



DRAFT

SMALLPOX

SMALLPOX FACT SHEET

INVESTIGATIONAL VACCINIA IMMUNE GLOBULIN (VIG) INFORMATION

Vaccinia Immune Globulin (VIG) may help people who have certain serious reactions to the smallpox vaccine. VIG is an investigational new drug (IND) made from plasma from the blood of people who have immunity to smallpox. If you develop a serious reaction to the smallpox vaccine, you may be offered VIG.

VIG Information

- VIG is an immune globulin made from human blood. VIG is made from the blood of people who have been vaccinated more than once (usually many times) with the smallpox vaccine. The part of the blood that gives protection from vaccinia infection is taken out, purified (cleaned), and bottled. It is called the immune globulin.
- VIG is not licensed (approved) by the Food and Drug Administration (FDA). It is "investigational."
- There are two types of VIG available for use. One is called VIG-intramuscular (VIG-IM), and the other is called VIG-intravenous (VIG-IV). At one time, VIG-IM was approved by the FDA. It is now investigational due to a color change. However, this color change does not appear to affect the safety or ability of the product to treat vaccine reactions. VIG-IV has never been approved by the FDA, however, it is very similar to VIG-IM and will be further evaluated for licensure.

How is VIG administered?

VIG is given by a needle in the muscle in the arm (VIG-IM), or by a needle in a vein in the arm (VIG-IV). The type of VIG (IM vs. IV) given will depend on which is available.

Side Effects

- VIG is made from human blood plasma. Products made from human blood may contain infectious agents, such as viruses, that can cause disease. The risk that such products carry viruses has been lowered by checking plasma donors for prior contact with certain viruses, by testing for the presence of certain viruses, and by killing and/or removing viruses if they are there. However, there still exists a chance that the VIG may give you a disease.
- Immune globulin products like VIG may cause allergic reactions that can be mild or they may be serious and cause life-threatening breathing and heart problems. If you have a serious or life-threatening reaction, you will be given medical care and drugs to help you.
- People who have a deficiency in an antibody called IgA or who have had a serious allergic reaction to human antibody products before are at risk for an allergic reaction to VIG.
- Most side effects from similar products are mild and do not last for very long. You may experience back pain, chills, headache, muscle pain, joint pain, itching, weakness, fever, nausea, vomiting, abdominal cramps, flushing, tightness of the chest, sweating, changes in blood pressure, dizziness, paleness, shortness of breath, and wheezing. Rashes occur rarely.
- Some people experience pain and soreness at or near the site where the VIG is given. While this is unpleasant, it is not serious and can be treated with common pain relievers such as acetaminophen (like Tylenol).

For more information, visit www.cdc.gov/smallpox, or call the CDC public response hotline at (888) 246-2675 (English), (888) 246-2857 (Español), or (866) 874-2646 (TTY)

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