



Better Pharmacist Knowledge

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Jordan Drug Information and Toxicology Center 2021

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Coronavirus (COVID-19) Update: FDA Allows More Flexible Storage, Transportation Conditions for Pfizer-BioNTech COVID-19 Vaccine

The FDA has approved alternative storage requirements allowing **undiluted frozen vials** of the Pfizer-BioNTech COVID-19 Vaccine to be transported and stored at **conventional freezer temperatures (-25 to -15°C [-13 to 5°F]) for a period of up to 2 weeks**. This is an alternative to the preferred storage of the undiluted vials in an ultra-low temperature freezer between -80 to -60°C (-112 to -76°F). Vials stored at -25 to -15°C (-13 to 5°F) for up to 2 weeks may be returned 1 time to the recommended storage condition of -80 to -60°C (-112 to -76°F). [1]

Thawing Frozen Vaccine

- Frozen vaccine must be thawed before using.
- Thaw vaccine in the refrigerator **or** at room temperature: ,

Refrigerator: Between 2°C and 8°C (36°F and 46°F)
Unpunctured vials may be stored in the refrigerator for up to 120 hours (5 days). ,

Room temperature(for immediate use): Up to 25°C (77°F)
Unpunctured vials cannot be kept at room temperature for more than 2 hours (including thaw time).[2]

Infectious diseases; emergency medicine (adult and pediatric) / Tocilizumab for COVID-19

For hospitalized adults with COVID-19 who, within the prior 24 to 48 hours, have initiated high-flow supplemental oxygen, non-invasive ventilation, or mechanical ventilation, we suggest adding **Tocilizumab** to usual care (which includes **Dexamethasone**)(Grade 2C).

For hospitalized adults with COVID-19 who are receiving low-flow supplemental oxygen and have both progressively increasing oxygen requirements despite dexamethasone and significantly elevated inflammatory markers, we suggest adding tocilizumab to usual care(Grade 2C).

More specifically, we would give tocilizumab to such patients if they have progressively greater oxygen requirements for reasons related to COVID-19 but not if their oxygen requirement is stable or is worsening due to other causes of respiratory decompensation (eg, asthma exacerbation, congestive heart failure).

We only use **tocilizumab** in patients who are also taking **dexamethasone** (or another glucocorticoid) and generally limit it to a single dose.

Recommendations from expert and governmental guideline groups vary slightly. The National Institutes of Health (NIH) COVID-19 Treatment **Guidelines Panel recommends adding tocilizumab to dexamethasone in recently hospitalized patients who are on high-flow oxygen or greater support and have either been admitted to the ICU within the prior 24 hours or have significantly increased inflammatory** .[3]

COVID-19 Vaccine (Adenovirus Vector): Canadian National Advisory Committee on Immunization (NACI) AstraZeneca COVID-19 Vaccine Recommendations

The Canadian National Advisory Committee on Immunization (NACI) has recommended that the **AstraZeneca COVID-19 vaccine not be used** in adults younger than 55 years at this time while the safety signal of vaccine-induced prothrombotic immune thrombocytopenia (VIPIT) following vaccination is investigated further. **Rare cases** of thromboembolic events, including cerebral venous sinus thrombosis, associated with thrombocytopenia have been reported in Europe following post-licensure use of the AstraZeneca COVID-19 vaccine.

Cases have been reported primarily in women younger than 55 years and most commonly between 4 and 16 days after receipt of the vaccine. **The exact mechanism by which the AstraZeneca vaccine triggers VIPIT is still under investigation**. At this time, no other risk factors have consistently been identified in patients who develop VIPIT. This adverse event has not been identified following receipt of mRNA COVID-19 vaccines to date. [4]



References:

1. Coronavirus (COVID-19) Update: FDA Allows More Flexible Storage, Transportation Conditions for Pfizer-BioNTech COVID-19 Vaccine, accessed online via <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda>.
2. Pfizer-BioNTech COVID-19 Vaccine Preparation and Administration Summary.CDC .pdf
3. Practice Changing UpDates 2021, accessed online via UpToDate
4. COVID-19 adenovirus vector vaccine (United States and Canada: Authorized for use): Drug information, accessed online via UpTo-Date

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If the patient taking immunosuppressants – can he have the vaccine?

YES ; as the vaccine is **not a live vaccine**, it can be given if you are taking the medications listed below:

There are some drugs used to treat rheumatology related conditions which **suppress the immune system** such as:

- Steroids • Methotrexate • Leflunomide
- Mycophenolate • Azathioprine • Ciclosporin
- Tacrolimus • Cyclophosphamide
- **Biologic medications including:**
 - Adalimumab • Etanercept • Golimumab • Infliximab
 - Sarilumab • Tocilizumab • Abatacept • Apremilast
 - Ixekizumab • Secukinumab • Ustekinumab • Anakinra
 - Belimumab • Rituximab

• **JAK inhibitors:** Baracitinib, Tofacitinib, Upadacitinib.
When taking these medications it is possible that your response to the vaccine may be dampened. As such, you should continue to follow government guidance on reducing your risk of infection.

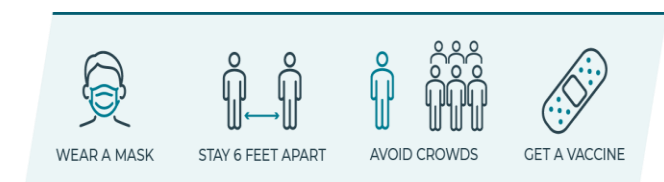
People who have recently had **Rituximab** (also known as Truxima, Rixathon, and MabThera) may be less likely to make an immune response to the COVID-19 vaccine. **This means the vaccine may be less effective if you have had Rituximab within 6 months before or 4 weeks after the vaccine is given.** However, it is still safe to have the vaccine if you have recently had Rituximab and you may get some benefit from it. For Rheumatology patients receiving Rituximab we would advise the following:

- If you are offered the COVID-19 vaccine and your last Rituximab infusion was more than 8 weeks ago, please have the vaccination when you are offered it - do not delay the vaccine.
- If you are offered the COVID-19 vaccine less than 8 weeks after your Rituximab infusion please call the Rheumatology advice line to discuss the best timing of your COVID-19 vaccination. You will be advised depending on your personal circumstances.
- If you are due your next Rituximab infusion and have a planned date for a COVID-19 vaccination please contact us by telephone to discuss if it is appropriate to delay your Rituximab infusion by a few weeks in order to get the best response to the vaccine dose. [5]

Premedications to Prevent Post vaccination

Symptoms

The CDC **does not recommend routine** prophylactic administration of antihistamines or antipyretic/analgesic medications eg, acetaminophen, nonsteroidal anti-inflammatory



drugs)(for the purpose of preventing post vaccination symptoms. **Antihistamines** may mask cutaneous symptoms of anaphylaxis, which could delay the diagnosis and management of the reaction. The impact of antipyretic/analgesic medications on antibody response is unknown. Antipyretic/analgesic medications may be taken after vaccination for the treatment of post vaccination local/systemic symptoms (if medically appropriate).[6]

After getting a COVID-19 vaccine, will I test positive for COVID-19 on a viral test?

No. Neither the recently authorized and recommended vaccines nor the other COVID-19 vaccines currently in clinical trials in the United States can cause you to test positive on viral tests, which are used to see if you have a current infection.

If your body develops an immune response—the goal of vaccination—there is a possibility you may test positive on some antibody tests. Antibody tests indicate you had a previous infection and that you may have some level of protection against the virus. Experts are currently looking at how COVID-19 vaccination may affect antibody testing results. [7]



Characteristics of select COVID-19 vaccines:[8]

Company	Doses / Efficacy against symptomatic COVID-19	Common side effects
Pfizer/BioNTech	2 doses 3weeks apart	Local injection site reactions Systemic symptoms (fevers, chills, fatigue, myalgias, headache)
mRNA	95%	
Astra-Zeneca	2 doses 4 to 12 weeks Apart (Manufacturer)	Local injection site reactions Systemic symptoms (fevers, chills, fatigue, myalgias, headache)
Replication-incompetent adenovirus vector	8 to 12 weeks apart (WHO) 70%	

References:

5. Royal United Hospitals Bath NHS Foundation Trust, Date of first publication. Updated 14 Feb 2021 v1.3, accessed online via www.ruh.nhs.uk
6. COVID-19 adenovirus vector vaccine (United States and Canada: Authorized for use): Drug information, accessed online via Up-to-date
7. Myths and Facts about COVID-19 Vaccines, accessed online via CDC
8. Characteristics of select COVID-19 vaccines, accessed online via UpToDate.