

**患者資訊** 僅供處方使用  
**BEYFORTUS™(Bay for tus)**  
**(nirsevimab-alip)**  
**注射劑,用於肌肉注射**

**什麼是 BEYFORTUS?**

BEYFORTUS 為處方藥物,用於幫助以下群體預防因感染呼吸道融合病毒(RSV)而導致的嚴重肺部疾病:

- 正值或進入第一個RSV好發季節時出生的新生兒或未滿1歲的嬰兒。
- 在第二個RSV好發季節仍有高風險罹患嚴重RSV疾病的24個月以下兒童。

BEYFORTUS是一種含有nirsevimab-alip的抗體,用於幫助預防RSV疾病,保護力持續時間為5個月。

BEYFORTUS對24個月以上兒童的安全性和有效性仍不清楚。

**若您的孩子對nirsevimab-alip或BEYFORTUS 的任何成分有嚴重的過敏反應史,請勿接種BEYFORTUS。欲瞭解BEYFORTUS完整成分清單,請參見本患者資訊頁末。**

**在您的孩子接種BEYFORTUS之前,請將孩子的所有醫療狀況告知您的醫療保健人員,包括如果孩子:**

- 曾對BEYFORTUS出現反應。
- 曾發生出血或瘀青問題。若您的孩子有容易出血或瘀青的問題,可能因注射導致傷害。

**請告知醫療保健人員關於孩子的所有用藥情況**,包括處方和非處方藥物,維他命以及草本保健品。如果嬰兒在同一個RSV好發季節已經接種BEYFORTUS,請勿再使用Palivizumab藥物。

**BEYFORTUS 如何給藥?**

- BEYFORTUS是一種注射劑,通常由醫療保健人員注射於大腿肌肉。
- **您的孩子應該在RSV好發季節之前或期間接受BEYFORTUS。** RSV季節是一年中RSV感染最普遍的時期,通常發生在秋季至春季。您可以詢問醫療保健人員您所在地區何時開始進入RSV好發季節。
- **您的孩子在注射BEYFORTUS後仍有可能感染RSV疾病。** 請和孩子的醫療保健人員討論該注意哪些可能出現的症狀。
- 如果您的孩子接受心臟手術,孩子的醫療保健人員可能需要在術後盡快幫孩子注射額外的BEYFORTUS注射劑。

**BEYFORTUS 可能有哪些副作用?**

- 使用BEYFORTUS藥物曾發生過**嚴重的過敏反應**。
- 若您的孩子有以下嚴重過敏反應的徵兆或症狀,請立即尋求醫療協助:
  - 臉部、口腔或舌頭腫脹
  - 皮膚、嘴唇或指甲內的顏色呈藍色
  - 吞嚥或呼吸困難
  - 肌肉無力
  - 無意識
  - 嚫重紅疹、蕁麻疹或瘙癢

**BEYFORTUS最常見的副作用為**紅疹與注射部位疼痛、腫脹或出現硬塊。但BEYFORTUS仍可能引發其他副作用。關於副作用,請致電醫生尋求醫療建議。您可以透過1-800-FDA-1088向FDA通報副作用。

**關於安全有效使用BEYFORTUS的一般資訊**

藥品有時會被使用於患者資訊手冊中所列之外的醫療用途。您可以向您的藥師或醫療保健人員詢問有關BEYFORTUS的資訊,這些資訊是為醫療專業人員所編寫的。

**BEYFORTUS的成分有哪些?**

**活性成分:**nirsevimab-alip

**非活性成分:**精胺酸鹽酸鹽、組胺酸、L-組胺酸鹽酸鹽、聚山梨醇酯 80、蔗糖和注射用水。

生產商:AstraZeneca AB, Södertälje, Sweden SE-15185

美國執照號:2059

經銷商:Sanofi Pasteur, Inc., Swiftwater, PA 18370 USA。

BEYFORTUS 是 Sanofi 集團公司的商標。

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欲瞭解更多資訊,請瀏覽 <https://www.Beyfortus.com/cn>, 或致電 1-855-239-3678 (1-855-BEYFORTUS)。

本患者資訊已獲美國食品和藥物管理局核准。

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MAT-US-2402650-v1.0-03/2024

<p><b>PATIENT INFORMATION</b></p> <p><b>BEYFORTUS™ (Bay for tus)</b> (nirsevimab-alip) injection, for intramuscular use</p>	<p><b>Rx Only</b></p>	<p><b>The most common side effects of BEYFORTUS include</b> rash, and pain, swelling or hardness at the site of your child's injection.</p> <p>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>		
<p><b>What is BEYFORTUS?</b></p> <p>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"> <li>• newborns and babies under 1 year of age born during or entering their first RSV season.</li> <li>• children up to 24 months of age who remain at risk of severe RSV disease through their second RSV season.</li> </ul> <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><b>General information about the safe and effective use of BEYFORTUS.</b></p> <p>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><b>What are the ingredients in BEYFORTUS?</b></p> <p><b>Active ingredient:</b> nirsevimab-alip <b>Inactive ingredients:</b> arginine hydrochloride, histidine, L-histidine hydrochloride monohydrate, polysorbate 80, sucrose and water for injection.</p>		
<p><b>Your child should not receive BEYFORTUS if your child</b> 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>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 <a href="https://www.Beyfortus.com">https://www.Beyfortus.com</a> or call 1-855-239-3678 (1-855-BEYFORTUS).</p>	<p>This Patient Information has been approved by the U.S. Food and Drug Administration. Issued: February 2024</p>		
<p><b>Before your child receives BEYFORTUS, tell your healthcare provider about all of your child's medical conditions, including if your child:</b></p> <ul style="list-style-type: none"> <li>• has ever had a reaction to BEYFORTUS.</li> <li>• has bleeding or bruising problems. If your child has a problem with bleeding or bruises easily, an injection could cause a problem.</li> </ul> <p><b>Tell your child's healthcare provider about all the medicines your child takes,</b> 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-SA-AUG24</p>			
<p><b>How is BEYFORTUS given?</b></p> <ul style="list-style-type: none"> <li>• BEYFORTUS is given as an injection, usually in the thigh (leg) muscle, by your child's healthcare provider.</li> <li>• <b>Your child should receive BEYFORTUS before or during the RSV season.</b> 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.</li> <li>• <b>Your child may still get RSV disease after receiving BEYFORTUS.</b> Talk to your child's healthcare provider about what symptoms to look for.</li> <li>• If your child has heart surgery, your child's healthcare provider may need to give your child an additional BEYFORTUS injection soon after surgery.</li> </ul>				
<p><b>What are the possible side effects of BEYFORTUS?</b></p> <ul style="list-style-type: none"> <li>• <b>Serious allergic reactions</b> have happened with BEYFORTUS.</li> <li>• Get medical help right away if your child has any of the following signs or symptoms of a serious allergic reaction:</li> </ul> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; vertical-align: top; padding-right: 10px;"> <ul style="list-style-type: none"> <li>○ swelling of the face, mouth, or tongue</li> <li>○ difficulty swallowing or breathing</li> <li>○ unresponsiveness</li> </ul> </td> <td style="width: 50%; vertical-align: top; padding-left: 10px;"> <ul style="list-style-type: none"> <li>○ bluish color of skin, lips or under fingernails</li> <li>○ muscle weakness</li> <li>○ severe rash, hives or itching</li> </ul> </td> </tr> </table>	<ul style="list-style-type: none"> <li>○ swelling of the face, mouth, or tongue</li> <li>○ difficulty swallowing or breathing</li> <li>○ unresponsiveness</li> </ul>	<ul style="list-style-type: none"> <li>○ bluish color of skin, lips or under fingernails</li> <li>○ muscle weakness</li> <li>○ severe rash, hives or itching</li> </ul>		
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