Your guide to understanding BENLYSTA

intravenous (IV) infusion or subcutaneous (SC) injection

Welcome to the start of your BENLYSTA treatment journey

> BENLYSTA IV DIN: 02370050 (120 mg vial) or 02470069 (400 mg vial)

BENLYSTA SC autoinjector DIN: 02470489 (200 mg/mL)







Your BENLYSTA treatment journey starts here

If you're reading this, your doctor has just prescribed BENLYSTA (ben-LIST-ah) – a prescription drug used to treat adults with lupus (systemic lupus erythematosus, also called SLE) as well as adults with lupus-related kidney inflammation (active lupus nephritis) who are also receiving other medicines for lupus. At this point, you may have lots of questions about your new medication, and that's perfectly normal. It's why this booklet was created.

Over the next several pages, you'll find:

- Resources and tools
- Information that may help you during your treatment
- A brief overview of what BENLYSTA is, how it works, how it's given, and potential side effects
- A Weekly Tracking Diary where you can record how you're feeling and write down questions for your healthcare provider

After you've read this booklet, you may still have questions or concerns. Don't hesitate to discuss them with your healthcare provider. They're there to help you and give you information about your health.

lupus [loo-pus]: an autoimmune disease in which organs, tissues, and cells undergo damage caused by antibodies (also called systemic lupus erythematosus or SLE).



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About **BENLYSTA**



What is **BENLYSTA**?

- BENLYSTA (ben-LIST-ah) contains belimumab, which belongs to a group of drugs called "monoclonal antibodies".
- Monoclonal antibodies are synthetic (man-made) antibodies that act against proteins that attack normal tissues in people with autoimmune disorders.
- BENLYSTA binds to a molecule that's thought to play a role in lupus called B-lymphocyte stimulator **or** BLyS (pronounced "bliss").

What causes lupus?

- No one knows exactly what causes lupus, but it's thought that genes and some environmental factors play a role.
- Lupus is an autoimmune disease, meaning that your immune system mistakenly attacks your body's own cells and tissues.
- White blood cells called **B cells** make antibodies that normally attack germs that can make you sick.
- When you have lupus, some antibodies can damage the body's own cells.

How does **BENLYSTA** work?

BENLYSTA binds to, and limits the activity of a protein called BLyS. BLyS affects the functioning of **B cells**. People with active lupus often have high levels of **BLyS** in their blood.

How is **BENLYSTA** given?

You can receive BENLYSTA as an intravenous (IV) infusion or a subcutaneous (SC) injection using the BENLYSTA autoinjector.



BENLYSTA IV

Given through a needle placed in a vein (see page 10 for more info)



BENLYSTA SC autoinjector

Given as an injection under the skin (see page 12 for more info)

Who is **BENLYSTA** for?

BENLYSTA is used to treat adults with lupus or active lupus nephritis who are also receiving other medicines for lupus.

- It's not approved for use in children less than 18 years of age.
- It is not known if BENLYSTA is safe and effective in people with severe active central nervous system lupus.
- It is not known if BENLYSTA is effective in treating SLE in people of Black ethnicity.

What does **BENLYSTA** do?

When given along with other drugs for lupus, BENLYSTA decreased lupus disease activity and lupus-related kidney inflammation more than the other drugs alone.

What medicinal ingredient is in BENLYSTA?

The medicinal ingredient in BENLYSTA is called belimumab.

What nonmedicinal ingredients are in BENLYSTA IV?

Citric acid monohydrate, sodium citrate dihydrate, sucrose and polysorbate 80.

What nonmedicinal ingredients are in BENLYSTA SC?

L-arginine hydrochloride, L-histidine, L-histidine monohydrochloride, polysorbate 80, sodium chloride and water for injections.

When should BENLYSTA not be used?

Do not take BENLYSTA if you have an allergic reaction (hypersensitivity) to BENLYSTA or to any ingredients in it.

If you are to receive BENLYSTA SC, please skip to page 12. If you're unsure, please check with your healthcare provider.



IV infusion

You'll go to a clinic where you'll be given BENLYSTA through an IV infusion (through a needle in your arm).

• Your infusions will take place once every 2 weeks for the first 3 doses, then once every 4 weeks after that.

BENLYSTA DOSING SCHEDULE				
w	eek 0	Week 2	Week 4	Every 4 weeks thereafter

Your healthcare provider will do the calculations and decide on the correct dose of BENLYSTA depending on your body weight.

Missed Dose: If you miss your appointment to receive BENLYSTA, ask your nurse coordinator when to schedule your next dose.

What can I expect when getting my infusion?

- You will go to an infusion clinic to receive BENLYSTA
- The healthcare providers at the infusion clinic will:
 - Watch you closely during and after the infusion
- Make sure you're comfortable
- Answer any questions you have
- You might be given an antihistamine and a drug to treat fever before you receive BENLYSTA
- The infusion itself takes about an hour, but expect to be at the clinic for a few hours on the day of your infusion

How can I prepare for my infusion?

- Wear comfortable clothing
 - You will be sitting for about an hour while the infusion is being given
- Bring books or magazines
 - This will help pass the time
- Make sure you're comfortable and settled before your infusion starts
- Don't be afraid to ask questions
 - The nurses at the infusion clinic are there to help



Remember: It's important to keep up with your treatment. Only stop taking BENLYSTA if your doctor tells you to. If you need to cancel an appointment, be sure to reschedule a new appointment at the same time.

To help yourself get accustomed to your infusion schedule, try putting reminders in your calendar.

If you are to receive BENLYSTA IV, please go back to page 10. If you're unsure, please check with your healthcare provider.



Subcutaneous injection using the BENLYSTA autoinjector

BENLYSTA SC is administered using the BENLYSTA autoinjector.

- The autoinjector is for use under the skin only.
- If you're nervous about self-injecting, don't forget that your healthcare team is there to support you.

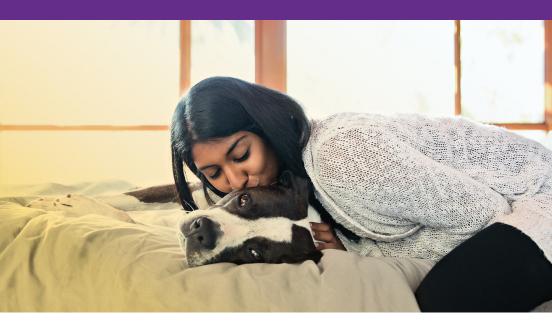
Your first injection

Your first injection will be given by a nurse at an infusion clinic. Your dosing schedule will be as prescribed by your physician. They will:

- Explain how to set up for an injection as well as where, how and when to inject
- Administer the injection while explaining each step along the way
- Talk to you about the signs and symptoms of allergic reactions to watch out for

After this first training session, you can self-inject with BENLYSTA as long as your nurse or healthcare provider decides it's okay to do so.

If you are unsure or have questions, talk to your healthcare team. Ask them to share the self-injection training video with you, and refer to the detailed **Instructions for Use** insert.

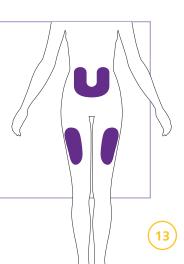


Administration

Lupus: The recommended dose of BENLYSTA for subcutaneous injection is 200 mg once a week, injected under your skin on the same day each week.

Lupus nephritis: At the start of your treatment the recommended dose of BENLYSTA for subcutaneous injection is 400 mg (two injections) weekly, injected under your skin on the same day each week for four weeks. After this, the recommended dose is 200 mg (one injection) once a week.

- Inject into the skin of your stomach (abdomen) or upper leg (thigh). Avoid injecting into the exact same place each time. You should not give injections into areas where the skin is tender, bruised, red, or hard.
- If you need two injections to complete your dose, leave at least 2 inches between each injection if using the same site.
- Do not inject within 2 inches of the belly button.



Before you get started

Read the **Instructions for Use** insert that comes with every BENLYSTA autoinjector.

Tips on using your BENLYSTA autoinjector

- Use your BENLYSTA autoinjector on the same day each week
- Avoid injecting into the same site each time
- Don't inject in areas where the skin is tender, bruised, red or hard

If you miss a dose of BENLYSTA:

- Inject the next dose as soon as possible
- After that, you can go back to having your injection on the usual day or start a new weekly schedule from the day that the missed dose was injected
- Do not inject two doses on the same day

In case of drug overdose:

 Contact a healthcare professional, hospital emergency department, or a regional Poison Control Centre immediately, even if there are no symptoms



How to store your BENLYSTA autoinjector

If you are using BENLYSTA at home, it is important that you store your BENLYSTA in your refrigerator at 2-8°C.

- Keep refrigerated until 30 minutes prior to use.
- Keep in the carton to protect from light.
- Keep out of reach of children.
- Do not freeze.
- Do not shake.
- Do not use if dropped onto a hard surface.
- Do not use if left out at room temperature for more than 12 hours.

How to dispose of your BENLYSTA autoinjector

Remember to dispose of your used BENLYSTA autoinjector immediately after use.

- Do not put the ring cap back onto the autoinjector
- Dispose of the used autoinjector and ring cap in an empty container with a tight-fitting lid (sharps container)
- Do not recycle or throw the used autoinjector or container of autoinjectors in household trash
 - Ask your healthcare provider for instructions on how to properly dispose of a used autoinjector or container of autoinjectors
 - Your pharmacy may be able to provide you with a secure disposal option

Please refer to the Consumer Information section of the **Product Monograph** for more information.

What should I tell my healthcare provider before treatment with BENLYSTA?

BEFORE you receive BENLYSTA, tell your healthcare provider about all of your medical conditions, including if you have or have had:

- An allergic reaction or hypersensitivity to other drugs or shots/injections.
 - You may be given medicines to help prevent reactions before you are given BENLYSTA.
- A current or long-term **infection** or if you often get infections. Your healthcare provider will decide if you can be given BENLYSTA.
- Been diagnosed with cancer.
- Memory loss, trouble thinking, difficulty with talking or walking, loss of vision, or similar problems.
- **Mental health problems** such as depression or thoughts of suicide. You may find it helpful to tell a relative or close friend and ask them to read this leaflet. You could ask them to tell you if they are worried about changes in your mood or behaviour.
- Recently received a vaccination (within the last 30 days) or if you think you
 may need a vaccination. If you're receiving BENLYSTA, you should not take
 live vaccines.

BEFORE you receive BENLYSTA, also tell your healthcare provider if you:

- Are pregnant, think you could be pregnant, or are planning to become pregnant.
 - The effects of BENLYSTA on pregnant women are not known. You and your healthcare provider need to consider the risks and benefits of taking BENLYSTA while you are pregnant.
 - Follow your healthcare provider's advice about contraception if you are treated with BENLYSTA and for at least 4 months after the last dose.
 - There is a registry for women with lupus who receive BENLYSTA while pregnant. The purpose of this registry is to collect information about the health of you and your baby. You can talk to your healthcare provider about how to take part in this registry or you can get more information and enrol by calling 1-877-311-8972 or visiting

https://mothertobaby.org/ongoing-study/benlystabelimumab/.

- Are nursing. It's likely that BENLYSTA can pass into human breast milk. You and your healthcare provider should decide if you will take BENLYSTA while breastfeeding.
- Have a baby while receiving BENLYSTA; tell your baby's healthcare provider, because your baby's vaccination schedule may be changed.



It's very important to view your next visit as an opportunity to open up about everything you're feeling. That's the only way your healthcare professional will truly understand what you're experiencing. That's why it's a good idea to record your BENLYSTA experience and bring it to your appointment. You can use the following diary pages to write down any changes, new or worsening symptoms, questions or concerns you may have.

In addition to sharing your BENLYSTA experience with your healthcare professional, tell him/her if:

- Your weight has changed
- You've changed the medications you take
- You've had an infection or been ill
- You've had any kind of reaction to BENLYSTA
- You've had any vaccinations
- You've noticed any change in your symptoms
- You've been experiencing symptoms that interfere with your normal activities

The more you share, the more you help yourself and your doctors. So take notes and don't hold back.

	If you are receiving BENLYSTA subcutaneous injection using the BENLYSTA autoinjector, you can use the following pages to keep a log of any notes or questions you may have for your doctor.
WEEK1	WEEK 3
Date:	Date:
My notes:	My notes:
Questions for my doctor:	Questions for my doctor:
Wellness tracker: With 1 being "Terrible" and 5 being "Great", please check off the	Wellness tracker: With 1 being "Terrible" and 5 being "Creat", please check off the
Wellness tracker: With 1 being "Terrible" and 5 being "Cirent", please check off the boas that corresponds to how you're feeling.	Wellness tracker: With 1 being "famble" and 5 being "Ones"; please check off the bor that correspond to how you're kering.
box that corresponds to how you're feeling.	box that corresponds to how you're feeling.
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10 20 30 40 50	bor that corresponds to how you're feeling.
10 20 30 40 50 WEEK 2	ber that corresponds to how you're feeling.
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Weekly/Monthly Tracking Diary

BENLYSTA SC DENLYSTA IV

Reminder: If you're taking BENLYSTA SC, you will inject yourself weekly. If you're taking BENLYSTA IV, you will receive your infusion monthly by a healthcare professional.

WEEK/MONTH 1
Did you receive a dose of BENLYSTA?
Date: Notes:
WEEK/MONTH 2
Did you receive a dose of BENLYSTA?
Date: Notes:
WEEK/MONTH 3
Did you receive a dose of BENLYSTA?
Date: Notes:

Use this section to take notes about your symptoms. Keeping track of your weekly/ monthly progress will help you prepare for future discussions with your doctor.

WEEK/MONTH 1	
Have you experienced new symptoms?	
What has changed?	
What has worsened?	
WEEK/MONTH 2	
Have you experienced new symptoms?	
What has changed?	
What has worsened?	
WEEK/MONTH 3	
Have you experienced new symptoms?	

What has changed?

What has worsened?

Weekly/Monthly Tracking Diary



Reminder: If you're taking BENLYSTA SC, you will inject yourself weekly. If you're taking BENLYSTA IV, you will receive your infusion monthly by a healthcare professional.

		WEEK/MONTH 4	
Did you receive a dose o	of BENLYSTA?		
YES O NO O			
Date: Notes:			
Notes.			
		WEEK/MONTH 5	
Did you receive a dose o	of BENLYSTA?		
Date:			
Notes:			
		WEEK/MONTH 6	
Did you receive a dose o	of BENLYSTA?		
YES O NO O			
Date:			
Notes:			

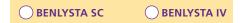
Use this section to take notes about your symptoms. Keeping track of your weekly/ monthly progress will help you prepare for future discussions with your doctor.

WEEK/MONTH 4
lave you experienced new symptoms?
What has changed?
What has worsened?
WEEK/MONTH 5
lave you experienced new symptoms?
What has changed?
What has worsened?
WEEK/MONTH 6
lave you experienced new symptoms?

What has changed?

What has worsened?

Weekly/Monthly Tracking Diary



Reminder: If you're taking BENLYSTA SC, you will inject yourself weekly. If you're taking BENLYSTA IV, you will receive your infusion monthly by a healthcare professional.

WEEK/MONTH 7
Did you receive a dose of BENLYSTA?
Date: Notes:
WEEK/MONTH 8
Did you receive a dose of BENLYSTA?
Date: Notes:
WEEK/MONTH 9
Did you receive a dose of BENLYSTA?
Date: Notes:

Use this section to take notes about your symptoms. Keeping track of your weekly/ monthly progress will help you prepare for future discussions with your doctor.

WEEK/MONTH 7
Have you experienced new symptoms?
What has changed?
What has worsened?
WEEK/MONTH 8
Have you experienced new symptoms?
What has changed?
What has worsened?
WEEK/MONTH 9
Have you experienced new symptoms?

What has changed?

What has worsened?

Weekly/Monthly Tracking Diary



Reminder: If you're taking BENLYSTA SC, you will inject yourself weekly. If you're taking BENLYSTA IV, you will receive your infusion monthly by a healthcare professional.

		WEEK/MONTH 10
Did you receive a dose of I	BENLYSTA?	
YES NO O		
Date: Notes:		
		WEEK/MONTH 11
Did you receive a dose of f	BENLYSTA?	
Date: Notes:		
		WEEK/MONTH 12
Did you receive a dose of B	BENLYSTA?	
Date: Notes:		

Use this section to take notes about your symptoms. Keeping track of your weekly/ monthly progress will help you prepare for future discussions with your doctor.

	WEEK/MONTH 10
Have you experienced new symptoms?	
What has changed?	
What has worsened?	
	WEEK/MONTH 11
	WEEK/MONTH TT
Have you experienced new symptoms?	
What has changed?	
What has worsened?	
	WEEK/MONTH 12

Have you experienced new symptoms?

What has changed?

What has worsened?

Weekly/Monthly Tracking Diary



Reminder: If you're taking BENLYSTA SC, you will inject yourself weekly. If you're taking BENLYSTA IV, you will receive your infusion monthly by a healthcare professional.

	WEE	K/MONTH 13	
Did you receive a dose of Bl	ENLYSTA?		
YES NO O			
Date: Notes:			
	WEE	K/MONTH 14	
Did you receive a dose of Bl	ENLYSTA?		
Date: Notes:			
	WEE	K/MONTH 15	
Did you receive a dose of Bl	ENLYSTA?		
YES NO			
Date: Notes:			

Use this section to take notes about your symptoms. Keeping track of your weekly/ monthly progress will help you prepare for future discussions with your doctor.

	WEEK/MONTH 13
Have you experienced new symptoms?	
What has changed?	
What has worsened?	
	WEEK/MONTH 14
Have you experienced new symptoms?	
What has changed?	
What has worsened?	
	WEEK/MONTH 15
Have you experienced new symptoms?	

What has changed?

What has worsened?

Weekly/Monthly Tracking Diary



Reminder: If you're taking BENLYSTA SC, you will inject yourself weekly. If you're taking BENLYSTA IV, you will receive your infusion monthly by a healthcare professional.

		WEEK/MONTH 16	
Did you receive a dose o	of BENLYSTA?		
YES NO O			
Date: Notes:			
		WEEK/MONTH 17	
Did you receive a dose o YES NO	of BENLYSTA?		
Notes:			
		WEEK/MONTH 18	
Did you receive a dose of YES NO	of BENLYSTA?		
Date: Notes:			

Use this section to take notes about your symptoms. Keeping track of your weekly/ monthly progress will help you prepare for future discussions with your doctor.

	WEEK/MONTH 16
Have you experienced new symptoms?	
What has changed?	
What has worsened?	
	WEEK/MONTH 17
Have you experienced new symptoms?	
What has changed?	
What has worsened?	
	WEEK/MONTH 18
Have you experienced new symptoms?	

What has changed?

What has worsened?

Serious warnings and precautions for BENLYSTA

Allergic and infusion/injection reactions including anaphylaxis

BENLYSTA can cause a reaction to the infusion/injection or an allergic (hypersensitivity) reaction. Occasionally, these reactions can be severe, and can cause death. They are more likely to happen on the day of treatment, but can happen later. Call your healthcare provider right away if you get any of the symptoms listed under **Allergic and infusion/injection reactions** in this brochure.

Severe infections

Patients receiving BENLYSTA may have a higher chance of getting infections. Infections may be serious and can lead to death. Call your healthcare provider right away if you feel sick or get any of the symptoms listed under **Infection** in this brochure.

Progressive multifocal leukoencephalopathy (PML)

PML is a serious brain condition that has been reported in patients receiving BENLYSTA and other drugs that weaken

the immune system. Death has occurred. The signs and symptoms of PML may include but are not limited to: memory loss, trouble thinking, confusion, problems with vision, difficulty with swallowing, talking, or walking, or seizures. Call your healthcare provider right away if you have any new or worsening experiences of the above symptoms. Please see the section called **Progressive multifocal leukoencephalopathy (PML)** in this brochure.

Suicidal thoughts, suicide attempts, or self-harm

Tell your healthcare provider right away if you have thoughts of harming yourself or committing suicide. Please see the section called **Mental health problems and suicide** in this brochure.

What are the side effects of BENLYSTA?

Very common side effects (either IV or SC) include:

- nausea
- diarrhea
- fever
- headache
- infections
- injection site pain/redness/itching/swelling/bruising*

Common side effects (either IV or SC) include:

- stuffy or runny nose
- sore throat
- bronchitis
- trouble sleeping
- pain in legs or arms
- depression
- vomiting
- stomach/abdomen pain
- bladder or kidney infections or painful urination
- toothache
- pain
- sudden high blood pressure
- speech difficulties

- painful joints
- yeast infection in women
- fast heartbeat
- fatty liver
- indigestion
- weight gain
- dry eyes
- allergic reaction
- changes in lab tests including: decreased white blood cell count (leucopenia/neutropenia), white blood cells in urine (leukocyturia), low potassium (hypokalemia)

These are not all the possible side effects you may have when taking BENLYSTA. If you experience any side effects not listed here, tell your healthcare professional.

* Subcutaneous injection only

Allergic and infusion/injection reactions: BENLYSTA can cause a reaction to the infusion/injection or an allergic (hypersensitivity) reaction. These can affect 1 to 10 users in 100. Occasionally, these reactions can be severe, and can cause death. They are more likely to happen on the day of treatment, but can happen later, even 5-10 days after a dose of medication (or before or after that time). Symptoms of a reaction to the infusion/injection and hypersensitivity (also known as anaphylaxis) are similar, and can include breathing difficulties or shortness of breath, wheezing, tongue, throat or face swelling, itching, rash, fever, low blood pressure (can cause light-headedness when you stand up), high blood pressure, slow heartbeat, muscle pain, joint pain, dizziness, nausea, fatigue, and headache. Tell your healthcare provider if you have any of these signs or symptoms.

Infection: BENLYSTA is a drug that affects your immune system. Patients receiving BENLYSTA may have a higher chance of getting sick or getting infections including chest infection, kidney infection, infection of nose and throat, bowel infection, etc. These can affect more than 1 in 10 users. More patients with serious infections receiving BENLYSTA in clinical trials died than did patients receiving placebo.

Call your healthcare provider right away if you feel sick or get any of the following symptoms, which may be early signs of a serious infection:

- fever
- feeling very tired
- cough, breathing problems
- flu-like symptoms

- warm, red, or painful skin
- diarrhea, vomiting
- burning sensation while passing urine

Other symptoms of infection may include:

chills

- bloody diarrhea
- pain with urination or urinating often
- coughing up mucus

You should not start taking BENLYSTA if you have an infection unless your healthcare provider says it's okay.

Progressive multifocal leukoencephalopathy (PML): PML is a serious and lifethreatening brain condition. Your chance of getting PML may be higher if you are treated with medicines that weaken your immune system, including BENLYSTA. Call your healthcare provider right away if you have memory loss, trouble thinking, confusion, difficulty with talking, swallowing, or walking, loss of vision, seizures, or similar problems that have lasted over several days. If you had these symptoms before treatment with BENLYSTA, tell your healthcare provider immediately about any changes in these symptoms. It is advisable that your healthcare provider refers you to a neurologist or an appropriate specialist.

Cancer: BENLYSTA may decrease your immunity. Medicines that affect the immune system may increase the risk of certain cancers.

Mental health problems and suicide: Symptoms of mental health problems when receiving BENLYSTA can include:

- thoughts of suicide or dying
- thoughts of hurting yourself or others
- attempting to commit suicide or acting on other dangerous impulses
- trouble sleeping (insomnia)
- new or worse anxiety
- new or worse depression
- other unusual changes in your behaviour or mood

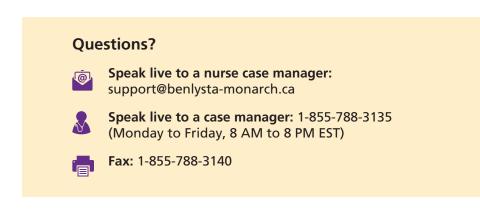
Tell your healthcare provider if these feelings change or get worse when using BENLYSTA.

For more information about BENLYSTA, please consult your healthcare provider or consult the Consumer Information section of the Product Monograph available at https://ca.gsk.com/media/6151/benlysta.pdf or by calling 1-800-387-7374.



The BENLYSTA MONARCH PROGRAM provides comprehensive information and support for people receiving BENLYSTA

By enrolling in The BENLYSTA MONARCH PROGRAM, you're eligible to receive toll-free access to experienced, English- and French-speaking case managers to help coordinate insurance coverage.



For more information about lupus, please visit: Lupus Canada (www.lupuscanada.org)*

* Please note that this is a third-party website and not affiliated with GSK.





