



A registry for people taking
Cholbam[®] (Cholic Acid)

Traverse is conducting a registry study to better understand how Cholbam[®] is used, how well it works, and its safety

The **REPLACE** Registry

An observational registry study sponsored by Traverse Therapeutics, the makers of Cholbam[®]

What is the purpose of this study?

The person you're caring for is taking Cholbam® (Cholic Acid) for one of the bile acid synthesis disorders (BASDs) or Zellweger Spectrum Disorders. A bile acid synthesis disorder is when people can sometimes get an illness where they cannot get as much energy as they should out of the food they eat and they feel sick. Travele, the maker of Cholbam®, is conducting a registry study to better understand how the medicine is used, how well it works, and its safety.

Registry studies are carried out to collect information from people who have a particular condition or are taking a certain medicine. This registry is observational, which means that no new treatment or drugs are given to patients as part of the registry. It will not change the way doctors treat their condition. Information will only be collected about people who are already taking Cholic Acid or who are going to start taking it, their illness, how they feel, and how much they are growing.

Why take part in the REPLACE Registry?

Because there are different forms of BASDs and Zellweger Spectrum Disorders, many types of people may take Cholbam® to treat their conditions. Each of these people can have a different experience with Cholbam®. For this reason, it is very important that as many people as possible participate in this registry.

BASDs and Zellweger Spectrum Disorders are considered rare diseases. This means they affect only a small number of people. Because these conditions are rare, we are inviting every person taking Cholbam® to consider taking part in this registry.

Please take some time to read this brochure and talk about it with your doctor. Ask as many questions as you need to make a decision about whether or not to take part in this registry.

What will I need to do?

If you and the one you're caring for choose to take part in The REPLACE Registry, you will first sign something called an Informed Consent Form. This document will give you more details about the registry.

The Study doctor, who is a doctor working on this registry, will then ask you and the person you're caring for some questions. These will include family history, medical treatment (including any tests that are usually performed), and how the person you are caring for is feeling.

At each follow-up visit, the Study Doctor will ask questions about their health and their use of medicines, including Cholbam®. If the person you're caring for or their partner becomes pregnant during the registry, you will need to tell the doctor. If they are pregnant, the Study doctor will ask questions about the pregnancy, and about the baby when he or she is born. Finally, it is important to let the doctor know if they breastfeed while taking Cholbam®.

Someone from the Direct to Patient (DPC) group may contact you regularly to collect information on the experience with Cholbam® treatment. This information will be confidential. You can choose whether you would like to receive these calls. If you choose not to, it will not affect your participation in the registry.



How will my information be used?

The information of the person you're caring for will be combined with information from other people in the registry. It will be used to help doctors understand how Cholbam[®] works in treating BASDs and Zellweger Spectrum Disorders.

How many people will participate?

Approximately 55 people will participate.

How long does the registry last?

The registry will last about 10 years.

Risks and benefits

The REPLACE Registry only involves the collection of information. So, taking part in the registry won't change the way the doctors treat the person you're caring for.

Since BASDs and Zellweger Spectrum Disorders are uncommon conditions, and only a small number of people have been treated with Cholbam[®], it is not known if Cholbam[®] causes harm to a pregnant mother or her unborn baby. The effect of Cholbam[®] on human sperm, unborn babies, or nursing infants is not known. You'll be told if information becomes available that might affect whether you want the person you're caring for to continue participating in the registry.

The benefit of taking part in this registry is that you could make a difference in the lives of people who are treated with Cholbam[®] in the future.

Your personal information

Information about the person you're caring for and their health will be collected during this registry, but all of their personal information will be removed before it is stored. They'll be identified by a unique number that only their Study Team will know. Their Study Team won't share their personal information with anyone.

The results of this registry could be published in scientific journals or presented at scientific meetings, but their identity will never be shared.

Now what?

Please discuss any questions or concerns you have with your Study Doctor before deciding whether to take part.



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THERAPEUTICS



*Thank you for taking the time to read this booklet,
and for considering taking part in The REPLACE Registry.*

The REPLACE Registry

*The REPLACE Registry Caregiver Brochure
(US version: Caregivers)*