



MD1003 Factsheet

MD1003 is a high-dose pharmaceutical preparation of a vitamin called biotin (also known as vitamin B7 or vitamin H) developed by the French company MedDay Pharmaceuticals. A member of the B-complex vitamins, biotin is essential for breaking down proteins, carbohydrates and fats into forms that the body can use. Biotin deficiency is common in pregnant women, and thus biotin supplementation may be recommended for these women as well as others who present with signs of biotin deficiency. Biotin is especially important for healthy skin, hair, eyes, liver, and nervous system functioning. Biotin can be found in food and supplements.

The dose of biotin that is currently being investigated in clinical trials for treatment of progressive MS and optic neuritis is 300mg/day. This dose is 10,000-fold higher than the Health Canada Recommended Daily Intake of 30µg/day, and 300-fold higher than the over-the-counter supplement dose of 1,000µg. In progressive MS clinical trials, because of the high dose of biotin that is being administered, it is considered an active drug that is believed to work by increasing energy production in demyelinated axons and enhance myelin production.

Although considered a vitamin in low doses, more information is needed on the long-term safety of taking ultra-high doses of biotin for a prolonged period of time. Taking high doses of biotin may also affect certain blood tests. Until more information is available, taking biotin at ultra-high doses should be an informed decision that is made through discussions with your healthcare team.

As of today, two phase III clinical trials testing the safety and benefits of MD1003 as a therapy for progressive MS have been completed (one focused on disability progression and the other on optic neuritis). A large [phase III clinical trial](#) is currently underway, and will include several Canadian study sites.:

Canadian recruitment for this trial has not begun. The MS Society does not oversee recruitment or any other logistics related to clinical trials however we will share information once it becomes available. For additional information about the trial including eligibility please speak with your healthcare team.

Currently known side-effects of MD1003:

Evidence from the two-completed phase III clinical trials suggests that MD1003 or high-dose biotin is generally safe and well tolerated over a one year period, but additional,

larger clinical trials will provide information related to safety and efficacy of higher doses of biotin over a longer period of time. Some side effects currently known include:

- Temporary diarrhea

- High doses of biotin can interfere with the results of certain blood tests such as thyroid function tests, some pregnancy blood tests, cardiac tests, cortisol levels and HIV serology. This will be a consideration for individuals who require periodic blood work (treatment monitoring) or those considering clinical trial participation. Ensure your health care provider is aware if you are taking high dose biotin prior to any blood work.

- Some animal studies have shown reproductive toxicity of high dose biotin therefore it is not recommended for women who are pregnant, considering pregnancy, or lactating.