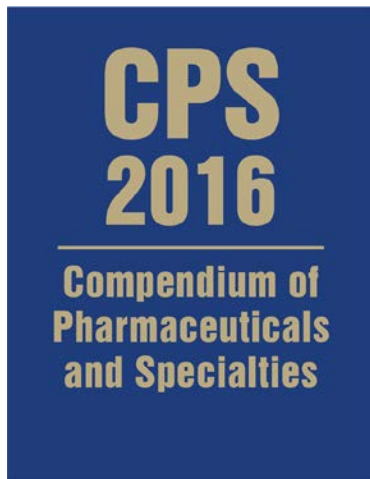


As listed in the Compendium of Pharmaceuticals and Specialties (CPS)



Immunocal®

Whey protein isolate
Glutathione Precursor
Immunotec
NPN(s): 80004370

Pharmacology

IMMUNOCAL is a natural source of the glutathione precursor cysteine for the maintenance of a strong immune system. It is fat-free and contains less than 1% lactose and has a high protein biological value (>110 BV) providing all essential amino acids.

The systemic availability of oral glutathione is negligible; the vast majority of it must be manufactured intracellularly from precursors. Glutathione is a tripeptide made intracellularly from its constituent amino acids L-glutamate, L-cysteine and glycine. The sulfhydryl (thiol) group (SH) of cysteine serves as a proton donor and is responsible for the biological activity of glutathione. Provision of this amino acid is the rate-limiting factor in glutathione synthesis by the cells since bioavailable cysteine is relatively rare in foodstuffs. Furthermore, cysteine if ingested as the free amino acid L-cysteine, has toxic potential and is spontaneously catabolized in the gastrointestinal tract and blood plasma. Toxicity is avoided when cysteine is integrated into larger proteins such as serum albumin, alpha lactalbumin and lactoferrin.

IMMUNOCAL is an undenatured bovine whey protein isolate specially prepared to provide a rich source of bioavailable cysteine. Following digestion, the cysteine remains as the stable form cystine (2 molecules of cysteine linked by a disulfide bond) and glutamylcystine. After absorption, these dipeptides travel safely in the blood stream and readily enter the cells to release free cysteine for intracellular glutathione synthesis. IMMUNOCAL is a cysteine delivery system.

The disulphide bond in cystine is pepsin and trypsin resistant but may be split by heat, low pH or mechanical stress, releasing free cysteine. When subject to heat or shearing forces (inherent in most extraction processes), the fragile disulfide bonds within the peptides are broken and the bioavailability of cysteine is greatly diminished.

Glutathione has multiple functions:

1. It is the major endogenous antioxidant produced by the cells, participating directly in the neutralization of free radicals and reactive oxygen compounds, as well as the maintenance of exogenous antioxidants such as vitamins C and E in their reduced (active) forms.
2. Through direct conjugation, it detoxifies many xenobiotics (foreign compounds) and carcinogens, both organic and inorganic such as heavy metals, aromatic hydrocarbons, nitrosamines, benzopyrines and others including pharmacological agents such as acetaminophen.
3. It is essential for the immune system to exert its full potential, e.g. (1) modulating antigen presentation to lymphocytes, thereby influencing cytokine production and the type of response (cellular or humoral) that develops, (2) enhancing proliferation of lymphocytes thereby increasing magnitude of response, (3) enhancing killing activity of cytotoxic T cells and NK cells, and (4) regulating apoptosis, thereby maintaining control of the immune response.
4. It plays a fundamental role in numerous metabolic and biochemical reactions such as DNA synthesis and repair, protein synthesis, prostaglandin synthesis, amino acid transport and enzyme activation. Many systems in the body are adversely affected by low glutathione levels, including the immune system, the nervous system, the gastrointestinal system and the cardiovascular-pulmonary system.

Health Claim

Glutathione augmentation is a strategy developed to address states of glutathione deficiency, high oxidative stress, immune deficiency, and xenobiotic overload in which glutathione plays a part in the detoxification of the xenobiotic in question. Many clinical pathologies are associated with glutathione deficiency and oxidative stress and are elaborated upon in numerous medical references. Low glutathione is also strongly implicated in cachexia and negative nitrogen balance seen in muscle wasting. Immunocal has been demonstrated to improve muscle function and it is clinically proven to raise glutathione.

Contraindications

In individuals who develop or have known hypersensitivity to specific milk proteins (this does not include lactose intolerance).



Warnings

Patients undergoing immunosuppressive therapy should discuss the use of this product with their health care practitioner.

Heating or adding IMMUNOCAL to a hot liquid or use of a high-speed blender to reconstitute it will significantly decrease the effectiveness of the product.

Precautions

Each pouch of IMMUNOCAL provides 9 g of protein. Patients on a protein-restricted diet need to take this into account when calculating their daily protein load. Although a bovine milk derivative, IMMUNOCAL is well tolerated by lactose-intolerant individuals. IMMUNOCAL is contraindicated in individuals who develop or have known hypersensitivity to specific milk proteins (this does not include lactose intolerance).

Individuals with the autosomal-recessive metabolic disorder cystinuria, are at higher risk of developing cysteine nephrolithiasis (1-2% of renal calculi).

Pregnancy - No adverse effects have been reported. A health care practitioner should be consulted prior to use if the patient is pregnant or has reason to believe she is.

Lactation – No adverse effects have been reported. A health care practitioner should be consulted prior to use if the patient breast feeds.

Geriatrics - Glutathione levels drop with age. Dosage recommendations may rise with increasing age.

Adverse Effects

IMMUNOCAL is a natural source of protein classified as a Natural Health Product and has not been statistically assessed for adverse effects. Gastrointestinal bloating and cramps are possible if the product is not sufficiently rehydrated. Transient urticarial-like skin rash has been reported in rare individuals undergoing severe detoxification reaction. Skin rash abates when the intake is stopped or reduced.



Overdose

Symptoms and Treatment - There have been no reports of toxicity from overdosing on IMMUNOCAL. Glutathione is a tightly regulated intracellular constituent and is limited in its production by negative feedback inhibition of its own synthesis through the enzyme gamma-glutamylcysteine synthetase.

For management of a suspected drug overdose, CPhA recommends that you contact your regional Poison Control Centre. See the eCPS Directory section for a list of Poison Control Centres.

Dosage

As a natural source of the glutathione precursor cysteine for the maintenance of a strong immune system, 20 g per day is recommended. 30-40 g per day has been used in clinical trials without ill effects.

IMMUNOCAL is best administered on an empty stomach or with a light meal. Concomitant intake of another high protein load may adversely affect absorption.

Supplied

Each individually-sealed foil pouch contains: 10 g of powder, 9 g of which is protein. The other is represented by naturally occurring ingredients including ash, trace minerals and trace amounts of vitamins. Boxes of 30 pouches.

IMMUNOCAL is a dehydrated powdered whey protein isolate. It must be appropriately rehydrated before use. Remains bioactive up to 12 hours after mixing. Ideally, it should be consumed immediately after mixing. Should the product be premixed for later consumption, it should be refrigerated and consumed within a short period after mixing. Do not heat or use a hot liquid to rehydrate the product or use a high-speed blender for reconstitution. These methods will decrease the effectiveness of the product. Proper mixing is imperative. Consult instructions included in packaging. Store in a cool dry environment. Avoid excessive heat. Refrigeration is not necessary.

*Compendium of Pharmaceuticals and Specialties, online version (e-CPS).
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