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Dr Kiran Mazumdar-Shaw

Chairperson and Managing Director
Biocon Limited

METHYLCOBALAMIN

Its Importance

The science of Methylcobalamin : Part THREE

What are the fundamental requirements of diet? The diet we take should be well balanced and be providing all nutrients required for our body to function for maintaining structure and for good health and reproductive capability. Our body can synthesize many molecules required from the organic precursors, but there are some nutrients that need to be consumed from food. These are termed essential nutrients: **they cannot be produced by the body.** Vitamins, minerals, amino acids are substances found in the food we eat. The body needs them for growth and development.

Minerals ~ Minerals are inorganic compounds, mainly salts, that are essential for life. Found in bones and teeth, they are involved in metabolic and biochemical processes. Minerals are the elements on the earth and in foods that our bodies need to develop and function normally. Those that are essential for health include **calcium, phosphorus, potassium, sodium, chloride, magnesium, iron, zinc, iodine, chromium, copper, fluoride, molybdenum, manganese, and selenium.** Like all nutrients, minerals are found in

basic foods such as meat, milk, fish, vegetables, fruits, and cereals.

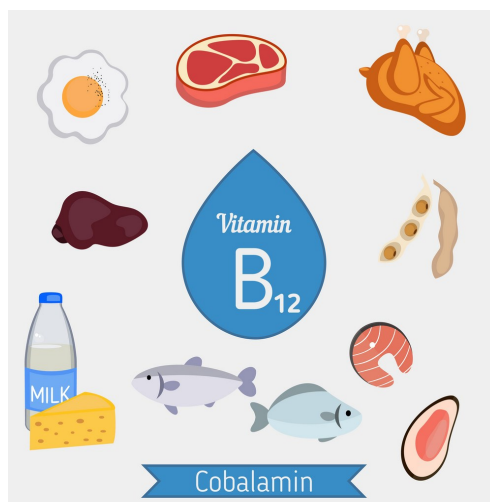
In addition to minerals, there are certain amino acids that must also be procured from food and cannot be synthesized by the body. These amino acids are known as “**essential**” amino acids. *The human body can synthesize only 11 out of the 20 required amino acids.* The rest must be obtained from food. Amino acids are compounds that combine to make proteins. amino acids build muscles, and chemical reactions in the body, transport nutrients, prevent illness, and carry out many other functions. Amino acid defi-

ciency can result in decreased immunity, digestive problems, depression, fertility issues, lower mental alertness, slowed growth in children, and many other health issues.

Ester --A chemical substance made when an acid and an alcohol combine and water is removed. Esters are found in essential oils (scented oils that come from plants). Esters are sweet-smelling liquids used to flavor foods and sweets. Ethyl ethanoate, for example, is used in pear drops, (a hard candy) because of its peculiar aroma which is similar to pears.



Vitamin~ Vitamin is an organic compound required as a nutrient in tiny amounts by an organism. A compound is called a vitamin when it cannot be synthesized in sufficient quantities by an organism, and must be obtained from the diet. The term vitamin neither does include other essential nutrients such as dietary minerals, essential fatty acids, or essential amino acids, nor does it encompass the large number of other nutrients that promote health but are otherwise required less often. Vitamins are classified by their biological and chemical activity, not by their structure. Thus, each "vitamin" may refer to several vitamer compounds that all show the biological activity associated with a particular vitamin. Such a set of chemicals are grouped under an alphabetized vitamin "generic descriptor" title, such as "vitamin B12, vitamin A. Vitamers are often inter-converted in the body. Vitamins have been produced as commodity chemicals



and made widely available as inexpensive pills for several decades, allowing supplementation of the dietary intake.

Vitamers are Chemical compounds structurally related to a vitamin, and converted to the same overall active metabolites in the body. They thus possess the same kind of biological activity, although sometimes with lower potency.

B₁₂ also known as Cobalamin is the most chemically complex of all the vitamins. Vitamin B₁₂ is a generic descriptor name referring to a collection of cobalt and corrin molecules, which are defined by their particular vitamin function in the body. All of the substrate cobalt-corrin molecules from which B₁₂ is made must be synthesized by bacteria. After this synthesis is complete, the human body has the ability (except in rare cases) to convert any form of B₁₂ to an active form, by means of enzymatically removing certain prosthetic chemical groups from the cobalt atom and replacing them with others.

The four vitamers of B₁₂ are all deeply red-colored crystals and water solutions, due to the color of the cobalt-corrin complex.

- **Adenosylcobalamin (AdoCbl)**
- **Cyanocobalamin (CNCbl)**
- **Hydroxocobalamin (HOCbl)**
- **Methylcobalamin (MeCbl)**

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Methylcobalamin and Adenosylcobalamin are two different co-enzymes and the body requires both of them for different processes.

Cyanocobalamin is the most commonly found form in supplements and fortified foods. It is considered to be the most stable form of all the forms of B12 available because of the side group, cyanide, which is believed to be having the strongest attraction to the cobalamin molecule. It is also considered to be stable in extreme conditions like high temperatures compared to other forms.

Hydroxocobalamin is the form of B12 commonly found in foods. There are not many oral formulations available for people to take and it is normally injected in B12 shots. It is not recommended to be taken orally as the hydroxyl side group has the least attraction to the cobalamin molecule.

Adenosylcobalamin's chemically known as 5'-deoxy-5'-adenosylcobalamin is also known as dibenzocozide, cobamide, and cobinamide.

METHYLCOBALAMIN Vs CYNO-COBALAMIN

Cyanocobalamin is synthetic in nature , methylcobalamin is a naturally occurring form of vitamin B12 which can be obtained through supplements, as well as food sources like fish, meat, eggs and

milk. Methylcobalamin, is the king-pin, one of the two active, natural forms of B12. It helps in reducing homocysteine concentrations and is the the most important methyl donor in our body, methyl groups are for critical chemical reactions to help maintain our health. Methylcobalamin shows its greatest utility with people suffering form acute or chronic degenerative neurological symptoms, here it is considered as the only promising treatment available. It bypasses several potential issues in the absorption cycle and helps relieve or completely reverse symptoms.

Cyanocobalamin takes a lot of effort to reduce it to the active form, hence cyanocobalamin absorption varies greatly between individuals. Methylcobalamin is considered significantly better utilized compared to other forms and is around 2.5 times more potent (about 1/3 less is excreted in the urine) than cyanocobalamin. Even though similar doses are “absorbed”, but once absorbed, Methylcobalamin is accumulated and retained in the body much better than cyanocobalamin therefore the retention time is more. In any form, methylcobalamin levels are better retained and maintained than cyanocobalamin.

~**Dr Sanjay Agrawal**



Dr Sanjay Agrawal

Dr Agrawal founded PHARMA CONSULTANTS and INVENTOR to fulfill his passion, capabilities and desire to assist pharmaceutical companies around the globe. He has actively worked in pharmaceutical and related industries for more than 28 years and started this firm in 2005. He is **Editor-in-Chief** of renowned IJM Today and honorable member of the editorial board of **The Antiseptic**.

Methylcobalamin-Approved by CDSCO but Banned by FSSAI [without clarification]

Central Drugs Standard Control Organization of India is the National Regulatory Authority (NRA) of India for Drug products whereas Food Safety and Standards Authority of India (FSSAI) is an autonomous body established under the Ministry of Health & Family Welfare, Government of India. The FSSAI has been established under the Food Safety and Standards Act, 2006 which is a consolidating statute related to food safety and regulation in India. FSSAI covered eight categories of Functional foods, namely, Health Supplements, Nutraceu-

ticals, Food for Special Dietary Use, Food for Special Medical Purpose, Specialty food containing plant or botanicals, Foods containing Probiotics, Foods containing Prebiotics and Novel Foods.

It is very confusing and surprising for the Indian user to understand that how an essential product like Methylcobalamin is banned by FSSAI and approved by CDSCO as both drug and food products are equally critical. CDSCO has allowed usage of Methylcobalamin in various

products but Gujarat FDA through a notification has banned Methylcobalamin in nutraceutical products.

In the original regulation only Cynocobalamin and Hydroxycobalamin were allowed but in the extension issued in 2017 derivatives of Vitamins were also acceptable. Considering methylcobalamin as a derivative of Vitamin, manufacturers continued to manufacture methylcobalamin but due to recent notification it is considered as banned.

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