

37 **What is BENLYSTA?**

38 BENLYSTA is a prescription medicine used to treat adults with active systemic lupus
39 erythematosus (SLE or lupus) who are receiving other lupus medicines.

40 BENLYSTA contains *belimumab* which is in a group of medicines called *monoclonal*
41 *antibodies*. Lupus is a disease of the immune system (the body system that fights infection).
42 People with active lupus often have high levels of a certain protein in their blood. BENLYSTA
43 binds to and limits the activity of the protein. When given together with other medicines for
44 lupus, BENLYSTA decreases lupus disease activity more than other lupus medicines alone.

- 45 • It is not known if BENLYSTA is safe and effective in people with severe active lupus
46 nephritis or severe active central nervous system lupus.
- 47 • It is not known if BENLYSTA is safe and effective in children.

48 **Who should not receive BENLYSTA?**

49 **Do not receive BENLYSTA if you:**

- 50 • are allergic to belimumab or any of the ingredients in BENLYSTA. See the end of this
51 Medication Guide for a complete list of ingredients in BENLYSTA.

52 **What should I tell my healthcare provider before receiving BENLYSTA?**

53 Before you receive BENLYSTA, tell your healthcare provider if you:

- 54 • think you have an infection or have infections that keep coming back. You should not
55 receive BENLYSTA if you have an infection unless your healthcare provider tells you to.
56 **See “What is the most important information I should know about BENLYSTA.”**
- 57 • have or have had mental health problems such as depression or thoughts of suicide
- 58 • have recently received a vaccination or if you think you may need a vaccination. If you
59 are receiving BENLYSTA, you should not receive live vaccines.
- 60 • are receiving other biologic medicines, monoclonal antibodies or IV infusions of
61 cyclophosphamide (Cytosan[®])
- 62 • have or have had any type of cancer
- 63 • have any other medical conditions
- 64 • are pregnant or plan to become pregnant. It is not known if BENLYSTA will harm your
65 unborn baby. Tell your healthcare provider if you become pregnant during your treatment
66 with BENLYSTA.
- 67 • If you become pregnant while receiving BENLYSTA, talk to your healthcare provider
68 about enrolling in the BENLYSTA Pregnancy Registry. You can enroll in this
69 registry by calling 1-877-681-6296. The purpose of this registry is to monitor the
70 health of you and your baby.

71 • are breastfeeding or plan to breastfeed. It is not known if BENLYSTA passes into your
72 breast milk. You and your healthcare provider should decide if you will receive
73 BENLYSTA or breastfeed. You should not do both.

74 **Tell your healthcare provider about all the medicines you take**, including prescription and
75 non-prescription medicines, vitamins, and herbal supplements.

76 Know the medicines you take. Keep a list of your medicines with you to show to your
77 healthcare provider and pharmacist when you get a new medicine.

78 **How will I receive BENLYSTA?**

- 79 • You will be given BENLYSTA by a healthcare provider through a needle placed in a
80 vein (IV infusion). It takes about 1 hour to give you the full dose of BENLYSTA.
- 81 • Your healthcare provider will tell you how often you should receive BENLYSTA.
- 82 • Your healthcare provider may give you medicines before you receive BENLYSTA to
83 help reduce your chance of having a reaction. A healthcare provider will watch you
84 closely while you are receiving BENLYSTA and after your infusion for signs of a
85 reaction.

86 **What are the possible side effects of BENLYSTA?**

87 **BENLYSTA can cause serious side effects.**

88 • See **“What is the most important information I should know about BENLYSTA?”**

89 **1. Cancer.** BENLYSTA may reduce the activity of your immune system. Medicines that affect
90 the immune system may increase your risk of certain cancers.

91 **2. Allergic (hypersensitivity) and infusion reactions.** Serious allergic or infusion reactions
92 can happen on the day of or the day after receiving BENLYSTA. Symptoms of an allergic or
93 infusion reaction may include:

- 94 • itching
- 95 • swelling of the face, lips, mouth, tongue, or throat
- 96 • trouble breathing
- 97 • anxiousness
- 98 • low blood pressure
- 99 • dizziness or fainting
- 100 • headache
- 101 • nausea
- 102 • skin rash, redness, or swelling

103 Your healthcare provider will watch you closely while you are receiving BENLYSTA and
104 after your infusion for signs of a reaction.

105 **The most common side effects of BENLYSTA include:**

- 106 • nausea
- 107 • diarrhea
- 108 • fever
- 109 • stuffy or runny nose
- 110 • sore throat
- 111 • cough (bronchitis)
- 112 • trouble sleeping
- 113 • leg or arm pain
- 114 • headache (migraine)
- 115 • urinary tract infection
- 116 • decreased white blood cell count (leukopenia)
- 117 • vomiting
- 118 • stomach pain

119
120 Tell your healthcare provider if you have any side effect that bothers you or that does not go
121 away.

122 These are not all the possible side effects of BENLYSTA. For more information, ask your
123 healthcare provider.

124 Call your doctor for medical advice about side effects. You may report side effects to FDA at
125 1-800-FDA-1088.

126 **General information about the safe and effective use of BENLYSTA**

127 Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.
128 Do not use BENLYSTA for a condition for which it was not prescribed.

129 This Medication Guide summarizes the most important information about BENLYSTA. For
130 more information about BENLYSTA, talk with your healthcare provider.

131 You can ask your healthcare provider or pharmacist for information about BENLYSTA that is
132 written for healthcare professionals.

133 For more information about BENLYSTA, go to www.BENLYSTA.com or call 1-877-423-6597.

134 **What are the ingredients in BENLYSTA?**

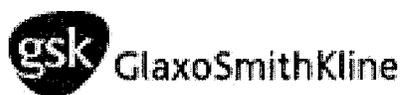
135 **Active ingredient:** belimumab.

136 **Inactive ingredients:** citric acid, polysorbate 80, sodium citrate, sucrose.

137 RX Only
138
139 BENLYSTA is a registered trademark of Human Genome Sciences, Inc., used under license by
140 GlaxoSmithKline.

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142 Human Genome Sciences, Inc.
143 Rockville, Maryland 20850
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SCIENCES**



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148 This Medication Guide has been approved by the U.S. Food and Drug Administration.

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