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SHARING EXPERTISE

Propofol-Lipuro 1 % (propofol)

Injectable emulsion for infusion – 1,000 mg in 100 ml (10 mg / ml)

FACT SHEET FOR PATIENTS, PARENTS, AND CAREGIVERS

EMERGENCY USE AUTHORIZATION (EUA) OF PROPOFOL-LIPURO 1 % (PROPOFOL) INJECTABLE EMULSION FOR INFUSION DURING CORONAVIRUS DISEASE 2019 (COVID-19) PANDEMIC

This fact sheet contains information to help you understand the risks and benefits of Propofol-Lipuro 1 % (10 mg / ml) injectable emulsion for infusion that 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. Propofol-Lipuro 1% injectable emulsion for infusion is not an FDA-approved medicine in the United States. **Propofol-Lipuro 1 % injectable emulsion for infusion contains the same active ingredient, propofol, at the same strength as Diprivan Injectable Emulsion and other propofol products** approved in the United States. Propofol-Lipuro 1 % injectable emulsion for infusion is currently approved in Europe and other international countries. Read this Fact Sheet for information about Propofol-Lipuro 1 % injectable emulsion for infusion. Talk to your healthcare provider if you have questions. It is your choice to take Propofol-Lipuro 1 % injectable emulsion for infusion 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 PROPOFOL-LIPURO 1 % INJECTABLE EMULSION FOR INFUSION?

Propofol-Lipuro 1 % injectable emulsion for infusion belongs to a group of medicines called sedatives/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.

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WHAT DO I NEED TO KNOW BEFORE I RECEIVE PROPOFOL-LIPURO 1 % INJECTABLE EMULSION FOR INFUSION?

Who should not receive Propofol-Lipuro 1 % injectable emulsion for infusion?

Do not receive Propofol-Lipuro 1 % injectable emulsion for infusion if:

- You have received propofol before and have had an allergic reaction to it
- You are allergic (hypersensitive) to soy, peanut, or any of the other ingredients of this medicine
- You are 16 years of age or younger

What should I tell my healthcare provider before I receive Propofol-Lipuro 1 % injectable emulsion for infusion?

Please tell your healthcare provider about all of your medical conditions, including if you have:

- Serious head injuries
- Mitochondrial disease
- A disorder in which your body does not handle fat properly or any other health problems in which giving you fat emulsions may cause a health problem
- Dehydration (your blood volume is too low, or hypovolemia)
- Heart, kidney, or liver problems
- High pressure within your brain
- Problems with your breathing
- Epilepsy
- Are pregnant or plan to become pregnant.
- Are breastfeeding or plan to breastfeed
- Are taking any medicines, including prescription, over-the-counter, vitamins, or herbal products

Your healthcare provider will consider that other medicines with an inhibiting effect on the central nervous system may increase the effects of propofol when given together with propofol. Special care will be taken if you are also receiving an antibiotic containing rifampicin or an anti-seizure medication containing valproate.

How will I receive PROPOFOL-LIPURO 1 % INJECTABLE EMULSION FOR INFUSION?

Propofol-Lipuro 1 % injectable emulsion for infusion 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 Propofol-Lipuro 1 % injectable emulsion given to you.

Dosage

The dose you are given will vary depending on your age, body weight, and physical condition. The doctor will give the correct dose to achieve the required level of sedation, by carefully watching your responses and vital signs (pulse, blood pressure, breathing, etc).

Propofol-Lipuro 1 % injectable emulsion will be given by infusion and only for a maximum of 7 days.

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WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF PROPOFOL-LIPURO 1 % INJECTABLE EMULSION FOR INFUSION?

The most common side effects are:

- Pain at the injection site
- Drop in blood pressure
- Changes in heart rate
- Changes in breathing, coughing, and hiccups
- Headache, nausea, or vomiting during recovery from propofol sedation

Less common side effects are:

- Blood clots in veins or inflammation of veins at the injection site
- Seizures
- Allergic reactions, which can include swelling of the face, tongue and / or throat, wheezing and / or difficulty breathing, skin redness, and low blood pressure
- Fluid on lungs (lung edema)
- Inflammation of the pancreas
- Loss of sexual control during the time of recovery
- Change in color of your urine after
- Skin or tissue damage if the medicine is accidentally injected outside of a vein
- Involuntary movements
- Mood changes
- Drug abuse and drug dependence
- Heart failure
- Shallow breathing
- Pain and / or swelling at the injection site after the medicine was accidentally injected outside of a vein

WHAT OTHER TREATMENT CHOICES ARE THERE?

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

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WHAT IF I AM PREGNANT OR BREASTFEEDING?

Tell your healthcare provider if you are pregnant, think you may be pregnant, or are planning to have a baby. **Propofol-Lipuro 1 % injectable emulsion for infusion may harm your unborn baby. Propofol-Lipuro 1 % injectable emulsion for infusion should be used in pregnant women only if there are no other FDA-approved medicines available for your medical condition.**

Propofol-Lipuro 1 % injectable emulsion for infusion may pass into breast milk. You should stop breastfeeding and throw away (discard) breast milk for 24 hours after you have received Propofol-Lipuro 1 % injectable emulsion for infusion.

HOW DO I REPORT SIDE EFFECTS WITH PROPOFOL-LIPURO 1 % INJECTABLE EMULSION FOR INFUSION?

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 the B. Braun Medical Inc. USA by phone at 1-833-425-1464 or by email at productqualityexcellence@bbraunusa.com.

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 Propofol-Lipuro 1 % injectable emulsion for infusion 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.

Propofol-Lipuro 1 % injectable emulsion for infusion 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 those 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 Propofol-Lipuro 1 % injectable emulsion for infusion 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).

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