

# **Important Information for Extavia® (interferon beta 1-b) Patients Regarding Triad Group's Alcohol Prep Products**

Jan 10, 2011

East Hanover, NJ, January 10, 2011 – Novartis Pharmaceuticals Corporation (Novartis) has become aware of a United States market recall of all lots of alcohol prep pads, swabs and swabsticks manufactured by the Triad Group and marketed under various brand names. The recall has been initiated due to concerns about potential microbial contamination of the alcohol products with *Bacillus cereus*, that could potentially lead to life-threatening infections.

Some of these alcohol prep pads from Triad may have been included in U.S. packaging for Extavia, a product marketed by Novartis. The Triad alcohol prep pads should not be used.

There is NO involvement or potential contamination of the Extavia vial or other components of the Extavia US packaging. This issue is confined to the Triad alcohol prep products.

Patient safety is a top priority and Novartis wants to ensure that U.S. patients and physicians using Extavia are aware of the Triad recall and what they should do.

Patients using Extavia should immediately discontinue using the Triad alcohol prep pads included in the Extavia packaging and dispose of those pads in the trash. When preparing to take their Extavia injection, patients should prepare the injection site in either of the following ways: By rubbing the area with (i) sterile gauze and 70% isopropyl alcohol, or (ii) alcohol prep pads -- from another manufacturer -- which are not the subject of a recall. These items are generally available at most retail pharmacies.

Please note that any products with the following names are being recalled and should not be used: Any alcohol pad with "Triad Group" listed as the manufacturer, or products with the following names in their packaging: Cardinal Health, PSS Select, VersaPro, Boca/ Ultilet, Moore Medical, Walgreens, CVS, Conzellan.

Novartis is currently in the process of gathering additional information from both Triad and the U.S. Food and Drug Administration (FDA). In the interim, Novartis has halted all shipments of Extavia containing the Triad alcohol prep products to its distribution network. We will provide additional information when it becomes available.

Further information on this Triad recall can be found on the FDA website at <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm239319.htm>. If you have additional questions, please consult with your pharmacist or healthcare provider or contact 1-888-NOW NOVA.

## **Extavia Indication and Important Safety Information**

### **Indication**

EXTAVIA (interferon beta-1b) is a prescription medication approved for the treatment of relapsing forms of multiple sclerosis (MS) to reduce the frequency of episodes. EXTAVIA is also for patients who have had a single episode and MRI findings consistent with MS.

### **Important Safety Information**

Do not take EXTAVIA if you are allergic to any of its ingredients or have had an allergic reaction such as trouble

breathing, skin flushing, or hives with another interferon beta product, or to human albumin.

Possible serious side effects with EXTAVIA include:

**Depression.** Some people who take EXTAVIA become seriously depressed (feeling sad or sinking spirits) and/or have thoughts about killing themselves (suicidal thoughts) or try to kill themselves. Tell your doctor if you take medicines for depression or have had mental illness, including depression. If you feel sadder/helpless or like hurting yourself or others, tell a family member or friend and call your doctor right away. You may need to stop taking EXTAVIA.

**Redness, pain, or swelling at the injection site.** Serious skin reactions, including infections or severe damage to skin and tissue below skin (necrosis), can occur. Call your doctor right away if you have any of these signs of a serious problem at an injection site: swelling and pain, infection that does not heal within a few days; draining fluid; or breaks in your skin that may have blue-black discoloration. To lessen your chance of having a serious skin reaction, rotate injection sites.

**Severe allergic reactions,** such as trouble breathing and swallowing. Significant swelling of the mouth and tongue may occur. These reactions can happen quickly and occur after your first dose of EXTAVIA or may not happen until after you have taken EXTAVIA many times. If you think you are having an allergic reaction, stop taking EXTAVIA and call your doctor right away.

**Flu-like symptoms.** Most people have flu-like symptoms (fever, chills, sweating, muscle aches, and tiredness), which may lessen or go away over time. Talk to your doctor about taking a nonprescription medicine for pain or fever before or after you take EXTAVIA.

**Blood, liver, and thyroid problems.** You may have a decrease in the amount of white blood cells (cells that fight infection), red blood cells (cells that carry oxygen to body tissues), or platelets (cells that help form clots). If this decrease is severe, you may be less able to fight infection, feel tired or sluggish, or bruise or bleed easily. Tell your doctor if you have symptoms of liver problems such as yellowing of the skin and whites of the eyes, easy bruising, or right-sided stomach (abdominal) pain. Your thyroid function may also change, which may include feeling hot or cold or changes in your weight. Your doctor will do blood tests at regular intervals to help detect blood, liver, and thyroid problems.

**Risk to pregnancy.** If you become pregnant while taking EXTAVIA, stop taking EXTAVIA and call your doctor right away, as EXTAVIA may cause you to lose your pregnancy (miscarriage) or cause harm to your unborn child. You and your doctor will need to decide whether the possible benefit of taking EXTAVIA outweighs the possible risks to your unborn child.

Tell your doctor about all the medicines you take and your medical conditions, including if you have or had depression, anxiety, trouble sleeping, liver or thyroid problems, bleeding or bruising easily, low red or white blood cells, or are breastfeeding or plan to breastfeed.

The most common side effects with EXTAVIA (at least 2% more than placebo) were: decreased white blood cells, enlarged lymph nodes, headache, trouble sleeping, incoordination, high blood pressure, thirst, abdominal pain, increased liver enzymes, rash, skin disorder, increased muscle tone, muscle pain, urinary urgency, vaginal bleeding, impotence, injection site reaction, excessive fatigue, flu-like symptom complex, pain, fever, chills, tissue swelling, chest pain, malaise, and injection site necrosis.

For Important Product Information, including Medication Guide, log onto [www.extavia.com](http://www.extavia.com).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

The foregoing release contains forward-looking statements that can be identified by terminology such as “potential,” “potentially,” “may,” “will,” or similar expressions, or by express or implied discussions regarding potential future recalls of Extavia, or regarding potential future revenues from Extavia. You should not place undue reliance on these statements. Such forward-looking statements reflect the current views of management regarding future events, and involve known and unknown risks, uncertainties and other factors that may cause actual results to be materially different from any future results, performance or achievements expressed or implied by such statements. There can be no guarantee that Extavia will be subject to any recalls in the future as a result of the alcohol prep pads from Triad. Nor can there be any guarantee that Extavia will achieve any particular levels of revenue in the future. In particular, management’s expectations regarding Extavia could be affected by, among other things, unexpected regulatory actions or delays or government regulation generally; unexpected consumer activity in response to the Triad recall announcement; competition in general; government, industry and general public pricing pressures; the company’s ability to obtain or maintain patent or other proprietary intellectual property protection; the impact that the foregoing factors could have on the values attributed to the Novartis Group’s assets and liabilities as recorded in the Group’s consolidated balance sheet, and other risks and factors referred to in Novartis AG’s current Form 20-F on file with the US Securities and Exchange Commission. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those anticipated, believed, estimated or expected. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

#### About Novartis

Novartis Pharmaceuticals Corporation researches, develops, manufactures and markets innovative prescription drugs used to treat a number of diseases and conditions, including cardiovascular, dermatological, central nervous system, bone disease, cancer, organ transplantation, psychiatry, infectious disease and respiratory. The company’s mission is to improve people’s lives by pioneering novel healthcare solutions. Located in East Hanover, New Jersey, Novartis Pharmaceuticals Corporation is an affiliate of Novartis AG, which provides healthcare solutions that address the evolving needs of patients and societies. Focused solely on healthcare, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic pharmaceuticals, preventive vaccines, diagnostic tools and consumer health products. Novartis is the only company with leading positions in these areas. In 2009, the Group’s continuing operations achieved net sales of USD 44.3 billion, while approximately USD 7.5 billion was invested in R&D activities throughout the Group. Headquartered in Basel, Switzerland, Novartis Group companies employ approximately 102,000 full-time-equivalent associates and operate in more than 140 countries around the world. For more information, please visit <http://www.novartis.com>.

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**List of links present in page**

1. <https://prod1.novartis.com/us-en/us-en/news/media-releases/important-information-extavia-interferon-beta-1-b-patients-regarding-triad-groups-alcohol-prep-products>
2. <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm239319.htm>
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