Pr Benlysta™ (belimumab)

The Benlysta™ monarchprogram

MEDICAL ORDER FORM

Send the completed form by **fax (to 1-855-788-3140)** or by **email (to Benlysta-Monarch@supportprogram.com)**.

PATIENT INFORMATION

Last Name: _____ First Name: _____

Date of Birth: _____mm_____ _____dd_____ _____yy_____ Gender: ☐ M ☐ F

Address: _____

City: _____ Postal Code: _____ Province: _____

Phone (Work): _____ Phone (Home): _____

Phone (Mobile): _____

Allergies: _____

_____

Patient's weight: _____kg

BENLYSTA™ R_x (Dose of BENLYSTA™ is 10 mg/kg)

Dose: Give _____mg Infuse over at least one hour as per BENLYSTA™ product monograph.

Frequency of administration: ☐ **Initial Order:** Weeks 0, 2, and 4, then every 4 weeks ☐ **Renewal Order:** Every 4 weeks

Duration of order: ☐ 52 weeks or ☐ _____ weeks

Pre-treatment orders: Please ☑ desired pre-treatment medication(s) administered prior to infusion at clinic (e.g. oral antihistamine, antipyretic).

☐ No premeds required

☐ Premed: _____ Dose: _____mg _____min prior to infusion ☐ PO ☐ IV

☐ Premed: _____ Dose: _____mg _____min prior to infusion ☐ PO ☐ IV

☐ Premed: _____ Dose: _____mg _____min prior to infusion ☐ PO ☐ IV

Special Instructions for Infusion Nurse: _____

_____

_____

PHYSICIAN INFORMATION

Last Name: _____ First Name: _____

Prescriber Number: _____

Address: _____

City: _____ Postal Code: _____ Province: _____

Phone: _____ Fax: _____

Please indicate alternate contact number, should the Infusion Nurse need to contact you in your absence during normal business hours prior to starting to infuse BENLYSTA™. _____

Physician Signature: _____ Date: _____mm_____ _____dd_____ _____yy_____

BENLYSTA™ is indicated in addition to standard therapy for reducing disease activity in adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE). Please refer to the Product Monograph for contraindications, warnings, precautions and adverse events.

gsk GlaxoSmithKline

Member PAAB R&D

Indications and Clinical Use:

BENLYSTA™ (belimumab) is indicated in addition to standard therapy for reducing disease activity in adult patients with active, autoantibody-positive, systemic lupus erythematosus (SLE).

The safety and efficacy of BENLYSTA™ have not been evaluated in patients with severe active lupus nephritis or severe active central nervous system lupus.

The efficacy of BENLYSTA™ in patients of black African heritage has not been clearly established.

Safety and efficacy have not been established in children.

Most Serious Warning and Precautions:

Infusion and Hypersensitivity Reactions: Administration of BENLYSTA™ may result in infusion and hypersensitivity reactions, which can be severe, and can be fatal. Delay in the onset of acute hypersensitivity reactions and recurrence of clinically significant reactions after initial resolution of symptoms following appropriate treatment, have been observed. Serious infusion reactions have occurred in clinical trials with BENLYSTA™. Serious anaphylaxis/hypersensitivity was observed in 5/1458 (0.3%) of patients receiving BENLYSTA™ and 0/675 receiving placebo. BENLYSTA™ should be administered under the supervision of healthcare professionals, and with immediate access to resuscitation equipment. Stop infusion and discontinue treatment if a severe or life-threatening infusion reaction occurs.

Other Relevant Warnings and Precautions:

- Monitor patients for infusion and hypersensitivity reactions during and for an appropriate amount of time after administration of BENLYSTA™. Patients treated with BENLYSTA™ should be made aware of these potential risks, the signs and symptoms of such reactions, and the importance of immediately seeking medical attention.
- Live vaccines should not be given for 30 days before, or concurrently with BENLYSTA™.
- BENLYSTA™ has not been studied thus is not recommended in combination with biologic therapies or intravenous cyclophosphamide.
- As with other immunomodulating agents, the mechanism of action of BENLYSTA™ could increase the risk for the development of malignancies, however the effect of treatment with BENLYSTA™ on the development of malignancies is not known.
- As with other immunomodulating agents, the mechanism of action of belimumab may increase the potential risk for the development of infections. Patients who develop an infection while undergoing treatment with BENLYSTA™ should be monitored closely. Physicians should exercise caution when considering the use of BENLYSTA™ in patients with chronic infections. Patients receiving any therapy for chronic infections should not begin therapy with BENLYSTA™.
- Depression, suicidality and suicides have been reported in BENLYSTA™ studies. Patients should be instructed to contact their healthcare provider if they experience new or worsening depression, suicidal thoughts or other mood changes.
- There were more deaths reported with BENLYSTA™ than with placebo during the controlled period of the clinical trials.
- Although data are limited, dosage adjustment is not recommended in patients > 65 years of age.
- There are limited data on the use of BENLYSTA™ in pregnant women. Adequate contraception should be used while using BENLYSTA™ and for at least 4 months after the last BENLYSTA™ treatment. BENLYSTA™ should not be used during pregnancy unless the potential benefit to the mother justifies the potential risk to the fetus. A pregnancy registry has been established to monitor outcomes (please call 1-877-681-6296).
- The safety of BENLYSTA™ for use during lactation has not been established.

Dosage and Method of Administration:

BENLYSTA™ is for intravenous infusion (not IV push or bolus) and must be reconstituted and diluted prior to administration.
Recommendations: 1 hour administration period via a dedicated IV line; 10 mg/kg at 2-week intervals for the first three doses and at 4-week intervals thereafter; administer a missed dose as soon as possible; premedicate with an oral antihistamine, with or without an antipyretic, monitor for, and manage any infusion reactions (including anaphylaxis) during and after infusion.

Adverse Events:

Common adverse events (incidence >1% and >1% vs. placebo) in patients treated with BENLYSTA™ include nausea (15%), diarrhea (12%), pyrexia (10%), nasopharyngitis (9%), bronchitis (9%), insomnia (7%), pain in extremity (6%), depression (5%), migraine (5%), pharyngitis (5%), cystitis (4%), leukopenia (4%), gastroenteritis viral (3%), hypokalaemia (3%), dysuria (3%), neutropenia (3%), toothache (3%), pain (2%), infusion related reaction (2%), hypertensive crisis (1%), dysphonia (1%).

See also Other Relevant Warnings and Precautions, above.

For More Information:

Please consult the BENLYSTA™ Product Monograph at http://www.gsk.ca/english/docs-pdf/product-monographs/Benlysta.pdf for important details relating to adverse reactions, drug interactions, dosing, and other information which have not been discussed in this piece. The Product Monograph is also available by calling 1-800-387-7374.

GlaxoSmithKline