Fact Sheet For Patients And Parent/Caregivers
Emergency Use Authorization (EUA) for REGIOCIT (Sodium Chloride and Sodium Citrate Renal Replacement and Regional Anticoagulant Solution)

You are being given REGIOCIT: a replacement solution for Continuous Renal Replacement Therapy (CRRT) that also reduces the risk of filter clotting. This fact sheet contains information to help you understand the risks and benefits of taking the REGIOCIT you have received or may receive.

There is currently a shortage of U.S. Food and Drug Administration (FDA)-approved replacement solutions that may be used to provide CRRT. REGIOCIT is not an FDA-approved medicine in the United States. REGIOCIT is currently approved in Europe and other countries. Read this Fact Sheet for information about REGIOCIT. Talk to your health care provider if you have questions. It is your choice to receive REGIOCIT 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 virus 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.

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

What is REGIOCIT?
Regiocit is a replacement solution for CRRT, which is a form of “dialysis” treatment, that also reduces the risk of filter clotting. Replacement solutions are used during CRRT to help correct acid-base abnormalities and electrolyte abnormalities, remove “uremic” and other toxins and facilitate the use of CRRT to control fluid overload.

What should I tell my healthcare provider before I receive REGIOCIT?
Tell your healthcare provider about all of your medical conditions, including if you:

- Have any allergies
- Have liver disease
- Are pregnant or plan to become pregnant

- Are breast-feeding or plan to breastfeed
- Are taking any medicines (prescription, over-the-counter, vitamins, or herbal products)

Who should not receive REGIOCIT?
Do not take Regiocit if you**:**

- Have severe liver failure
- Have shock with decreased blood flow to the muscles (muscle hypoperfusion)
- Are allergic to any of the ingredients in REGIOCIT

What are the important possible side effects for REGIOCIT?
Possible side effects of **REGIOCIT** include:

- Low levels of calcium in your blood
- Low levels of magnesium, potassium, or phosphate in your blood, or changes in the glucose level in your blood
- Too much acid or base in your blood (acid-base status)

What other treatment choices are there?
Your healthcare provider may use a different replacement solution for CRRT or a type of "dialysis" that does not require a replacement solution.

How do I report side effects with REGIOCIT?
Tell your healthcare provider right away if you have any side effects that bother you or do not go away. Report side effects to **FDA MedWatch** at www.fda.gov/medwatch or call 1-800-FDA-1088 or contact Baxter Healthcare Corporation at 1-866-888-2472 or global_pharmacovigilance_deerfield@baxter.com.

How can I learn more?

- Ask your healthcare provider
- Visit www.cdc.gov/COVID19
- Contact your local or state public health department
- Visit www.baxter.com

What is an Emergency Use Authorization (EUA)?

The United States FDA has made REGIOCIT 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.

REGIOCIT has not undergone the same type of review as an FDA-approved or cleared product. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, 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 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, and that the known and potential benefits outweigh the known and potential risks for such use.

The EUA for REGIOCIT 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).