

PATIENT INFORMATION BEYFORTUS™ (Bay for tus) (nirsevimab-alip) injection, for intramuscular use	Rx Only
<p>What is BEYFORTUS? BEYFORTUS is a prescription medicine that is used to help prevent a serious lung disease caused by Respiratory Syncytial Virus (RSV) in:</p> <ul style="list-style-type: none"> • newborns and babies under 1 year of age born during or entering their first RSV season. • children up to 24 months of age who remain at risk of severe RSV disease through their second RSV season. <p>BEYFORTUS is an antibody that contains nirsevimab-alip which is used to help prevent RSV disease for 5 months. It is not known if BEYFORTUS is safe and effective in children older than 24 months of age.</p>	<p>General information about the safe and effective use of BEYFORTUS. Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about BEYFORTUS that is written for health professionals.</p> <p>What are the ingredients in BEYFORTUS? Active ingredient: nirsevimab-alip Inactive ingredients: arginine hydrochloride, histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose and water for injection.</p> <p>Manufactured by: AstraZeneca AB, Södertälje, Sweden SE-15185 US License No. 2059 Distributed by: Sanofi Pasteur, Inc., Swiftwater, PA 18370 USA BEYFORTUS is a trademark of the Sanofi group of companies. ©AstraZeneca 2024 For more information, go to https://www.Beyfortus.com or call 1-855-239-3678 (1-855-BEYFORTUS).</p>
<p>Your child should not receive BEYFORTUS if your child has a history of serious allergic reactions to nirsevimab-alip or any of the ingredients in BEYFORTUS. See the end of this Patient Information leaflet for a complete list of ingredients in BEYFORTUS.</p>	<p>This Patient Information has been approved by the U.S. Food and Drug Administration. Issued: February 2024</p>
<p>Before your child receives BEYFORTUS, tell your healthcare provider about all of your child's medical conditions, including if your child:</p> <ul style="list-style-type: none"> • has ever had a reaction to BEYFORTUS. • has bleeding or bruising problems. If your child has a problem with bleeding or bruises easily, an injection could cause a problem. <p>Tell your child's healthcare provider about all the medicines your child takes, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Your infant should not receive a medicine called palivizumab if they have already received BEYFORTUS in the same RSV season.</p>	<p>NIR-PPI-SL-FEB24</p>
<p>How is BEYFORTUS given?</p> <ul style="list-style-type: none"> • BEYFORTUS is given as an injection, usually in the thigh (leg) muscle, by your child's healthcare provider. • Your child should receive BEYFORTUS before or during the RSV season. RSV season is the time of year when RSV infections are most common, usually occurring fall through spring. Your healthcare provider can tell you when the RSV season starts in your area. • Your child may still get RSV disease after receiving BEYFORTUS. Talk to your child's healthcare provider about what symptoms to look for. • If your child has heart surgery, your child's healthcare provider may need to give your child an additional BEYFORTUS injection soon after surgery. 	
<p>What are the possible side effects of BEYFORTUS?</p> <ul style="list-style-type: none"> • Serious allergic reactions have happened with BEYFORTUS. • Get medical help right away if your child has any of the following signs or symptoms of a serious allergic reaction: <ul style="list-style-type: none"> ○ swelling of the face, mouth, or tongue ○ difficulty swallowing or breathing ○ unresponsiveness ○ bluish color of skin, lips or under fingernails ○ muscle weakness ○ severe rash, hives or itching <p>The most common side effects of BEYFORTUS include rash, and pain, swelling or hardness at the site of your child's injection. These are not all of the possible side effects of BEYFORTUS. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</p>	