



FIRST INFUSION GUIDEBOOK

Benlysta
(belimumab)
Intravenous Use 120 mg/vial



Welcome to your first infusion of BENLYSTA

Today you may be feeling mixed emotions—excitement, nervousness, and more. We want you to know that we're here by your side, for this infusion and each one that follows.

What is BENLYSTA?

BENLYSTA is a prescription medication used to treat patients with active systemic lupus erythematosus (SLE or lupus) who are receiving other lupus medicines. Intravenous dosing of BENLYSTA is approved for adults and children aged 5 years and older. Subcutaneous dosing of BENLYSTA is only approved for adult patients.

It is not known if BENLYSTA is safe and effective in people with severe active lupus nephritis or severe active central nervous system lupus, and it has not been studied in combination with other biologics or intravenous cyclophosphamide. Use of BENLYSTA is not recommended in these situations.

Your personal guidebook

This guidebook includes tips and tools to help make your appointment as smooth as possible. You'll find answers to frequently asked questions, ideas on how to spend your time at the infusion center, information about BENLYSTA, and pages for you to write on and explore. We've even included encouraging stories from others like you who share their experiences with BENLYSTA.

Print this guidebook to keep and use for each of your infusions. Be sure to adjust your printer's setting according to your choice of color, grayscale, or black only.

Do not receive BENLYSTA if you are allergic to belimumab or to any of the ingredients in BENLYSTA.

Important Safety Information

The most important information to know about BENLYSTA

BENLYSTA can cause serious side effects. Some of these side effects may cause death. It is not known if BENLYSTA causes these serious side effects.

Please see full Important Safety Information on pages 26 and 27.

Please see accompanying Important Facts About BENLYSTA.

BENLYSTA is available by prescription only.

A positive step

You're taking this time for your health and for your loved ones. And even though you aren't certain it will work for you, you and your doctor are open to trying it. That's a positive step. If you have any issues, talk to your doctor. But don't skip your infusions.

Take your guidebook with you and use it as you settle in for the hour during your infusion. Then let it help as you prepare for your next visit. And don't forget to take it back with you for your next infusion!

Important Safety Information (cont'd)

Tell your healthcare provider right away if you have any of the symptoms listed below while receiving BENLYSTA

- **Infections:** fever, chills, pain or burning with urination, urinating often, coughing up mucus, or warm, red, or painful skin or sores on your body.
- **Heart problems:** chest discomfort or pain, shortness of breath, cold sweats, nausea, dizziness, or discomfort in other areas of the upper body.
- **Allergic (hypersensitivity) reactions:** itching, swelling of the face, lips, mouth, tongue, or throat, trouble breathing, anxiousness, low blood pressure, dizziness or fainting, headache, nausea, or skin rash. Serious allergic reactions can happen on the day of, or in the days after, receiving BENLYSTA and may cause death.
- **Mental health problems and suicide:** thoughts of suicide or dying, attempt to commit suicide, trouble sleeping (insomnia), new or worse anxiety or depression, acting on dangerous impulses, other unusual changes in your behavior or mood, or thoughts of hurting yourself or others.

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Please see full Important Safety Information on pages 26 and 27.

Please see accompanying Important Facts About BENLYSTA.

SECTION 1: Get to Know the Infusion Center

Starting on any new medication can be a big decision for you and your doctor. Choosing BENLYSTA (belimumab) brings with it what may be a new experience for you: receiving an infusion.

? Do you have questions?

Whether you are visiting your doctor's office, a hospital, or a dedicated infusion center, be sure to ask any questions you have. In the meantime, you may be wondering if you should:

- **Talk to the nurses?** No matter where you receive your infusions, the staff is there for you. You should feel comfortable to discuss your concerns. In fact, a strong relationship, built on honest communication, can go a long way to help make your experience more positive.
- **Talk to other patients?** Speaking with others at the infusion center can be a good idea. They may have tips and you may meet a new friend! Approach it as you would at any other public place, taking your cues from those around you.

Important Safety Information (cont'd)

Before receiving BENLYSTA also discuss with your healthcare provider if you:

- think you have an infection or have infections that keep coming back. You should not receive BENLYSTA if you have an infection unless your healthcare provider tells you to.
- have or have had mental health problems such as depression or thoughts of suicide.
- have recently received a vaccination or if you think you may need a vaccination. If you are receiving BENLYSTA, you should not receive live vaccines.
- are taking other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- are allergic to other medicines.
- are receiving other biologic medicines, monoclonal antibodies, or IV infusions of cyclophosphamide (CYTOXAN).
- have or have had any type of cancer.
- have any other medical conditions.

- **Take someone?** You may enjoy having a friend or family member with you for support and conversation. You may also receive medicine beforehand that can make you drowsy. If so, it's a good idea to have someone with you who can drive you home afterward.
- **Talk on the phone?** As with most public spaces, it's usually not a good idea to talk on the phone. If you must take a call, be sure to keep it brief and at a low volume.
- **Eat or drink?** Ask the staff at your center about their policy. Most will allow you to have water and a snack.

Remember to treat the infusion center as you would any other public place. Use your best judgment. And don't hesitate to ask the staff any of your questions.



"During my first BENLYSTA infusion, I was certainly nervous. My mother was there with me—she's always there helping me and coming along for the ride. Those poor nurses—I never stopped talking."

MORGAN, Real lupus patient who was taking BENLYSTA at the time of photoshoot. Individual results may vary.

Important Safety Information (cont'd)

Before receiving BENLYSTA also discuss with your healthcare provider if you: (cont'd)

- are pregnant or plan to become pregnant. It is not known if BENLYSTA will harm your unborn baby. You should talk to your healthcare provider about whether to prevent pregnancy while on BENLYSTA. If you choose to prevent pregnancy, you should use an effective method of birth control while receiving BENLYSTA and for at least 4 months after the final dose of BENLYSTA. Tell your healthcare provider right away if you become pregnant during your treatment with BENLYSTA or if you think you may be pregnant.
- become pregnant while receiving BENLYSTA. Talk to your healthcare provider about enrolling in the BENLYSTA Pregnancy Registry. You can enroll in this registry by calling 1-877-681-6296. The purpose of this registry is to monitor the health of you and your baby.
- are breastfeeding or plan to breastfeed. It is not known if BENLYSTA passes into your breast milk. You and your healthcare provider should talk about whether or not you should receive BENLYSTA and breastfeed.

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What you may experience

Your appointment will vary depending on where you'll be receiving your infusions, but these are some things you may experience.

- You may be asked to arrive early to complete any paperwork.
- As you get prepped for your infusion, you may be asked how you are feeling and some questions about your medical history.
- You may have your vital signs taken, such as temperature and blood pressure.
- You may be given medication to help reduce the chance of an allergic reaction. It is not known if these medications will help reduce the chance of an allergic reaction to BENLYSTA (belimumab).
- Your arm or hand will be prepared. The needle will be inserted and held in place with tape.
- Your vital signs will be monitored regularly.
- You'll have about an hour to relax in the infusion chair. With the help of Section 2 of this guidebook, you can determine what you like to do best during your infusion time. We've even included specific ideas and activity pages.
- **Most important:** Notify the staff immediately if you're not feeling "right" at any point during your infusions. Serious allergic or infusion reactions can happen, and your healthcare provider will watch you closely while you are receiving BENLYSTA and after your infusion for signs of a reaction. Symptoms may include: itching; swelling of the face, lips, mouth, tongue, or throat; trouble breathing; anxiousness; low blood pressure; dizziness or fainting; headache; nausea; or skin rash, redness, or swelling.

Important Safety Information (cont'd)

Possible side effects of BENLYSTA

- **Progressive multifocal leukoencephalopathy (PML).** PML is a serious and life-threatening brain infection. PML can result in death or severe disability. Tell your healthcare provider right away if you notice any new or worsening medical problems: memory loss, trouble thinking, dizziness or loss of balance, difficulty talking or walking, or loss of vision.
- **Cancer.** Medicines that affect the immune system, including BENLYSTA, may increase your risk of certain cancers.

TIPS for your infusion time

As you receive your infusions, keep in mind:

- **You may see different staff members at each of your infusions.** They're all there for your safety and comfort. Feel free to ask questions and share your feelings and concerns with any of them.
- **Don't assume the staff knows your entire medical history.** Being open and honest is important for your health—and may help you feel more confident and comfortable with the infusion process.
- **At your first infusion, make notes for the next time.** Are you too hot or too cold? Wish you had remembered to bring a favorite book or created a playlist of relaxing music? Make a list of what to bring (such as a pillow and blanket, a snack, or headphones). Use the lined pages at the end of this guidebook or your smartphone.
- **The staff at the center can help you not only with medical questions but also with billing, appointments, and more.** Don't hesitate to reach out to them with any of your questions.

Important Safety Information (cont'd)

The most common side effects of BENLYSTA are nausea, diarrhea, fever, stuffy or runny nose and sore throat, cough, trouble sleeping, leg or arm pain, depression, headache, and pain, redness, itching, or swelling at the site of injection (when given subcutaneously). These are not all the possible side effects of BENLYSTA. Call your doctor for medical advice about side effects.

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SECTION 3: Explore Your Options

Divercion

For a little diversion, enjoy the puzzles and activities included on the next few pages. You may also want to:

- Watch a movie on your tablet or phone (remember headphones)
- Listen to music (remember headphones)
- Read a book or magazine
- Journal
- Work on your laptop (many centers offer free WiFi)

Did you know studies show that coloring is a way to improve health and overall wellbeing?

It lets you release your creativity and distract thoughts away from illness. Grab some colored pencils or thin markers and see if it works for you with the coloring pages we've included here.

"Mostly I try and relax. You can read, you can play a game on your phone or watch a movie. My mother takes me to most of my BENLYSTA treatments. She sits right next to me and we spend the time together talking."

SHEBA, ACTUAL PATIENT OF BENLYSTA (belimumab)
Paid spokesperson. Individual results may vary.

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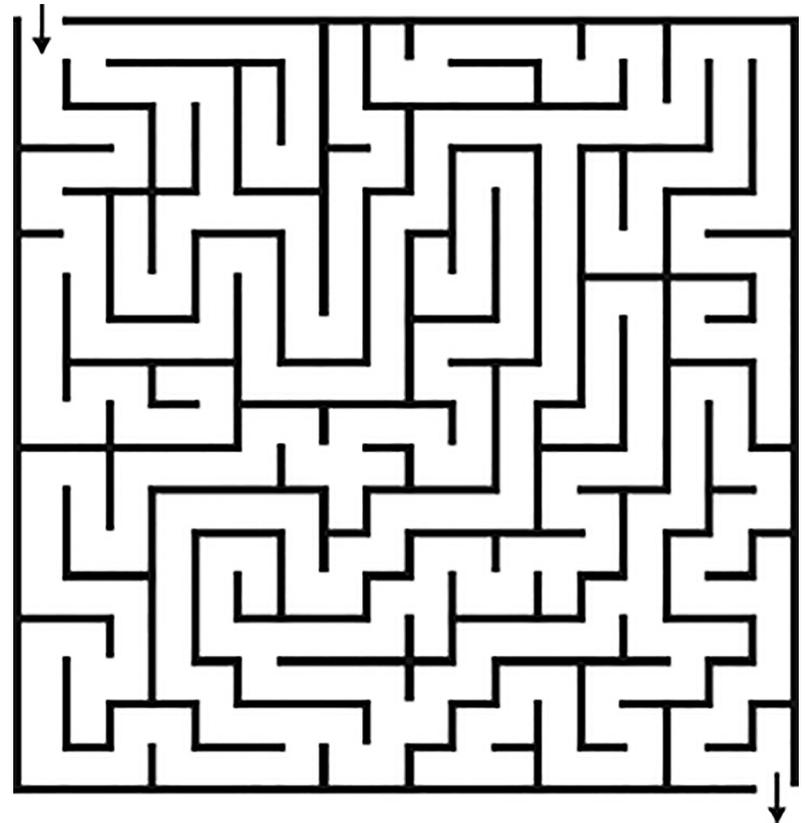
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Maze



Please see accompanying Important Facts About BENLYSTA.

Word Search



ADORE
CARING
EXPLORE
FAMILY
GIGGLE
HELPFUL
JOY
KINDNESS

LOVE
MEMORIES
PEACE
READ
RELAX
SHINE
SUPPORT
TEACH

Word Search



ADMIRATION
DELIGHT
DISCOVERY
ENJOY
EXCITEMENT
FRIENDS
FUN
GIVING

GOODNESS
LAUGH
LEARN
PARTY
PATIENCE
REFLECT
SMILE
SPARKLE

Sudoku: Fill in empty squares so that the numbers 1–9 appear just one time in each column, row, and 3x3 box.

1

	4		2			3	6	
	9				7	4	2	
		6			3			8
3		9	5			2		
			7		2		1	
7		8				5		
				1	9		3	
	7	4					9	1
		1	8		4	6		

Answer

1	4	7	2	5	8	3	6	9
8	9	3	1	6	7	4	2	5
2	5	6	4	9	3	1	7	8
3	1	9	5	4	6	2	8	7
4	6	5	7	8	2	9	1	3
7	2	8	9	3	1	5	4	6
5	8	2	6	1	9	7	3	4
6	7	4	3	2	5	8	9	1
9	3	1	8	7	4	6	5	2

Sudoku: Fill in empty squares so that the numbers 1–9 appear just one time in each column, row, and 3x3 box.

2

5				2			4	
7				4	5		2	
	3			8				5
				7	9			
8		3	1				6	
		5	6			2	1	4
3		9		1	2			
	6		8			1		2
		2					3	8

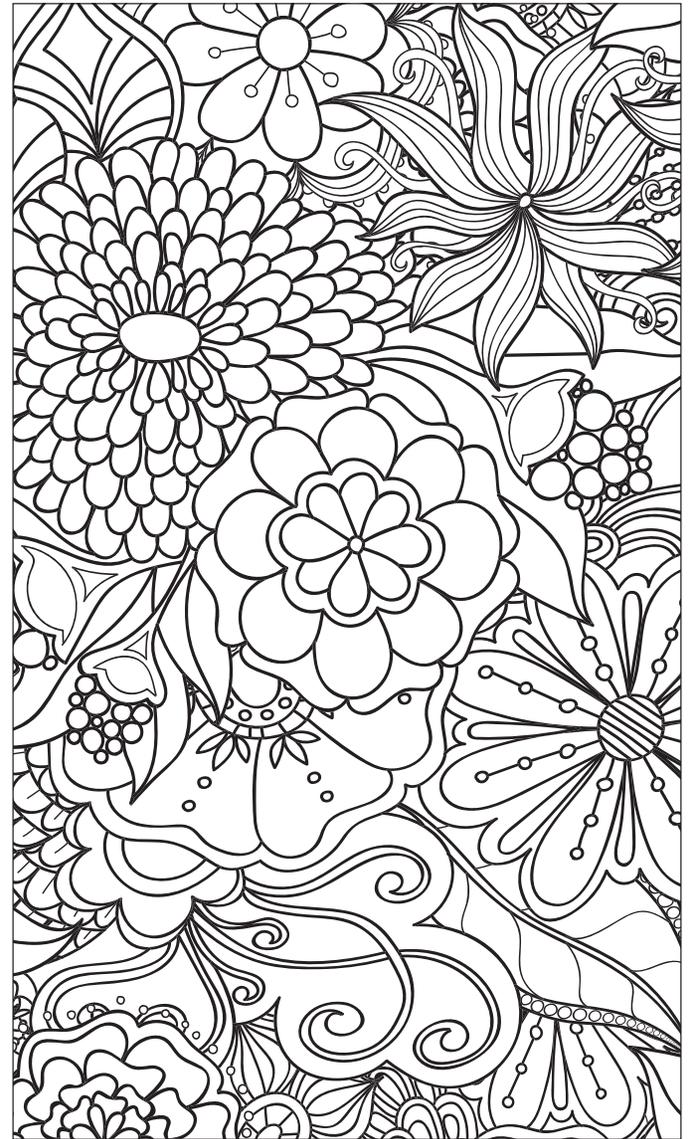
Answer

5	1	8	9	2	6	3	4	7
7	9	6	3	4	5	8	2	1
2	3	4	7	8	1	6	9	5
6	4	1	2	7	9	5	8	3
8	2	3	1	5	4	7	6	9
9	7	5	6	3	8	2	1	4
3	8	9	5	1	2	4	7	6
4	6	7	8	9	3	1	5	2
1	5	2	4	6	7	9	3	8

Color



Color



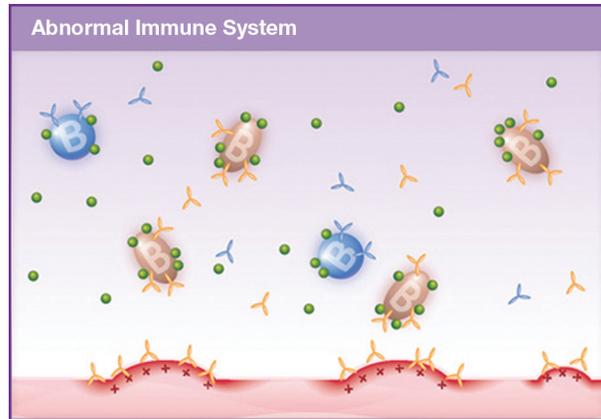
Information

If you've found you'd rather learn more about your treatment, this section was created for you.

A review of lupus

Typically, B cells in our immune system produce proteins called antibodies that protect the body from invaders such as viruses, bacteria, and other germs. In people with lupus, certain B cells stay in the body longer than they should. These are called autoreactive B cells.

These autoreactive B cells are abnormal cells that react against your own body in lupus. The autoreactive B cells produce a type of protein called an autoantibody. Unlike normal antibodies, which react against foreign invaders, autoantibodies end up attacking your own body. In lupus, this can lead to inflammation in various organs throughout the body.



-  **Normal B Cell:** This type of white blood cell produces antibodies
-  **Antibody:** Antibodies attach themselves to germs and try to control or destroy them
-  **Autoreactive B Cell:** These are the "bad" version of B cells that make harmful autoantibodies
-  **Autoantibody:** While antibodies protect the body, autoantibodies work against the body
-  **Chemicals that cause inflammation**
-  **Inflamed body tissue:** A sign of lupus disease activity
-  **BlyS:** B Lymphocyte Stimulator (BlyS) is a protein that helps some cells grow

Please see full Important Safety Information on pages 26 and 27.

How BENLYSTA (belimumab) works

Not only do the antibodies produced by autoreactive B cells harm the body, these cells survive longer than normal B cells. A protein called B lymphocyte stimulator, or BlyS (pronounced "bliss"), helps this longer survival. BENLYSTA binds to BlyS which helps autoreactive B cells die sooner.

Continue the commitment

Remember, every patient responds differently to BENLYSTA. You and your doctor can't be certain when or if it will work for you. But you've made the commitment to add BENLYSTA to your treatment plan—and that's an important step.

Communicate all your questions and concerns with your healthcare provider and continue to receive BENLYSTA as prescribed. As you go along, you'll become more familiar with the infusion process. If you have any issues, talk to the infusion staff, your nurse, or your doctor. But do not skip your infusions unless directed by your doctor.

It's important to continue to receive BENLYSTA as prescribed, even if you are feeling better. Talk to your doctor honestly about any positive and negative experiences of your treatment.

Important Safety Information (cont'd)

Tell your healthcare provider right away if you have any of the symptoms listed below while receiving BENLYSTA

- **Infections:** fever, chills, pain or burning with urination, urinating often, coughing up mucus, or warm, red, or painful skin or sores on your body.
- **Heart problems:** chest discomfort or pain, shortness of breath, cold sweats, nausea, dizziness, or discomfort in other areas of the upper body.
- **Allergic (hypersensitivity) reactions:** itching, swelling of the face, lips, mouth, tongue, or throat, trouble breathing, anxiousness, low blood pressure, dizziness or fainting, headache, nausea, or skin rash. Serious allergic reactions can happen on the day of, or in the days after, receiving BENLYSTA and may cause death.
- **Mental health problems and suicide:** thoughts of suicide or dying, attempt to commit suicide, trouble sleeping (insomnia), new or worse anxiety or depression, acting on dangerous impulses, other unusual changes in your behavior or mood, or thoughts of hurting yourself or others.

Please see accompanying Important Facts About BENLYSTA.

Q&A Frequently asked questions

Q. Why must BENLYSTA (belimumab) be given by infusion?

BENLYSTA is made of complex proteins. It cannot be taken orally because it would be broken down in the stomach before reaching the bloodstream. Once BENLYSTA is broken down, it cannot work properly. For this reason, it's given directly into the bloodstream.

Q. Can I stop taking my other medications while on BENLYSTA?

BENLYSTA is intended to be added to other lupus treatments. You should not make any changes to your current treatment plan without first talking to your doctor.

Q. How will I know if I'm having an allergic or infusion reaction after receiving BENLYSTA?

Symptoms of an allergic or infusion reaction may include: itching; swelling of the face, lips, mouth, tongue, or throat; trouble breathing; anxiousness; low blood pressure; dizziness or fainting; headache; nausea; or skin rash, redness, or swelling. Your healthcare professional will watch you closely while you are receiving BENLYSTA and after your infusion for signs of a reaction. Tell your healthcare professional or get emergency medical help right away if you have any of these symptoms.

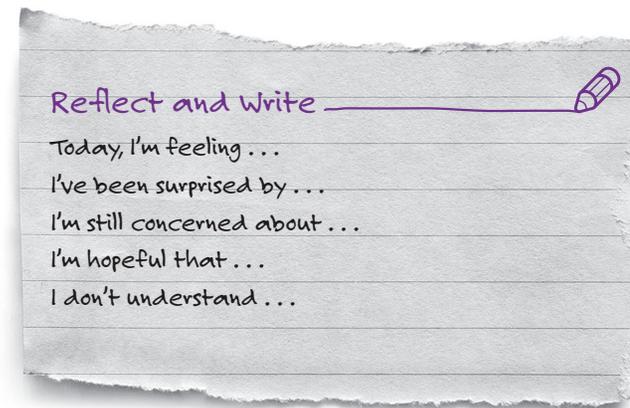
Q. What might I experience after my infusion?

After the infusion, you may feel some discomfort where you had the IV line inserted. That should go away within a few hours. Depending on how you feel, you may be able to return to your usual activities once the infusion process is over. If you don't feel well or have any soreness or tenderness that doesn't go away, contact your healthcare provider.

Please see full Important Safety Information on pages 26 and 27.

Ask your own questions

You may have your own questions about lupus or about treatment with BENLYSTA. Feel free to discuss them with the staff at the infusion center or your rheumatologist. Use the lined pages included in this guidebook to write down any of your concerns, questions, or thoughts.



Important Safety Information (cont'd)

Before receiving BENLYSTA also discuss with your healthcare provider if you:

- think you have an infection or have infections that keep coming back. You should not receive BENLYSTA if you have an infection unless your healthcare provider tells you to.
- have or have had mental health problems such as depression or thoughts of suicide.
- have recently received a vaccination or if you think you may need a vaccination. If you are receiving BENLYSTA, you should not receive live vaccines.
- are taking other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- are allergic to other medicines.
- are receiving other biologic medicines, monoclonal antibodies, or IV infusions of cyclophosphamide (CYTOXAN).
- have or have had any type of cancer.
- have any other medical conditions.

Please see accompanying Important Facts About BENLYSTA.

Relaxation

A nap or even meditation is a relaxing, renewing way to spend your time in the infusion chair. Soothing music or white noise (such as the sounds of rain or wind rustling leaves) can block out any extra sounds from around you and help you truly relax. Build your own playlist or download a white noise app. And don't forget your headphones!

You may also want to try progressive muscle relaxation (PMR).

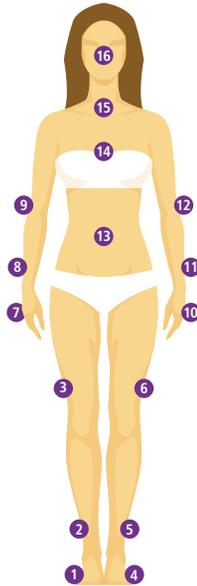
PMR is a two-step process of deliberately tensing and then relaxing certain muscles. With practice, you can quickly learn to distinguish between tension and total relaxation—a skill you can use anytime you need it.

PMR: STEP-BY-STEP

You'll work with most of the major muscle groups in your body. Imagine a progression from your feet upward.

Note: If you are left-handed, you might want to start with your left foot, and so on.

- 1 Right foot
- 2 Right lower leg and foot
- 3 Entire right leg
- 4 Left foot
- 5 Left lower leg and foot
- 6 Entire left leg
- 7 Right hand
- 8 Right forearm and hand
- 9 Entire right arm
- 10 Left hand
- 11 Left forearm and hand
- 12 Entire left arm
- 13 Abdomen
- 14 Chest
- 15 Neck and shoulders
- 16 Face



Step one: Tense

Applying tension to a muscle is the same no matter the muscle group. First, focus your mind on the muscle. Then inhale and squeeze the muscles for about 8 seconds. For example, focus on your right hand. Then make a fist and hold it for a slow count of 8.

Take care not to hurt yourself while trying PMR. You should never feel intense or shooting pain during this exercise. Think about making your muscle tense in a gentle way.

When you first try PMR, you may accidentally tense other muscles, as well. For example, when tensing your right hand, you might also tense the muscles in your right arm. With practice, you'll learn to isolate each muscle group as you come to it.

Step two: Release

After the 8-second hold, quickly and suddenly let go. Exhale as you let all the tightness flow out of the muscles. In the example, imagine tightness flowing out of your hand through your fingertips as you exhale. Feel the muscles become loose and limp.

Important Safety Information (cont'd)

Before receiving BENLYSTA (belimumab) also discuss with your healthcare provider if you: (cont'd)

- are pregnant or plan to become pregnant. It is not known if BENLYSTA will harm your unborn baby. You should talk to your healthcare provider about whether to prevent pregnancy while on BENLYSTA. If you choose to prevent pregnancy, you should use an effective method of birth control while receiving BENLYSTA and for at least 4 months after the final dose of BENLYSTA. Tell your healthcare provider right away if you become pregnant during your treatment with BENLYSTA or if you think you may be pregnant.
- become pregnant while receiving BENLYSTA. Talk to your healthcare provider about enrolling in the BENLYSTA Pregnancy Registry. You can enroll in this registry by calling 1-877-681-6296. The purpose of this registry is to monitor the health of you and your baby.
- are breastfeeding or plan to breastfeed. It is not known if BENLYSTA passes into your breast milk. You and your healthcare provider should talk about whether or not you should receive BENLYSTA and breastfeed.

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SECTION 4: Understand What's Next

Soon enough, you'll become more comfortable with the infusion process. As your first infusion winds down, take a little time to read about what you may experience in the coming days, how to prepare for your next one, and how GSK, the maker of BENLYSTA (belimumab), is here to support you.

Right after your infusion

Before you leave the infusion center, it's important to remember a few things:

- Make sure you understand any post-infusion instructions the staff gives you.
- Any discomfort where the IV line was inserted should go away within a few hours.
- Depending on how you feel, you may be able to return to normal activities right away.
- If you were given a pre-infusion medication, you may feel drowsy. If so, be sure to have someone drive you home.

Reflect and Write 

Something I learned today is ...

Important Safety Information (cont'd)

Possible side effects of BENLYSTA

- **Progressive multifocal leukoencephalopathy (PML).** PML is a serious and life-threatening brain infection. PML can result in death or severe disability. Tell your healthcare provider right away if you notice any new or worsening medical problems: memory loss, trouble thinking, dizziness or loss of balance, difficulty talking or walking, or loss of vision.
- **Cancer.** Medicines that affect the immune system, including BENLYSTA, may increase your risk of certain cancers.

What to look out for in the coming days

If you have any questions or are worried about anything, reach out to your healthcare team. They are your primary partners in your health.

- If you don't feel well or have any soreness or tenderness at the infusion site that doesn't go away, contact your healthcare provider.
- Be aware of any symptoms of an allergic or infusion reaction. These may include: itching; swelling of the face, lips, mouth, tongue, or throat; trouble breathing; anxiousness; low blood pressure; dizziness or fainting; headache; nausea; or skin rash, redness, or swelling. Tell your healthcare professional or get emergency medical help right away if you have any of these symptoms.

Before your next infusion

Before your next infusion, review what you've written down in this guidebook. Reach out to your healthcare team with any questions. Then, look over your notes to see what you need to remember to take next time.

Reflect and Write 

Something I learned today is ...

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Find ongoing support

BENLYSTA Gateway can provide resources and information as your access needs change. BENLYSTA Gateway can help you understand your insurance coverage for BENLYSTA and determine if you are eligible for the BENLYSTA Co-pay Program.

If you haven't enrolled with BENLYSTA Gateway, get started before your next infusion. Simply work with your doctor to register.

Have questions?

For information on access and coverage to help you get your medications, the staff of BENLYSTA Gateway is just a call away.
Insured • Underinsured • Uninsured

Benlysta Gateway
(belimumab) 

Call us toll-free at 1-877-4-BENLYSTA (1-877-423-6597).



BENLYSTA Co-pay Program:

If approved, you could pay as little as \$0 for BENLYSTA. Call 1-877-4-BENLYSTA (1-877-423-6597) to learn more.

The BENLYSTA Co-Pay Program helps eligible approved patients with their out-of-pocket costs for BENLYSTA up to **[\$11,000]** every 12 months.

Medicare eligible patients, and patients enrolled in government-funded programs, are not eligible for the BENLYSTA Co-pay Program.

Patients must submit a Service Request Form so their eligibility can be determined.

For full Program Terms & Conditions please visit www.GSKCopolyPrograms.com

BENLYSTA Connects

Go to BENLYSTA.com and register for ongoing support and exclusive benefits such as:

Benlysta Connects
(belimumab) 

- Tailored communications with the latest info about BENLYSTA
- Personal stories and tips from patients like you
- Tools to help you set goals and expectations
- A subscription to *Connections*, a magazine created with you in mind

Important Safety Information (cont'd)

The most common side effects of BENLYSTA are nausea, diarrhea, fever, stuffy or runny nose and sore throat, cough, trouble sleeping, leg or arm pain, depression, headache, and pain, redness, itching, or swelling at the site of injection (when given subcutaneously). These are not all the possible side effects of BENLYSTA. Call your doctor for medical advice about side effects.

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SECTION 5

Do not receive BENLYSTA if you are allergic to belimumab or to any of the ingredients in BENLYSTA.

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- think you have an infection or have infections that keep coming back. You should not receive BENLYSTA if you have an infection unless your healthcare provider tells you to.
- have or have had mental health problems such as depression or thoughts of suicide.
- have recently received a vaccination or if you think you may need a vaccination. If you are receiving BENLYSTA, you should not receive live vaccines.
- are taking other medicines, including prescription and over-the-counter medicines, vitamins, and herbal supplements.
- are allergic to other medicines.
- are receiving other biologic medicines, monoclonal antibodies, or IV infusions of cyclophosphamide (CYTOXAN).
- have or have had any type of cancer.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if BENLYSTA will harm your unborn baby. You should talk to your healthcare provider about whether to prevent pregnancy while on BENLYSTA. If you choose to prevent pregnancy, you should use an effective method of birth control while receiving BENLYSTA and for at least 4 months after the final dose of BENLYSTA. Tell your healthcare provider right away if you become pregnant during your treatment with BENLYSTA or if you think you may be pregnant.
- become pregnant while receiving BENLYSTA. Talk to your healthcare provider about enrolling in the BENLYSTA Pregnancy Registry. You can enroll in this registry by calling 1-877-681-6296. The purpose of this registry is to monitor the health of you and your baby.

- are breastfeeding or plan to breastfeed. It is not known if BENLYSTA passes into your breast milk. You and your healthcare provider should talk about whether or not you should receive BENLYSTA and breastfeed.

Possible side effects of BENLYSTA

- **Progressive multifocal leukoencephalopathy (PML).** PML is a serious and life-threatening brain infection. PML can result in death or severe disability. Tell your healthcare provider right away if you notice any new or worsening medical problems: memory loss, trouble thinking, dizziness or loss of balance, difficulty talking or walking, or loss of vision.
- **Cancer.** Medicines that affect the immune system, including BENLYSTA, may increase your risk of certain cancers.

The most common side effects of BENLYSTA are nausea, diarrhea, fever, stuffy or runny nose and sore throat, cough, trouble sleeping, leg or arm pain, depression, headache, and pain, redness, itching, or swelling at the site of injection (when given subcutaneously). These are not all the possible side effects of BENLYSTA. Call your doctor for medical advice about side effects

Please see accompanying Important Facts About BENLYSTA.

Benlysta
(belimumab) 



IMPORTANT FACTS ABOUT BENLYSTA

The risk information presented here is not comprehensive. To learn more, talk to your healthcare provider (HCP). Visit www.BENLYSTA.com or call 1-877-423-6597 to get FDA-approved product labeling, including Medication Guide.

What is the most important information I should know about BENLYSTA?

BENLYSTA can cause serious side effects. Some of these side effects may cause death. It is not known if BENLYSTA causes these serious side effects. Tell your HCP right away if you get any of the following signs or symptoms while receiving BENLYSTA:

- **Infections.** Symptoms can include: fever, chills, pain or burning with urination, urinating often, coughing up mucus, warm, red, or painful skin or sores on your body.
- **Heart problems.** Symptoms can include: chest discomfort or pain, shortness of breath, cold sweats, nausea, dizziness, discomfort in other areas of the upper body.
- **Allergic (hypersensitivity) reactions.** Serious allergic reactions can happen on the day of, or in the days after, receiving BENLYSTA and may cause death. Symptoms can include: itching, swelling of the face, lips, mouth, tongue, or throat, trouble breathing, anxiousness, low blood pressure, dizziness or fainting, headache, nausea, skin rash.
- **Mental health problems and suicide.** Symptoms can include: thoughts of suicide or dying, attempt to commit suicide, trouble sleeping, new or worse anxiety, new or worse depression, acting on dangerous impulses, other unusual changes in your behavior or mood, thoughts of hurting yourself or others.

What is BENLYSTA?

BENLYSTA is a prescription medicine used to treat patients with active systemic lupus erythematosus (SLE or lupus) who are receiving other lupus medicines. Intravenous dosing of BENLYSTA is approved for adults and children aged 5 years and older. Subcutaneous dosing of BENLYSTA is only approved for adult patients.

It is not known if BENLYSTA is safe and effective in people with severe active lupus nephritis or severe active central nervous system lupus.

Who should not use BENLYSTA?

Do not use BENLYSTA if you are allergic to belimumab or any of the ingredients in BENLYSTA.

What should I tell my HCP before receiving BENLYSTA?

Before you receive BENLYSTA, tell your HCP about all of your medical conditions, including if you:

- think you have an infection or have infections that keep coming back. You should not receive BENLYSTA if you have an infection unless your HCP tells you to. **See “What is the most important information I should know about BENLYSTA?”**
- have or have had mental health problems such as depression or thoughts of suicide.
- have recently received a vaccination or if you think you may need a vaccination. If you are receiving BENLYSTA, you should not receive live vaccines.
- are allergic to other medicines.
- are receiving other biologic medicines, monoclonal antibodies, or IV infusions of cyclophosphamide (CYTOXAN).
- have or have had any type of cancer.
- are pregnant or plan to become pregnant. It is not known if BENLYSTA will harm your unborn baby. You should talk to your HCP about whether to prevent pregnancy while on BENLYSTA. If you choose to prevent pregnancy, you should use an effective method of birth control while receiving BENLYSTA and for at least 4 months after the final dose of BENLYSTA. Tell your healthcare provider right away if you become pregnant during your treatment with BENLYSTA or if you think you may be pregnant.

- are breastfeeding or plan to breastfeed. It is not known if BENLYSTA passes into your breast milk. You and your HCP should talk about whether or not you should receive BENLYSTA and breastfeed.

Tell your HCP about all medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

What are the possible side effects of BENLYSTA?

BENLYSTA can cause serious side effects including:

- **Progressive multifocal leukoencephalopathy (PML).** PML is a serious and life-threatening brain infection. Your chance of getting PML may be higher if you are treated with medicines that weaken your immune system, including BENLYSTA. PML can result in death or severe disability. Tell your HCP right away if you notice any new or worsening medical problems such as: memory loss, trouble thinking, dizziness or loss of balance, difficulty talking or walking, loss of vision.
- **Cancer.** BENLYSTA may reduce the activity of your immune system. Medicines that affect the immune system may increase your risk of certain cancers.

The most common side effects of BENLYSTA include: nausea, diarrhea, fever, stuffy or runny nose and sore throat, cough, trouble sleeping, leg or arm pain, depression, headache, and pain, redness, itching, or swelling at the site of injection.

These are not all the possible side effects of BENLYSTA. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Keep BENLYSTA and all medicines out of reach of children.

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BELBROC200051 May 2020
Produced in USA.