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Methylcobalamin proven effective for diabetic neuropathy, but regulatory delay stalls official ban lift

Shardul Nautiyal, Mumbai Thursday, August 29, 2024, 08:00 Hrs [IST]

Despite scientific evidence supporting the efficacy of methylcobalamin, particularly in the treatment of diabetic neuropathy, the Union ministry of health's lifting of the ban on this essential nutrient has yet to be formalized through a gazette notification.

In 2021, the central government had announced its decision to lift the ban on methylcobalamin, which was originally imposed in 2016. The decision was made after the Government of India's Scientific Committee reviewed the safety of the molecule and gave its approval in December 2019.

"Methylcobalamin is recognized internationally for its safety and effectiveness. It has been approved by the US FDA for use as a dietary supplement and is listed in the US Pharmacopoeia (USP). Despite this, the Union health ministry has yet to release the necessary gazette notification that would officially lift the ban on methylcobalamin in India," said Dr. Sanjay Agrawal, a leading pharmaceutical consultant.

Dr Agrawal has been a vocal advocate for the issuance of this notification, having previously appealed to former Union health minister Dr Mansukh Mandaviya and Prime Minister Narendra Modi to expedite the process. He emphasizes that methylcobalamin is an essential nutrient for critical bodily functions, including cell multiplication, blood formation, and protein synthesis.

Dr Agrawal explained, "The correct levels of homocysteine should range between 5 to 15 micromoles per litre. If the level exceeds 15 micromoles, it leads to hyperhomocysteinemia, which can cause the constriction of blood vessels. This condition often results in hypertension and neurological complications. For example, excessive homocysteine levels can reduce blood flow to the optic nerve, potentially contributing to conditions like glaucoma. It can also affect the heart and other organs due to hypertension."

To manage homocysteine levels effectively, Dr. Agrawal recommends a combination of methylcobalamin, vitamin B6, and folic acid. "This combination supports the homocysteine cycle and helps prevent serious complications," he added.

Methylcobalamin has been extensively studied for its potential benefits beyond just homocysteine regulation. Clinical trials have shown that it can improve nerve function, promote nerve regeneration, and reduce pain, making it highly effective in treating diabetic neuropathy. In addition, methylcobalamin has demonstrated promise in treating Alzheimer's disease, rheumatoid arthritis, and even in reducing symptoms of low back pain and neuralgia.

"Methylcobalamin helps protect neurons by promoting nerve regeneration and reducing neurotoxicity caused by glutamate. Studies have suggested its analgesic properties, making it an excellent agent for pain management in conditions like diabetic neuropathy," noted Dr. Agrawal.

Despite the proven benefits of methylcobalamin, the lack of a gazette notification has left the market in a state of confusion. There are currently no clear guidelines on the recommended dietary allowance (RDA) or tolerable upper limit (TUL) for methylcobalamin-containing products. Consequently, numerous brands have flooded the market with formulations containing RDAs as high as 1500 mcg for prophylactic use. This contradicts the Government of India recommended RDA of just 1 mcg.



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