Merck Voluntarily Recalls One Lot of GARDASIL® in the United States

Terms:
Company Statements

Published Date and Time:
12/20/13 2:37 pm EST

News Organization:
Merck

News Organization Location:
WHITEHOUSE STATION, N.J.

Merck (NYSE: MRK), known as MSD outside the United States and Canada, is voluntarily recalling one lot of its human papillomavirus (HPV) vaccine, GARDASIL® [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant], in the United States, including Puerto Rico. The recall is due to the potential for a limited number of vials to contain small glass particles.

The recall pertains to 743,360 single dose 0.5mL vials which were distributed by Merck between August 20, 2013 and October 9, 2013. Merck estimates that the issue may have affected approximately 10 vials out of the 743,360 being recalled.

The recall does not affect any other lots of GARDASIL or any other vaccines manufactured by Merck. The overall supply of GARDASIL is not affected, and Merck expects the financial impact to be immaterial. Merck distributed 11.2 million vials of GARDASIL in the United States in 2013.

“We are fully committed to ensuring the high quality of our vaccines,” said Greg Guyer, Ph.D., senior vice president, Global Quality, Merck Manufacturing Division. "We know that our vaccines can play an important role in the nation's public health system."

Merck is working closely with the U.S. Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC) on this recall. The CDC has also issued a statement on this. Please click here.

About GARDASIL

GARDASIL is indicated in the United States for use in girls and young women 9 through 26 years of age for the prevention of cervical, vulvar, vaginal and anal cancers caused by HPV types 16 and 18; genital warts caused by HPV types 6 and 11; and precancerous or dysplastic lesions caused by HPV types 6, 11, 16 and 18. GARDASIL is also approved for use in boys and men 9 through 26 years of age for the prevention of anal cancer caused by HPV types 16 and 18; genital warts caused by HPV types 6 and 11; and precancerous or dysplastic lesions caused by HPV types 6, 11, 16 and 18.

Important information about GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant]

GARDASIL does not eliminate the necessity for women to continue to undergo recommended cervical cancer screening. Recipients of GARDASIL should not discontinue anal cancer screening if it has been recommended by a health care provider.

GARDASIL has not been demonstrated to provide protection against diseases from vaccine and non-vaccine HPV types to which a person has previously been exposed through sexual activity.

GARDASIL is not intended to be used for treatment of active external genital lesions; cervical, vulvar, vaginal and anal cancers; cervical intraepithelial neoplasia, vulvar intraepithelial neoplasia, vaginal intraepithelial neoplasia, or anal intraepithelial neoplasia.

GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant] has not been demonstrated to protect against disease due to HPV types not contained in the vaccine.

Not all vulvar, vaginal and anal cancers are caused by HPV, and GARDASIL protects only against those vulvar, vaginal and anal cancers caused by HPV Types 16 and 18.

Select safety information for GARDASIL

GARDASIL is contraindicated in individuals with hypersensitivity, including severe allergic reactions to yeast, or after a previous dose of GARDASIL.

Because vaccinees may develop syncope, sometimes resulting in falling with injury, observation for 15 minutes after
administration is recommended. Syncope, sometimes associated with tonic-clonic movements and other seizure-like activity, has been reported following vaccination with GARDASIL. When syncope is associated with tonic-clonic movements, the activity is usually transient and typically responds to restoring cerebral perfusion.

GARDASIL is not recommended for use in pregnant women.

The most common adverse reaction was headache. Common adverse reactions that were observed among recipients of GARDASIL at a frequency of at least 1.0 percent and greater than placebo were: fever, nausea, dizziness; and injection-site pain, swelling, erythema, pruritus and bruising.

**Dosage and administration for GARDASIL**

GARDASIL is a ready-to-use, three-dose, intramuscular vaccine. GARDASIL should be administered in three separate intramuscular injections in the deltoid region of the upper arm or in the higher anterolateral area of the thigh. The following dosage schedule is recommended: first dose at elected date, second dose two months after the first dose and the third dose six months after the first dose.

**About Merck**

Today's Merck is a global healthcare leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies, and consumer care and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to healthcare through far-reaching policies, programs and partnerships. For more information, visit [www.merck.com](http://www.merck.com) and connect with us on [Twitter](http://twitter.com), [Facebook](http://facebook.com) and [YouTube](http://youtube.com).

**Forward-Looking Statement**

This statement includes “forward-looking statements” within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of Merck’s management and are subject to significant risks and uncertainties. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; Merck’s ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of Merck’s patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck’s 2012 Annual Report on Form 10-K and the company’s other filings with the Securities and Exchange Commission (SEC) available at the SEC’s Internet site ([www.sec.gov](http://www.sec.gov)).


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**Language:**

English