Frequently Asked Questions Regarding the Janssen COVID-19 Vaccine

1. **Why did the FDA and CDC pause the use of the Janssen (Johnson & Johnson) COVID-19 vaccine?**

   There were six reports to the Vaccine Adverse Event Reporting System (VAERS) of a rare but serious complication in people who had received this vaccine. Most cases were in females 18-49 years old. Affected individuals had low levels of platelets (blood cells that help your body stop bleeding) in their blood and serious blood clots called cerebral venous sinus thrombosis, and in some cases blood clots in large veins in the abdomen.

   The use of the vaccine was paused so that these serious side effects could be reviewed. In addition to the six reported cases, the FDA and CDC reviewed information from clinical trials of the Janssen COVID-19 vaccine. They also reviewed reports and clinical trials of the AstraZeneca COVID-19 vaccine, which is not approved in the United States but has been used in Europe and other countries and uses a similar method of delivering the vaccine.

2. **Is it safe to get the Janssen (Johnson & Johnson) vaccine?**

   After reviewing all available evidence, the FDA determined that the benefits of the vaccine in preventing severe COVID-19 disease are greater than the potential risk of rare, severe side effects. The vaccine is very effective in preventing moderate to severe COVID-19, hospitalizations, and deaths from the disease.

   Health care providers across the country have been provided with information on how to identify and treat cases of severe side effects, including blood clots. While we don’t anticipate rare side effects to occur, Hartford Healthcare is well-prepared to care for patients if they do happen.

3. **If I get this vaccine, what side effects should I look out for?**

   - **Injection site reactions** include pain at the site, redness, swelling
   - **General side effects** include headache, feeling tired, muscle aches, nausea, and fever
   - **Allergic reactions** would usually happen within a few minutes to an hour of getting the vaccine. Signs of a severe allergic reaction could include difficulty breathing, swelling of your face and throat, a fast heartbeat, a rash all over your body, feeling dizzy or weak.
   - **Blood clots** after the vaccine are rare. Symptoms started 1-2 weeks after getting the vaccine and included shortness of breath, chest pain, leg swelling, severe abdominal pain, severe headaches or blurry vision, easy bruising or tiny blood spots under the skin beyond the site of the injection.

   (continued on back)
4. **When should I contact my doctor or seek medical attention after getting a vaccine?**

   If you have any symptoms of a severe allergic reaction, call 911 or go to a hospital for medical attention.

   If you have any symptoms of blood clots listed above within 3 weeks of receiving your vaccine, seek medical attention immediately.

5. **How can I report adverse reactions or side effects after getting the vaccine?**

   Sign up for V-safe at [vsafe.cdc.gov](http://vsafe.cdc.gov) This smartphone-based tool checks in on you after you receive your vaccine.

   You can also report side effects to the FDA/CDC Vaccine Adverse Event Reporting System (VAERS) at 1-800-822-7967 or [https://vaers.hhs.gov/reportevent.html](https://vaers.hhs.gov/reportevent.html)