

Consumer ISI

Indication

What is RETHYMIC?

RETHYMIC is a tissue-based therapy used to build missing parts of the immune system in children with congenital athymia.

Who shouldn't use RETHYMIC?

RETHYMIC should not be used in patients who have been diagnosed with severe combined immunodeficiency (SCID).

Important Safety Information

Time to develop thymic and immune function and fight infections:

After treatment with RETHYMIC, it usually takes 6 to 12 months to establish thymic function, which is needed for the body to produce cells in the immune system to fight infection. Your child's doctor should advise you of infection control measures followed immediately after treatment and until the immune system starts working at a sufficient level.

Autoimmune Disorders: Treatment with RETHYMIC may increase the risk of the development of conditions that are autoimmune, meaning your immune cells attack your body by mistake. Your doctor will monitor your child weekly for the first 2 months post-treatment and then monthly through 12 months post-treatment.

Transmission of Serious Infection and Infectious Diseases: Because RETHYMIC is made from human tissue, and animal products are used in the manufacturing process, transmission of infectious diseases may occur. Donors are screened for increased risk of multiple infectious diseases and donor/infant blood is tested for various diseases and the manufacturing materials are tested for safety. However, this testing does not completely eliminate the risk of transmitting these or other transmissible infectious diseases and disease agents.

Graft versus Host Disease: Your child will also be monitored for graft versus host disease, which is when the immune cells from the implanted tissue (i.e., RETHYMIC) attack the recipient's (patient's) body. Prior to administration of RETHYMIC your child will be prescribed medications that suppresses their immune system if they have elevated immune activity.

Cytomegalovirus Infection: In clinical studies with RETHYMIC, all (3 out of 3) patients with preexisting CMV infection prior to the transplantation with RETHYMIC died. The benefits/risks of treatment should be considered prior to treating patients with pre-existing CMV infection.

Anti-HLA Antibodies: Your child will be tested for HLA antibodies, which are proteins that may be present in your child's blood. If your child has these antibodies, he/she will need to receive RETHYMIC from a donor that does not express those HLA proteins.

HLA Typing: If your child has received a hematopoietic cell transplantation (HCT) or a solid organ transplant, they will have a test to look for specific antibodies that could interfere with the effect of RETHYMIC. If they are present, then it will be necessary to receive RETHYMIC from a certain group of donors that do not have these proteins.

Vaccinations: Live virus vaccinations before treatment and 2 years after treatment is not recommended. Your child's doctor may administer inactive vaccinations before giving you the live virus vaccination, once certain criteria are met, which typically occurs 9 months after treatment with RETHYMIC. Talk to your child's doctor prior to any vaccinations.

Cancer: Due to your child's weakened immune system, there is increased risk of developing certain cancers. Your child's doctor should monitor your child through testing for Epstein-Barr virus (EBV) and cytomegalovirus (CMV), which are two viruses that can cause cancer.

What are the most common side effects with RETHYMIC?

The most common side effects with RETHYMIC are low platelet blood count, low white blood cell count, fever, excess protein in urine, hair loss, opening at the site of incision, disorder where red blood cells are destroyed faster than they are made (called Coombs-positive hemolytic anemia), reaction where patient's body causes destruction of red blood cells, rash, decreased levels of blood bicarbonate (which regulates blood pH) diarrhea, and disease caused by body's immune system attacking the liver (called autoimmune hepatitis).

These are not all of the possible side effects of RETHYMIC. Talk to your child's doctor about any side effect that bothers your child or does not go away.

You are encouraged to report suspected side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/safety/medwatch, or contact Enzyvant at 833-369-9868.