

衛生署藥物辦公室
藥物註冊及進出口管制部

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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND
IMPORT/EXPORT CONTROL DIVISION
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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dear Healthcare Professionals,

Biotin (Vitamin B7): Safety Communication: May Interfere with Lab Tests

Your attention is drawn to the United States Food and Drug Administration's (FDA) announcement that the public, healthcare providers, lab personnel and lab test developers are alerted biotin can significantly interfere with certain lab tests and cause incorrect test results which may go undetected.

Biotin in blood or other samples taken from patients who are ingesting high levels of biotin in dietary supplements can cause clinically significant incorrect lab test results. The FDA has seen an increase in the number of reported adverse events, including one death, related to biotin interference with lab tests. Biotin in patient samples can cause falsely high or falsely low results, depending on the test. Incorrect test results may lead to inappropriate patient management or misdiagnosis. For example, a falsely low result for troponin, a clinically important biomarker to aid in the diagnosis of heart attacks, may lead to a missed diagnosis and potentially serious clinical implications. The FDA has received a report that one patient taking high levels of biotin died following falsely low troponin test results when a troponin test known to have biotin interference was used.

Many lab tests use biotin technology due to its ability to bond with specific proteins which can be measured to detect certain health conditions. For example, biotin is used in hormone tests and tests for markers of cardiac health like troponin. Biotin, also known as vitamin B7, is a water-soluble vitamin often found in multi-vitamins, prenatal vitamins, and dietary supplements marketed for hair, skin, and nail growth.

The FDA is aware of people taking high levels of biotin that would interfere with lab tests. Many dietary supplements promoted for hair, skin, and nail benefits contain biotin levels up to 650 times the recommended daily intake of biotin. Physicians may also be recommending high levels of biotin for patients with certain conditions such as multiple sclerosis (MS). Biotin levels higher than the recommended daily allowance may cause interference with lab tests. Patients and physicians may be unaware of biotin interference in laboratory assays. Even physicians who are aware of this interference are likely unaware as to whether, and how much biotin, patients are taking. Since patients are unaware of biotin interference, patients may not report taking biotin supplements to their physicians, and may even be unaware they are taking biotin (e.g., when taking products generally labeled for their benefits to hair and nails).

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aspire to be an internationally renowned public health authority*

The FDA is working with stakeholders to better understand biotin interference with laboratory tests, and to develop additional future recommendations for safe testing in patients who have taken high levels of biotin when using laboratory tests that use biotin technology. The FDA is monitoring reports of adverse events associated with biotin interference with laboratory tests and will update the public if significant new information becomes available.

Please refer to the following website in FDA for details:

<https://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm586641.htm>

In Hong Kong, there are 258 registered pharmaceutical products containing biotin. So far, the Department of Health (DH) has not received any case of adverse drug reaction related to biotin. DH will remain vigilant on safety update regarding biotin issued by other overseas drug regulatory authorities. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,



(Joseph LEE)

for Assistant Director (Drug)