UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION

الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع

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MOHAP/O/18/013010

تعميم اداري رقم (3010) لسنة 018

السادة/ مدراء المناطق الطبية المحترمين
السادة / مدراء المستشفيات الحكومية والخاصة المحترمين
السادة / الأطباء والصيادلة ومساعدي الصيادلة المحترمين
السادة / مدراء الصيدليات الحكومية والخاصة المحترمين

تحية طيبة ويعد،،

الموضوع: تنبيه حول استخدام المكملات الغذائية المحتوية على البيوتين(الفيتامين B7)

بداية يهديكم قطاع سياسة الصحة العامة والتراخيص اطيب التحيات ونتقدم إلى مقام سعادتكم بالشكر والتقدير على جهودكم الطيبة والخيرة والتواصل الدائم المثمر مع وزارة الصحة ووقاية المجتمع.

نود أن نلفت انتباهكم الى ما وردنا من هيئة الغذاء والدواء الأمريكية بخصوص حقيقة تتعلق باستخدام المكملات الغذائية المحتوية على البيوتين (الفيتامين B7). حيث تبين أن إستخدام جرعات عاليه من المكملات الغذائيه المحتويه على البيوتين (فيتامين B7) قد يؤدي إلى نتائج مخبريه خاطئه و ذلك بناءا على تزايد التقارير الوارده إلى هيئة الغذاء و الدواء الأميريكيه التي تؤكد الآثار الجانبيه الناتجه عن إستخدام المواد المذكوره أعلاه بما في ذلك حالة وفاه واحده سببها النتائج المخبريه الخاطئه.

البيوتين مادة موجودة في العديد من الفيتامينات مثل فيتامينات قبل الولادة، مكملات البيوتين والمكملات الغذائية للحفاظ على الشعر والبشرة والأظافر. قد تحتوي على المكملات الغذائية على مستويات عالية من البيوتين يمكن وصفها لحالات طبية مثل مرض التصلب المتعدد ، والتي قد تتداخل مع اختبارات إنزيمات القلب قد تؤدي الى نتائج غير صحيحة وبالتالي الى تشخيص خاطئ.

حيث شملت التحذيرات التالي:

1. ضرورة اتخاذ الاحتياطات اللازمة عند تفسير الاختبارات المعملية بعد تناول جرعات عاليه من البيوتين.
2. على ممارسي الرعاية الصحية متابعة مرضاهم إذا كانوا يتناولون أي مكمّلات بيوتين عندما لا تعكس نتائج المختبر الحالة الصحية الفعلية للمريض
3. على العاملين في المختبرات الطبية التأكد من أن المريض لا يستخدم البيوتين عند القيام باختبارات تستخدم تكنولوجيا البيوتين لمنع حدوث نتائج خاطئة. يفضل مليء استمارة خاصة للمرضى الذين يستخدمون البيوتين
4. على العاملين في المختبرات الطبية الاستفسار من المريض عند أخذ عينات في المختبر إذا كان المريض يأخذ البيوتين.
5. على ممارسي الرعاية الصحية اعلام مرضاهم بأن استخدام بيوتين قد تسبب في حصول نتائج مخبرية خاطئة.

لمزيد من المعلومات عن التحذير يرجى مراجعة الموقع الإلكتروني:

https://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm586505.htm

لمزيد من الاستفسارات الرجاء التواصل على الأرقام التالية:

هاتف: 2301448 -04 أو فاكس:2301947 -04 أو البريد الالكتروني: py @moh.gov.ae

كما يمكنكم الاطلاع على التعاميم الصادرة على الموقع الإلكتروني:

http://www.mohap.gov.ae/en/OpenData/Pages/default.aspx

وتفضلوا بقبول فائق الاحترام والتقدير ،،،

د. أمين حسين الأميري
وكيل الوزارة المساعد لسياسة الصحة العامة والتراخيص
رئيس اللجنة العليا لليقظة الدوائية

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مدير إدارة الدواء

SFDA SAFETY COMMUNICATION

28/01/2018

Biotin and Vitamin B_7 containing products May End-up with Misleading Lab Results

The Saudi Food and drug Authority (SFDA) would like to draw Health Care Professionals (HCPs) attention to a fact concerning the use of biotin or vitamin B7 containing supplements. The use of high doses of biotin, or vitamin B_7, may interfere with some laboratory tests causing misleading results, including troponin as a diagnostic marker for cardiac muscle injury for myocardial infarction (MI). There have been several international case reports, highlighting how risky was the biotin interference with lab tests. One of those reported cases resulted in death.

Biotin exists in various multivitamin preparations including, prenatal multivitamins, biotin supplements, supplements to keep hair, skin, and nail healthy. Some supplements may contain high levels of biotin that could be prescribed for conditions such as multiple sclerosis, which may interfere with cardiac enzymes tests causing misleading findings.

The SFDA emphasizes that HCPs should take extra precautions when interpreting lab tests after ingestion of large amount of biotin. Additionally, the SFDA advises HCPs to ask their patients if they are taking any biotin supplements when lab results do not reflect the actual patient health status.

Report Adverse Drug Events (ADEs) to the SFDA

The SFDA urges both HCPs and patients to report ADEs resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road
Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
Toll free number: 19999
Tel: 01 2038222 ext. 2317, 2356, 2340, 5769
Fax: 01 2057662
Email: NPC.Drug@sfda.gov.sa

The FDA Warns that Biotin May Interfere with Lab Tests: FDA Safety Communication

Date Issued: November 28, 2017

Audiences:

- People taking or considering taking biotin, vitamin B7, supplements
- Physicians and other health care providers who order lab tests
- Lab personnel
- Lab test developers

Specialties:

All physicians and health care providers

Product:

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.

Purpose:

The FDA is alerting the public, health care providers, lab personnel, and lab test developers that biotin can significantly interfere with certain lab tests and cause incorrect test results which may go undetected.

Summary of Problem and Scope:

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.

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 unware they are taking biotin (e.g., when taking products generally labeled for their benefits to hair and nails).

Recommendations:

For Consumers:

- Talk to your doctor if you are currently taking biotin or are considering adding biotin, or a supplement containing biotin, to your diet.
- Know that biotin is found in multivitamins, including prenatal multivitamins, biotin supplements, and supplements for hair, skin, and nail growth in levels that may interfere with laboratory tests.
- Be aware that some supplements, particularly those labeled for hair, skin, and nail benefits, may have high levels of biotin, which may not be clear from the name of the supplement.
- If you have had a lab test done and are concerned about the results, talk to your health care provider about the possibility of biotin interference.

For Health Care Providers:

- Talk to your patients about any biotin supplements they may be taking, including supplements marketed for hair, skin, and nail growth.
- Be aware that many lab tests, including but not limited to cardiovascular diagnostic tests and hormone tests, that use biotin technology are potentially affected, and incorrect test results may be generated if there is biotin in the patient's specimen.
- Communicate to the lab conducting the testing if your patient is taking biotin.
- If a lab test result doesn't match the clinical presentation of your patient, consider biotin interference as a possible source of error.
- Know that biotin is found in multivitamins, including prenatal multivitamins, biotin supplements, and dietary supplements for hair, skin, and nail growth in levels that may interfere with lab tests.
- Report to the lab test manufacturer and the FDA if you become aware of a patient experiencing an adverse event following potentially incorrect laboratory test results due to biotin interference.

For lab personnel:

- If you use assays with biotin technology, be aware that it is difficult to identify samples that contain biotin; therefore, it is important to communicate with health care providers and patients to prevent incorrect test results.
- If you are collecting samples in the lab, ask whether the patient is taking biotin.
- Educate health care providers about biotin interference with certain lab tests used in your lab.
- Consider that the daily recommended allowance for biotin is 0.03 mg and these biotin levels do not typically cause significant interference. However, supplements containing high biotin levels including those marketed for hair, skin, and nail benefits, may contain up to 20 mg of biotin, and physicians may recommend up to 300 mg per day for conditions such as multiple sclerosis. Biotin levels higher than the recommended daily allowance may cause significant interference with affected lab tests.
- Be aware that specimens collected from patients taking high levels of biotin may contain more than 100 ng/mL biotin. Concentrations of biotin up to 1200 ng/mL may be present in specimens collected from patients taking up to 300 mg per day.
- Currently available data is insufficient to support recommendations for safe testing using affected tests in patients taking high levels of biotin, including about the length of time for biotin clearance from the blood.
- Communicate with the lab test manufacturer if you have questions about biotin interference.

For lab test manufacturers and developers:

- If your assay uses biotin technology, contact the FDA to discuss biotin interference.
- Investigate interference from biotin (up to at least 1200 ng/mL biotin) in your assays that use biotin technology. Determine the lowest concentration of biotin that may cause clinically significant interference with your test(s).
- Communicate with your customers if they may be unaware that your test uses biotin technology and how it may be affected.
- Contact the FDA if you have any questions about biotin technology and interference.

FDA Actions:

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.

Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with these products.

If you suspect or experience a problem with a laboratory test while taking biotin, we encourage you to file a voluntary report through **MedWatch (/Safety/MedWatch/default.htm)**, the FDA Safety Information and Adverse Event Reporting program. Health care personnel employed by facilities that are subject to FDA's user facility reporting requirements should follow the reporting procedures established by their facilities.

Additional Resources

- **NIH Biotin Fact Sheet for Consumers (https://ods.od.nih.gov/factsheets/Biotin-Consumer/)**

Contact Information:

If you have questions about this communication, please contact CDRH's Division of Industry Communication and Education (DICE) at **DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV)**, 800-638-2041, or 301-796-7100.

More in Safety Communications (/MedicalDevices/Safety/AlertsandNotices/default.htm)

2018 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm592582.htm)

2017 Safety Communications (/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm)