insufficiency	1.5-2 kcal/mL Lower electrolyte content per calorie Hypertonic	High caloric density
Patients who require low fat	High proportion of free amino acids  Low in fat	Elemental & Peptide based

Indications	Features	Category
Alternative to high-caloric density formulations, but generally more expensive	Caloric dense, Protein content varies, Low-electrolyte content	Kidney
Patients with hepatic encephalopathy	Increased branched-chain and decreased aromatic amino acids	Liver
Patients with ARDS and severe ALI	High fat, low carbohydrate Anti- inflammatory lipid profile and antioxidants	Lung
Alternative to standard, fiber-containing formulation in patients with uncontrolled hyperglycemia	Low carbohydrate	Diabetes
Patients undergoing major elective GI surgery, trauma, burns, head and neck cancer, and critically ill patients on mechanical ventilation Use with caution in patients with sepsis	Supplemented with glutamine, arginine, nucleotides, and/or omega-3 fatty acids	Immunemodulating



Standard
Over than 4 y
Gluten free
1ml= 1 kcal

**Nutrition Facts** Serving Size 1 Scoop (11.3 g) Serving Per Container 35

	Amount Per 11.3 g	%DV*	Amount Per 1000 ml Solution		Amount Per 11.3 g	%DV*	Amount Per 1000 ml Solution
Calories	50		1000	Biotin (mcg)	8.2	3	163.7
Protein (g)	1.8	3.6	36	Calcium (mg)	28.15	3	563
Total Carbohydrate (g)	6.76	2.2	135	Chromium (mcg)	1	0.8	19.2
Dietary Fiber (g)	0.23	0.9	4.4	Copper (mcg)	42	2	851
Total Fat (g)	1.8	3	36	Fluoride (mg)	0.1	†	2.2
Vitamin A (IU)	108	2	2160	lodine (mcg)	4.9	3.3	98.2
Vitamin D (IU)	9.8	2.5	196.4	Iron (mg)	0.48	2.7	9.5
Vitamin E (IU)	1.3	4	25.6	Magnesium (mg)	12.2	3	243.7
Vitamin K (mcg)	3.3	4	65.3	Manganese (mg)	0.08	4	1.6
Vitamin C (mg)	4.9	8	98.2	Molybdenum (mcg)	1.5	2	29.5
Vitamin B1 (mg)	0.08	5	1.6	Phosphorus (mg)	27	2.7	530
Vitamin B2 (mg)	0.09	5	1.7	Zinc (mg)	0.48	3	9.7
Niacin(mg)	0.65	3	13	Selenium (mcg)	1.8	2.6	36
Vitamin B6 (mg)	0.07	3	1.35	Sodium (mg)	50.7	2	1013.4
Folic Acid (mcg)	13.1	3	261.9	Potassium (mg)	73.2	2	1435.4
Vitamin B12 (mcg)	0.26	4	5.1	Chloride (mg)	42.8	1.2	855.7
Pantothenic Acid (mg)	0.3	3	6.5	L- Carnitine (mg)	4.5	†	90.1

<sup>\*</sup>Percent daily values are based on a2000 calorie diet.



High protein
Over than 4 y
Gluten free
1ml= 1.2 kcal
For patients in
catabolic state

Nutrition Facts Serving Size: 1 Scoop (13.25 g)

	Amount Per Serving	% Daily Value*	Amount Per 1000 ml Solution		Amount Per Serving	% Daily Value*	Amount Per 1000 ml Solution
Calories	60		1200	Calcium (mg)	42.4	4.2	845
Protein (g)	3	6	61	Chromium (mcg)	1.15	1	23
Total Carbohydrate(g)	6.8	2.2	135	Copper (mcg)	53	2.6	1057
Dietary Fiber (g)	0.27	1	5.3	Fluoride (mg)	0.1	†	2.6
Total Fat (g)	2.4	3.7	47.6	Iodine (mcg)	5.8	3.8	115.2
Vitamin A (IU)	127	2.5	2535	Iron (mg)	0.57	3.1	11.4
Vitamin D (IU)	11.5	2.9	230.5	Magnesium (mg)	14.3	3.6	286
Vitamin E (IU)	1.5	5.1	30.7	Manganese (mg)	0.09	4.6	1.8
Vitamin K (mcg)	3.8	4.8	76.6	Molybdenum (mcg)	1.74	2.3	34.6
Vitamin C (mg)	5.8	9.6	115.2	Phosphorus (mg)	41.1	4.1	819.4
Vitamin B1 (mg)	0.1	6.4	1.9	Zinc (mg)	0.57	3.8	11.4
Vitamin B2 (mg)	0.1	6	2	Selenium (mcg)	2.1	3	42.3
Niacin (mg)	0.8	3.8	15.3	Sodium (mg)	74	3.1	1475
Vitamin B6 (mg)	0.08	4	1.6	Potassium (mg)	99	2.8	1966
Folic Acid (mcg)	15.4	3.8	307.4	Chloride (mg)	47.7	1.4	951
Vitamin B12 (mcg)	0.3	5	6.1	L- Carnitine (mg)	7.9	†	158.6
Pantothenic Acid (mg)	0.4	3.8	7.7	L- Taurine (mg)	5.3	†	105.7
Biotin (mcg)	9.6	3.2	192.2				

<sup>\*</sup> Percent daily values are based on a 2000 calorie diet.



Diabetic
Over than 4 y
Gluten free
1ml=1 kcal

#### Nutrition Facts Serving size: 1 Scoop (10 g) Serving per container: 40

	Amount per serving	% Daily Value*	Amount per 1000 ml solution		Amount Per Serving	% Daily Value*	Amount per 1000 ml solution
Calories	48.6		1000.2	Calcium (mg)	62	6.2	1276
Protein (g)	2.1	4.2	43.2	Chromium (mcg)	1	0.9	21.6
Total Carbohydrate(g)	4.5	1.5	92.6	Copper (mcg)	50	2.5	1000
Dietary Fiber(g)	0.5	2	10.3	Fluoride (mg)	0.12	†	2.5
	1			odine (mcg)	5.2	3.5	107.6
Total Fat (g)	2.5	3.8	51.5	Iron (mg)	0.43	2.4	8.8
Vitamin A (IU)	115	2.3	2369.2	Magnesium(mg)	12.75	3.2	262.4
Vitamin D (IU)	10.5	2.6	215.3	Manganese(mg)	0.09	4.5	1.9
Vitamin E (IU)	1.4	4.6	28.6	Molybdenum(mcg)	1.6	2.1	32.3
Vitamin K (mcg)	3.5	4.4	71.8	Phosphorus(mg)	22.2	2.2	456.9
Vitamin C (mg)	5.2	8.7	107.6	Zinc (mg)	0.44	2.9	9.1
Vitamin B1 (mg)	0.09	6.0	1.9	Selenium(mcg)	1.9	2.7	39.5
Vitamin B2 (mg)	0.09	5.3	1.9	Sodium (mg)	38	1.6	782
Niacin(mg)	0.7	3.5	14.4	Potassium(mg)	70	2.0	1440.6
Vitamin B6 (mg)	0.07	3.5	1.4	Chloride (mg)	24	0.7	493.9
Folic Acid (mcg)	13.9	3.5	287.1	L-Carnitine(mg)	6	t	123.5
Vitamin B12 (mcg)	0.3	4.7	5.8	L-Taurine (mg)	4	†	82.3
Pantothenic Acid(mg)	0.35	3.5	7.2	Myo-Inositol(mg)	30	†	617.4
Biotin (mcg)	8.7	2.9	179.5				

\*Daily values are based on a 2000 calorie diet.



High fiber
Over than 4 y
Gluten free
1ml= 1 kcal

**Nutrition Fact** 

Serving Size: 1 scoop (11.2 g) Serving Per Container: 35

	Amount Per Serving	%DV*		Amount Per Serving	%DV*
Calories	50		Biotin (mcg)	8.1	2.7
Protein (g)	1.8	3.6	Calcium (mg)	35.8	3.6
Total Carbohydrate (g)	7	2.3	Chromium (mcg)	0.98	8.0
Dietary Fiber (g)	0.67	2.7	Copper (mcg)	40	2.1
Total Fat (g)	1.8	2.8	Fluoride (mg)	0.11	t
Vitamin A (IU)	107.4	2.1	lodine (mcg)	4.9	3.3
Vitamin D (IU)	9.8	2.4	Iron (mg)	0.48	2.7
Vitamin E (IU)	1.3	4.3	Magnesium (mg)	12.1	3
Vitamin K (mcg)	3.2	4	Manganese (mg)	0.08	4.1
Vitamin C (mg)	4.9	8.1	Molybdenum (mcg)	1.46	1.9
Vitamin B1 (mg)	0.08	5.4	Phosphorus (mg)	31.4	3.1
Vitamin B2 (mg)	0.09	5.1	Zinc (mg)	0.48	3.2
Niacin(mg)	0.65	3.25	Selenium (mcg)	1.8	2.6
Vitamin B6 (mg)	0.06	3.25	Sodium (mg)	60.5	2.5
Folic Acid (mcg)	13	3.3	Potassium (mg)	80.7	2.3
Vitamin B12 (mcg)	0.26	4.35	Chloride (mg)	34.7	1
Pantothenic Acid (mg)	0.32	3.25			
*Daily values are bas	sed on a 2000 calori	e diet.			



Pediatric 1-13 y Gluten free 1ml= 1 kcal

#### Nutrition Facts Serving Size 1 Scoop (11 g) Serving Per Container 36

g		_							
	Amount Per 11 g	%DV*	Amount Per 1000 ml Solution	%DV*		Amount Per 11 g	%DV*	Amount Per 1000 ml Solution	%DV*
Calories	50.6		1001		Calcium (mg)	33	3.3	652.8	65
Protein (g)	1.6	3.3	32.2	64	Phosphorus (mg)	16.5	1.7	326.4	33
Total Carbohydrate (g)	6.6	2.2	130.6	43	Chromium (mcg)	0.65	0.5	12.9	11
Sugar (g)	2	t	39.2	†	Copper (mcg)	28.27	1.4	559.2	28
Dietary Fiber (g)	0.33	1.3	6.5	26	Fluoride (mg)	0.08	t	1.5	t
Total Fat (g)	2.1	3.2	41.3	64	lodine (mcg)	3.26	2.2	64.5	43
Vitamin A (IU)	71.8	1.4	1419.4	28	Iron (mg)	0.47	2.6	9.4	52
Vitamin D (IU)	6.52	1.6	129	32	Magnesium (mg)	5.5	1.4	108.8	27
Vitamin E (IU)	0.87	2.9	17.2	57	Manganese (mg)	0.05	2.7	1	53
Vitamin K (mcg)	2.17	2.7	43	54	Molybdenum (mcg)	0.98	1.3	19.3	26
Vitamin C (mg)	3.26	5.4	64.5	107	Zinc (mg)	0.44	2.9	8.7	58
Vitamin B1 (mg)	0.05	3.6	1.07	71	Selenium (mcg)	1.2	1.7	23.6	34
Vitamin B2 (mg)	0.06	3.4	1.15	68	Sodium (mg)	26.4	1.1	522.2	22
Niacin(mg)	0.43	2.2	8.6	43	Potassium (mg)	39.6	1.1	783.4	22
Vitamin B6 (mg)	0.04	2.2	0.86	43	Chloride (mg)	11	0.3	217.6	6
Folic Acid (mcg)	8.7	2.2	172.1	43	L-Carnitine (mg)	1.1	t	21.8	t
Vitamin B12 (mcg)	0.17	2.9	3.4	57	L- Taurine (mg)	3.3	t	65.3	t
Pantothenic Acid (mg)	0.22	2.2	4.3	43	Myo- Inositol (mg)	3.3	t	65.3	t
Biotin (mcg)	5.43	1.8	107.5	36					

<sup>\*</sup>Percent daily values are based on a2000 calorie diet. †Daily value not established.





Standard
Over 10 y
Lactose free
Gluten free

Nutrients	Dilution Per 100 ml	Unit	Powder Per 100 g	مواد مغذی
Energy	100	Kcal	428	انرژی
protein	3.72	g	15.9	پروتئین
Fat	3.27	g	14	چربی
Omega 3	0.13	g	0.57	امگا 3
Omega 6	0.31	g	1.35	امگا 6
Carbohydrate	13.42	g	57.4	كربوهيدرات
Sugars	4.0	g	17	قندها
Fiber	1.01	g	4.3	فيبر
Vitamins	Dilition Per 100 ml	Unit	Powder Per 100 g	ويتامين ها
Vitamin A	351	IU	1500	ویتامین A
Vitamin D3	56	IU	240	ويتامين D3
Vitamin E	2.8	IU	12	ویتامین E
Vitamin K1	7.7	mcg	33	ويتامين K1
Vitamin C Folic acid	13 30	mg	54	ويتامين C
Vitamin B1	0.19	meg	130	فولیک اسید
Vitamin B2	0.19	mg mg	0.8	ویتامین B1 ویتامین B2
Vitamin B6	0.23	mg	1	ويتامين B6
Vitamin B12	0.35	mcg	1.5	ویتامین B12
Niacin	1.2	mg	5	نياسين
Pantothenic acid	0.98	mg	4.2	یانتوتنیک اسید
Biotin	4.2	mcg	18	بيوتين
Colin	32	mg	136	كولين
Minerals	Dilition Per 100 ml	Unit	Powder Per 100 g	مواد معدنی
Iron	0.94	mg	4	آهن
Zinc	1.1	mg	4.7	روي منگنز
Manganese	0.33	mg	1.4	
Copper	67 15	mg	285	مس
Selenium	5.1	mcg	64	يد
Chromium	5.4	mcg	22	سلنيوم
Molybdenum	9.8	mcg	42	کروم
Sodium	84	mg	360	مولیبدن سدیم
Potassium	157	mg	670	يتاسيم
Oldasiuiii	13/	mg	6/0	يتاسيم

mg

mg

mg

450

235

75

550

كلسيم

Chloride

Calcium

Phosphorus

Magnesium

105

55

18

128



**Standard** 



Diabetic patients

Omega-3 content



Age >3 y
Fiber content
Gluten free
Lactose free



High protein Fiber content



Peptide based

Age >10 y



Nutrition facts		per 100 g	per 100 ml *
Energy	kJ / kcal	2045/489	266/64
Fats, of which	g	25	3,2
saturated fatty acids	g	9,8	1,3
monounsaturated fatty acids	g	11	1,5
polyunsaturated fatty acids	g	3,7	0,5
arachidonic acid	mg	80	10
docosahexaenoic acid	mg	45	5,85
Carbohydrates, of which	g	53	6,8
Sugars	g	3,7	0,5
Lactose	g	0	0
Maltodextrin	g	49	6,3
Protein equivalent **	g	14	1,8
Amino acids	g	16	2,1
Salt	g	0,32	0,04

Elemental
Less than 1 y
Lactose, gluten free

### Fresubin Original Liquid



1kcal/ml oral nutritional supplement
Fiber free
For age of over than 1 year
For 24 h after opening

### Calorie meal



- کالری میل یک مکمل پودری با دانسیته کالری بالا است
- کالری میل همانند انترامیل ها غذای کامل نیست و باید در کنار غذای بیمار مصرف شود.
- کالری میل دارای غلظت بالایی بوده و نمی توان از آن به عنوان فرمولای آماده گاواژ استفاده کرد
  - مناسب دوران شیمی درمانی و رادیوتراپی
  - برای افراد در معرض سوء تغذیه به ویژه بیماران مبتلا به سرطان، سیستیک فیبروزیس و ایدز
    - حاوی مخلوط مناسبی از روغن های گیاهی دارای امگا ۳، ۶ و ۹
- هر ساشه به همراه ۲۴۰ میلی لیتر شیر پرچرب (۳٪)، حاوی ۵۹۶ کالری و ۱۵/۴ گرم پروتئین می باشد. نوشیدنی آماده شده ۱/۸ کیلوکالری به ازای هر میلی لیتر انرژی تامین می کند. هر ساشه به همراه ۲۴۰ میلی لیتر آب حاوی ۴۵۲ کالری و ۷/۸ گرم پروتئین می باشد



Each film-coated tablet contains:
α-Ketoanalogue to Isoleucine, Calcium Salt67 mg
(Calcium-3-methyl-2-oxo-valerate)
α-Ketoanalogue to Leucine, Calcium Salt101 mg
(Calcium-4-methyl-2-oxo-valerate)
α-Ketoanalogue to Phenylalanine, Calcium Salt68 mg
(Calcium-2-oxo-3-Phenylpropionate)
α-Ketoanalogue to Valine, Calcium Salt86 mg
(Calcium-3-methyl-2-oxo-butyrate) .
α-Hydroxy analogue to Methionine, Calcium Salt59 mg
(Calcium-DL-2-Hydroxy-4(methylthio)butyrate)
L-Lysine Acetate USP
L-Threonine USP53 mg
L-Tryptophan USP23 mg
L-Histidine USP38 mg
L-Tyrosine USP30 mg
Total Nitrogen content36 mg
Calcium content

For the dietary management of phenylketonuria (PKU) and hyperphenylalaninaemia (HPA)











#### **Galactomin 19**

For the dietary management of glucose plus galactose intolerance.

Suitable for use as a sole source of nutrition for infants under 1 year of age and as a supplement for young children



MCT is a medical food derived from fatty acids

MCT is for dietary use in people whose bodies cannot digest certain foods properly

CF, ketogenic diet, malabsorption of fat

### Adverse effects

Nausea, vomiting, distension, cramping

Diarrhea

Hyperglycemia

Electrolyte imbalance

Aspiration

Tube obstruction



### **Functional foods**

- Functional foods are **foods** that offer health benefits beyond their nutritional value.
- In addition to nutrient-rich ingredients like fruits and veggies, the category also includes foods fortified with vitamins, minerals, probiotics, and fiber
- Oats, for instance, contain a type of fiber called beta gluten, which has been shown to reduce inflammation, enhance immune function, and improve heart health



# **Functional foods**

**Conventional** 

**Modified** 

• Conventional foods are natural, whole-food ingredients that are rich in important nutrients like vitamins, minerals, antioxidants, and heart-healthy fats.

- Fruits: berries, kiwi, pears, peaches, apples, oranges, bananas
- Vegetables: broccoli, cauliflower, kale, spinach, zucchini
- Seafood: salmon, sardines, anchovies, mackerel, cod



- Modified foods have been fortified with additional ingredients, such as vitamins, minerals, probiotics, or fiber, to increase a food's health benefits.
- Fortified juices, fortified dairy products, such as milk and yogurt, fortified grains, such as bread and pasta



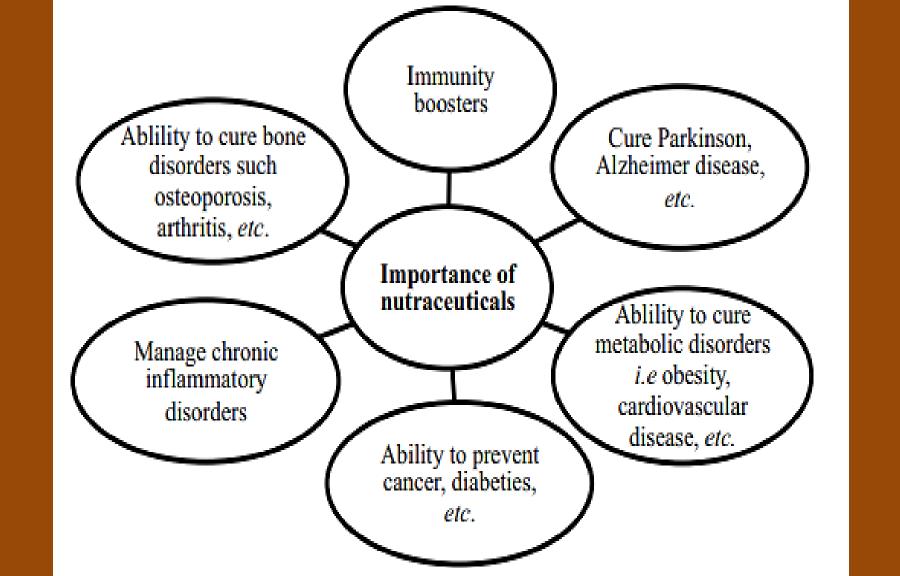
# **Potential benefits**

- Prevent nutrient deficiencies (iron deficiency anemia)
- Protect against disease
- ✓ Antioxidants: Prevent cell damage and certain chronic conditions, including heart disease, cancer, and diabetes
- ✓ Omega-3 fatty acids: reduce inflammation, boost brain function, and promote heart health
- ✓ **Fiber**: Blood sugar control digestive disorders, including diverticulitis, stomach ulcers, hemorrhoids, and acid reflux
- Promote proper growth and development



# **Nutraceutical**

- A substance that may provide medical or health benefits, encompassing prevention and treatment of disease
  - O Lipids, carbohydrates, proteins
  - O Minerals, vitamins and other dietary supplements
  - O Herbal products: garlic, ginger, echinacea, ginseng, liquorice, onion, senna, turmeric (curcumin)
  - O Dietary enzymes: bromelain
  - O Dietary fiber
  - O Carotenoids: lycopene
  - O Prebiotics, Probiotics



# List of some common medicinal plants used as herbal nutraceuticals Plant Species Medicinal Purpose Brand name

Plant Species	Medicinal Purpose	Brand name
Garlic	Chemoprevention, antitumor, antidiabetic,	Garlet tablet, Garlic drop, Garlicap

capsule

D-reglis

Barolojid capsule, barij aloe syrup

Vomiton drop, Curcumin capsule,

Barij block seed oil softgel

Turmerin capsule

Echinacea drop

Gingiton capsule

arteriosclerosis prevention, cholesterol-lowering,

Anti-inflammatory, anti-congestion, relief from

Analgesic, anticancer, anti-inflammatory, antioxidant

Inflammation reduction, indigestion, anti-oxidant,

Cold-flu, minor infections, and immunostimulant.

Improves digestion, anti-oxidant and controls

respiratory infection preventive

Immunomodulator, antihelminth

cough, and stomach aches

liver problems

cholesterol

antimicrobial, gastro-protective

Aloe vera

(Licorice)

Nigella sativa

Curcuma longa

Zingiber officinale

(Turmeric)

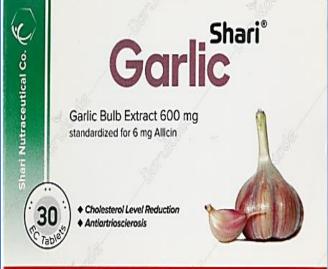
Echinacea

(Ginger)

Glycyrrhiza glabra







Shari Nutraceutical Co. - Tehran-Iran www.sharinutri.com













#### **Bromelain**

Bromelain is a group of enzymes found in pineapple

 Bromelain is used for pain, muscle soreness, burns, and many other conditions

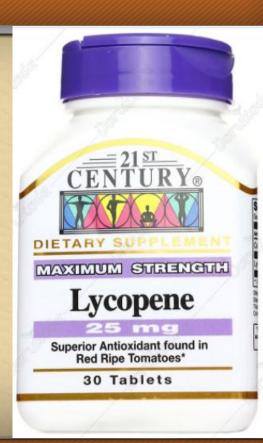


### lycopene

Lycopene is a type of organic pigment called a carotenoid. It is related to beta-carotene and gives some vegetables and fruits (e.g., tomatoes) a red color.

Lycopene is a powerful antioxidant that might help protect cells from damage. It's found in tomato, watermelon, red orange, pink grapefruit, apricot, rose hip, and guava.

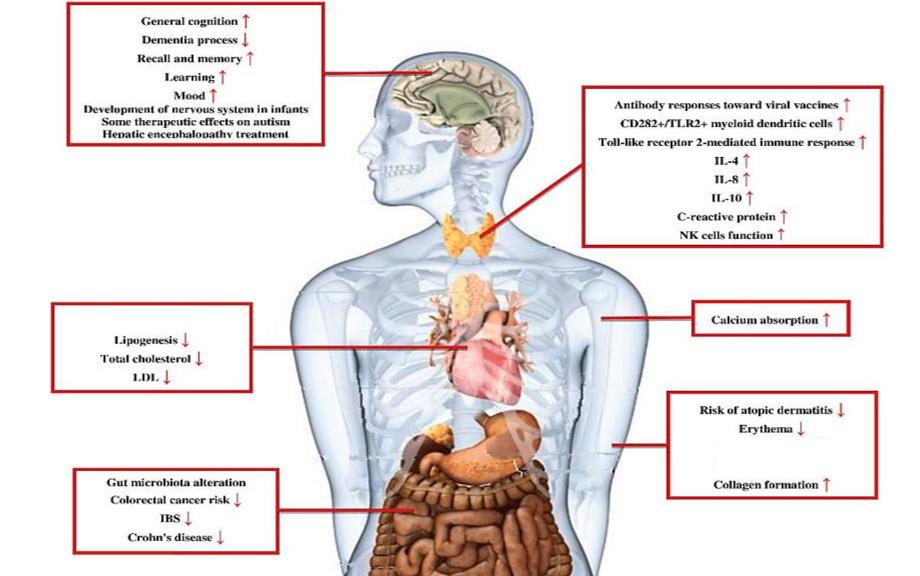
Lycopene is used for high blood pressure, high cholesterol, cancer, and many other conditions, but there is no good scientific evidence to support most of these uses.



## Prebiotics

- Prebiotics are special plant fibers that help healthy bacteria grow in your gut. This makes your digestive system work better.
- We can find prebiotics in many fruits, vegetables, and whole grains
  - Galactooligosaccharides
  - Fructooligosaccharides
  - Oligofructose
  - O Inulin
- The following criteria are used to classify a compound as a prebiotic: (i) it should be resistant to acidic pH of stomach, cannot be hydrolyzed by mammalian enzymes, and also should not be absorbed in the gastrointestinal tract, (ii) it can be fermented by intestinal microbiota, and (iii) the growth and/or activity of the intestinal bacteria can be selectively stimulated by this compound and this process improves host's

health



#### **Probiotics**

- Live microorganisms that, when administered in adequate amounts, confer a health benefit on the host
- The core genera of microbial organisms most often used in probiotic products are Lactobacillus, Bifidobacterium, and Bacillus.
- Atopic dermatitis, diarrhea, Irritable bowel syndrome, Hypercholesterolemia



