

**Fact Sheet for Patients And Parent/Caregivers
Emergency Use Authorization (EUA) of FRESenius PROPOVEN 2% (Propofol)
Emulsion during Coronavirus Disease 2019 (COVID-19) Pandemic**

Fresenius Propoven 2% Emulsion is used for sedation of patients who are on a machine that helps with breathing (ventilator). Fresenius Propoven 2% Emulsion is given through a vein by intravenous (IV) infusion in patients **16 years of age and older in the intensive care unit (ICU)**. Fresenius Propoven 2% Emulsion **should be not be used in pregnant women** unless there are no other FDA-approved medicines available for ICU sedation. This fact sheet contains information to help you understand the risks and benefits of Fresenius Propoven 2% Emulsion you have received or may receive.

There is currently a shortage of U.S. Food and Drug Administration (FDA)-approved propofol products that maintain sedation for patients who are on a machine that helps with breathing (ventilator) due to the COVID-19 pandemic. Fresenius Propoven 2% Emulsion is not an FDA-approved medicine in the United States. **Fresenius Propoven 2% Emulsion contains the same active ingredient, propofol, as Diprivan Injectable Emulsion and other propofol products** approved in the United States, but **contains double the concentration**. Fresenius Propoven 2% Emulsion is currently approved in Europe and other international countries. Read this Fact Sheet for information about Fresenius Propoven 2% Emulsion. Talk to your healthcare provider if you have questions. It is your choice to take Fresenius Propoven 2% Emulsion or stop it at any time.

What is COVID-19?

COVID-19 is caused by a virus called a coronavirus. This type of coronavirus has not been seen before. This new coronavirus was first found in people in December 2019. You can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. Older people and people of all ages with severe, long lasting (chronic) medical conditions like heart disease, lung disease and diabetes, for example seem to be at higher risk of being hospitalized for COVID-19.

The symptoms of COVID-19 are fever, cough and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

What is Fresenius Propoven 2% Emulsion?

Fresenius Propoven 2% Emulsion is the brand name for propofol which belongs to a group of medicines called sedative/hypnotics. It will be used to help calm (sedate) you if you need a tube inserted (intubation) and a machine to help you breathe (ventilator) while in an ICU.

What should I tell my healthcare provider before I receive Fresenius Propoven 2% Emulsion?

Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies
- Have kidney or liver problems
- Are pregnant or plan to become pregnant. **DUE TO POSSIBILITY OF BIRTH DEFECTS, FRESENIUS PROPOVEN 2% EMULSION SHOULD BE USED IN PREGNANT WOMEN ONLY IF THERE ARE NO OTHER FDA-APPROVED MEDICINES AVAILABLE FOR YOUR MEDICAL CONDITION.**
- Are breastfeeding or plan to breastfeed
- Are taking any medicines including prescription, over-the-counter, vitamins, or herbal products.

Who should not receive Fresenius Propoven 2% Emulsion?

Do not receive Fresenius Propoven 2% Emulsion if:

- You have ever received propofol before and have had an allergic reaction to it
- You have allergies to peanut or soy
- You are 16 years of age or younger

How will I receive Fresenius Propoven 2% Emulsion?

Fresenius Propoven 2% Emulsion is given to you through a vein (IV) under the direct supervision of an anesthesiologist or intensive care doctor who will closely control the amount of Fresenius Propoven 2% Emulsion given to you.

What are the important possible side effects of Fresenius Propoven 2% Emulsion?

The most common side effects are:

- Drop in blood pressure
- Changes in heart rate
- Hot flushes
- Changes in breathing, coughing and hiccups

Less common side effects are:

- Allergic reactions, for example swelling of the throat, difficulty breathing, reddening of the skin
- Inflammation of the pancreas
- Fluid in the lungs
- Skin or tissue damage if given or leaks outside of the vein
- Muscle damage
- Heart failure
- During recovery period, coughing or nausea, headache, dizziness, shivering, fever, epileptic movements, spasms, irregular heartbeat
- Change in color of your urine

What other treatment choices are there?

Your anesthesiologist or intensive care doctor may give you other sedation agents depending on your medical condition.

What if I am pregnant or breastfeeding?

It is not known if Fresenius Propoven 2% Emulsion is safe in pregnant women. It may harm your unborn baby. If you receive Fresenius Propoven 2% Emulsion during pregnancy, your baby may be at risk for birth defects that affect the brain or spinal cord (neural tube defects). **Fresenius Propoven 2% Emulsion should be used in pregnant women only if there are no other FDA-approved medicines available for your medical condition. Tell your doctor if you are pregnant or think that you may be pregnant.**

Fresenius Propoven 2% Emulsion may pass into your breast milk. You should stop breastfeeding and throw away (discard) breast milk for 24 hours after receiving Fresenius Propoven 2% Emulsion.

How do I report side effects with Fresenius Propoven 2% Emulsion?

Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to FDA MedWatch at www.fda.gov/medwatch or call 1-800-FDA-1088. You may also report the problem to Fresenius Kabir, Inc. at 1-800-551-7176, Monday – Friday, between the hours of 8 a.m. and 5 p.m. (CST).

How can I learn more about COVID-19?

- Ask your healthcare provider
- Visit <https://www.cdc.gov/COVID19>
- Contact your local or state public health department

What is an Emergency Use Authorization (EUA)?

The United States FDA has made Fresenius Propoven 2% Emulsion available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

Fresenius Propoven 2% Emulsion has not undergone the same type of review as an FDA-approved product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, and available alternatives. In addition, the FDA decision is based on the totality of scientific evidence available showing that it is reasonable to believe that the product meets certain criteria for safety, performance, and labeling and may be effective in treatment of patients during the COVID-19 pandemic. All of these criteria must be met to allow for the product to be used in the treatment of patients during the COVID-19 pandemic.

The EUA for Fresenius Propoven 2% Emulsion is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).