

PATIENT INFORMATION WAYRILZ™ (WAY-rilz) (rilzabrutinib) tablets, for oral use
<p>What is WAYRILZ? WAYRILZ is a prescription medicine that is used to treat adults with persistent or chronic immune thrombocytopenia (ITP) who have received a prior treatment that did not work well enough. It is not known if WAYRILZ is safe and effective in children.</p>
<p>Before taking WAYRILZ, tell your healthcare provider about all of your medical conditions, including if you:</p> <ul style="list-style-type: none"> • have liver problems • have kidney problems • are pregnant or plan to become pregnant. WAYRILZ may harm your unborn baby. If you are able to have a baby, your healthcare provider will do a pregnancy test before starting treatment with WAYRILZ. <ul style="list-style-type: none"> ◦ Females who are able to become pregnant should use effective birth control (contraception) during treatment with WAYRILZ and for 1 week after the last dose. • are breastfeeding or plan to breastfeed. It is not known if WAYRILZ passes into your breast milk. Do not breastfeed during treatment with WAYRILZ and for at least 1 week after the last dose. <p>Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Taking WAYRILZ with certain other medicines may affect how WAYRILZ works and can cause side effects. WAYRILZ may also affect how other medicines work. Know the medicines you take. Keep a list of them and show it to your healthcare provider and pharmacist when you get a new medicine.</p>
<p>How should I take WAYRILZ?</p> <ul style="list-style-type: none"> • Take WAYRILZ exactly as your healthcare provider tells you to take it. • Do not change your dose or stop taking WAYRILZ unless your healthcare provider tells you to. • Take WAYRILZ 2 times a day at about the same time each day. • Take WAYRILZ with or without food. • Swallow WAYRILZ tablets whole with a glass of water. Do not cut, crush, or chew the tablets. • If you experience diarrhea, nausea, or stomach area (abdominal) pain during treatment with WAYRILZ, taking it with food may reduce these side effects. • If you take an antacid or H2 blocker medicine, take your dose of WAYRILZ at least 2 hours before taking an antacid or H2 blocker medicine. If you take a Proton Pump Inhibitor (PPI) medicine, talk to your healthcare provider. • If you miss a dose of WAYRILZ, take the missed dose as soon as you remember on the same day and at least 2 hours apart from the next regular scheduled dose. • If you take too much WAYRILZ, call your healthcare provider or Poison Help Line at 1-800-222-1222.

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<p>What should I avoid while taking WAYRILZ?</p> <ul style="list-style-type: none"> • You should avoid grapefruit, starfruit and products that have these fruits, and Seville oranges (often used in marmalades) during treatment with WAYRILZ. These products may increase the amount of WAYRILZ in your blood, which increases the risk of side effects of WAYRILZ.
<p>What are the possible side effects of WAYRILZ? WAYRILZ may cause serious side effects, including:</p> <ul style="list-style-type: none"> • Serious infections. WAYRILZ can increase the risk of infections, including serious infections that can lead to death. Your healthcare provider will check you for signs and symptoms of infection during your treatment with WAYRILZ. Tell your healthcare provider right away if you get any signs or symptoms of infection, including fever, chills, or flu-like symptoms. • Liver problems including Drug-Induced Liver Injury (DILI). Liver problems, which may be severe, life-threatening, or lead to death have happened in people treated with Bruton's tyrosine kinase (BTK) inhibitors. Your healthcare provider will do blood tests to check your liver before and as necessary during treatment with WAYRILZ. Tell your healthcare provider right away if you have any signs or symptoms of liver problems, including stomach-area (abdominal) pain or discomfort, dark or "tea-colored" urine, or yellowing of the skin or the white part of your eyes. <p>The most common side effects of WAYRILZ include:</p> <ul style="list-style-type: none"> • diarrhea • nausea • headache • stomach area (abdominal) pain • COVID-19 <p>These are not all of the possible side effects of WAYRILZ. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</p>
<p>How should I store WAYRILZ?</p> <ul style="list-style-type: none"> • Store WAYRILZ at room temperature between 20°C to 25°C (68°F to 77°F). • Store WAYRILZ tablets in the original packaging. • Protect WAYRILZ from light and moisture. <p>Keep WAYRILZ and all medicines out of the reach of children.</p>
<p>General information about the safe and effective use of WAYRILZ. Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use WAYRILZ for a condition for which it was not prescribed. Do not give WAYRILZ to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about WAYRILZ that is written for health professionals.</p>
<p>What are the ingredients in WAYRILZ? Active ingredients: rilzabrutinib Inactive ingredients: Tablet core: crospovidone (Type A), microcrystalline cellulose, and sodium stearyl fumarate; Tablet coating: FD&C yellow #6/Sunset yellow FCF aluminum lake, macrogol/polyethylene glycol (PEG), polyvinyl alcohol partially hydrolyzed, talc, and titanium dioxide.</p>

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Manufactured for:
Genzyme Corporation
Cambridge, MA 02141
A SANOFI COMPANY
WAYRILZ is a trademark of Sanofi or an affiliate.
For more information go to www.wayrilz.com or call 1-833-723-5463.

This Patient Information has been approved by the U.S. Food and Drug Administration. Issued: 08/2025

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