

## Patient Medication Information - Intravenous

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

(ben-LIST-ah)

Pr **BENLYSTA**

**Belimumab lyophilized powder for intravenous infusion**

**120 mg in 5 mL vial**

**400 mg in 20 mL vial**

This Patient Medication Information is written for the person who will be taking **BENLYSTA**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **BENLYSTA**, talk to a healthcare professional.

### Serious Warnings and Precautions

#### 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 professional right away if you get any of the symptoms listed in the SIDE EFFECTS, Allergic and Infusion/Injection Reactions section.

#### 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 professional right away if you feel sick or get any of the symptoms listed in the SIDE EFFECTS, Infection section.

#### 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, walking, or seizures. Call your healthcare professional right away if you have any new or worsening experiences of the above symptoms. See SIDE EFFECTS, PML below.

#### Suicidal thoughts, or suicide attempts, or harming yourself.

Tell your healthcare professional right away if you have thoughts of harming yourself or committing suicide. See SIDE EFFECTS, Mental health problems and suicide, below.

Please also see the SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM table below.

### What **BENLYSTA** is used for:

**BENLYSTA** for injection is used with other medicines to treat patients aged 5 years and older with:

- lupus (systemic lupus erythematosus / SLE), and
- lupus-related kidney inflammation (active lupus nephritis), weighing 15 kg or more.

**How BENLYSTA works:**

BENLYSTA contains *belimumab* which belongs to a group of drugs called *monoclonal antibodies*.

Lupus is a disease of the immune system (the body system that fights infection). People with active lupus often have high levels of a protein called BLYS in their blood. BLYS plays a role in the functioning of white blood cells called B cells. The abnormal activity of B cells in lupus may lead to damage affecting multiple organ systems. BENLYSTA binds to BLYS and limits the activity of BLYS. When given together with other drugs for lupus, BENLYSTA decreased lupus disease activity and lupus-related kidney inflammation more than the other drugs alone.

**The ingredients in BENLYSTA are:**

Medicinal ingredients: belimumab

Non-medicinal ingredients: citric acid monohydrate, polysorbate 80, sodium citrate dihydrate, and sucrose

**BENLYSTA comes in the following dosage forms:**

BENLYSTA for intravenous infusion is supplied as a white to off-white powder, in a glass vial with a latex-free, siliconised rubber stopper and a flip-off aluminium seal. Each 5 ml vial contains 120 mg of BENLYSTA. Each 20 ml vial contains 400 mg of BENLYSTA.

The powder will be reconstituted and diluted into a solution by your healthcare professional and be given to you by intravenous infusion (through a needle placed in your vein).

**Do not use BENLYSTA if:**

- You have an allergic reaction (hypersensitivity) to BENLYSTA (also known as belimumab)
- You have an allergic reaction to any ingredient in BENLYSTA, including any non-medicinal ingredient (see the section *What are the ingredients in BENLYSTA*).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BENLYSTA. Talk about any health conditions or problems you may have, including if you:**

- Have severe active central nervous system lupus.
- Have had an allergic reaction (hypersensitivity) to other drugs or shots/injections. You may be given medicines to help prevent reactions before you are given BENLYSTA.
- Have a current or long-term infection or if you often get infections. Your healthcare professional will decide if you can be given BENLYSTA.
- Have been diagnosed with cancer.
- Have memory loss, trouble thinking, difficulty with talking or walking, loss of vision, or similar problems.
- Have had mental health problems such as depression or thoughts of suicide. There have been reports of depression, suicidal thoughts and suicide attempts during treatment with BENLYSTA. If you feel depressed or have thoughts of harming yourself or committing suicide, contact your health professional or go to a hospital straight away. 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.
- Have recently received a vaccination (within the last 30 days) or if you think you may need a

vaccination. If you are receiving BENLYSTA, you should not take live vaccines.

- 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 professional need to consider the risks and benefits of taking BENLYSTA while you are pregnant. Follow your healthcare professional'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 professional 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/benlysta-belimumab/>.

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

#### **Other warnings you should know about:**

The combination of BENLYSTA with other medicines that affect your B cells may make your immune system less effective and could increase your risk of serious infection.

**Patients of Black African Heritage:** Tell your healthcare professional if you are of black ethnicity. It is not known if BENLYSTA is effective in treating SLE in people of Black ethnicity.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with BENLYSTA:** biologic drugs or monoclonal antibodies that may affect your immune system.

#### **How to take BENLYSTA:**

- You will be given BENLYSTA by your healthcare professional through a needle placed in a vein (intravenously or IV). It takes about 1 hour to give you the full dose of drug.
- Your healthcare professional may decide to give you an antihistamine and a drug to treat fever before you receive BENLYSTA. A healthcare professional will watch you closely during and following the infusion. You will be treated if you have any reaction.

#### **Usual dose:**

- Your healthcare professional will decide on the correct dose of BENLYSTA depending on your body weight. The usual dose is 10 mg for each kilogram (kg) of your body weight.
- You will receive the first 3 doses of BENLYSTA once every 2 weeks. After this, you will receive BENLYSTA once every 4 weeks.

#### **Overdose:**

If you think that you or a person you are caring for have taken too much BENLYSTA, contact your healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

**Missed Dose:**

If you miss your appointment to receive BENLYSTA, ask your healthcare professional when to schedule your next dose.

**Possible side effects from using BENLYSTA:**

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.

Very common side effects in BENLYSTA studies (either IV infusion or subcutaneous injection) include:

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

*\*subcutaneous injection only*

Common side effects in BENLYSTA studies (either IV infusion or subcutaneous injection) 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).

**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 heart beat, muscle pain, joint pain, dizziness, nausea, fatigue, and headache. Tell your healthcare professional if you have any of these signs or symptoms. Please refer to the table below for more information.

**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 professional 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

You should not start taking BENLYSTA if you have an infection unless your healthcare professional says it is okay.

**Progressive Multifocal Leukoencephalopathy (PML):** Progressive multifocal leukoencephalopathy (PML) is a serious and life-threatening 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 professional 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 professional immediately about any changes in these symptoms. It is advisable that your healthcare professional refer you to a neurologist or an appropriate specialist.

**Cancer:** BENLYSTA may decrease your immunity. Medicines that affect the immune system may also increase your 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 professional if these feelings change or get worse when using BENLYSTA.

**Serious side effects and what to do about them**

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Very Common</b>			
Infections, which may become serious and may cause death: <ul style="list-style-type: none"> <li>• fever</li> <li>• chills</li> <li>• pain or burning with urination or urinating often</li> <li>• bloody diarrhea</li> <li>• coughing up mucus</li> </ul>		X	
<b>Common</b>			
<b>Depression:</b> <ul style="list-style-type: none"> <li>• new or worse depression</li> <li>• new or worse anxiety</li> <li>• trouble sleeping (insomnia)</li> <li>• other unusual changes in your behaviour or mood</li> </ul>			X

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Uncommon</b>			
<b>Severe allergic and infusion/injection reactions:</b> <ul style="list-style-type: none"> <li>• severe allergic reactions, sometimes with swelling of face or mouth causing difficulty in breathing</li> <li>• swelling of the face, lips and tongue</li> <li>• rash, possibly with itchy raised bumps or hives</li> <li>• low blood pressure (can cause light-headedness when you stand up)</li> <li>• slow heart beat</li> <li>• difficulty breathing, shortness of breath</li> </ul>			X
<b>Suicidal thoughts, or suicide attempts:</b> <ul style="list-style-type: none"> <li>• thoughts of suicide or dying</li> <li>• thoughts of hurting yourself or others</li> <li>• attempting to commit suicide or acting on other dangerous impulses</li> </ul>			X
<b>Rare</b>			
<b>Progressive multifocal leukoencephalopathy (PML):</b> <ul style="list-style-type: none"> <li>• memory loss, trouble thinking, confusion, difficulty talking, swallowing or walking, loss of vision, seizures</li> </ul>		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting ([canada.ca/drug-device-reporting](http://canada.ca/drug-device-reporting)) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### Storage:

Store vials of BENLYSTA refrigerated between 2° to 8°C. Vials should be protected from direct light and stored in the original carton until use. Do not freeze. Avoid exposure to heat.

Keep out of reach and sight of children.

### If you want more information about BENLYSTA:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada Drug Product Database website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website [www.gsk.ca](http://www.gsk.ca), or by calling 1-800-387-7374.

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## Patient Medication Information - Autoinjector

### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

(ben-LIST-ah)

<sup>Pr</sup>**BENLYSTA**

**Belimumab injection**

**200 mg/mL autoinjector for subcutaneous injection**

This Patient Medication Information is written for the person who will be taking **BENLYSTA**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **BENLYSTA**, talk to a healthcare professional.

### Serious Warnings and Precautions

#### **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 professional right away if you get any of the symptoms listed in the SIDE EFFECTS, Allergic and Infusion/Injection Reactions section.

#### **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 professional right away if you feel sick or get any of the symptoms listed in the SIDE EFFECTS, Infection, section.

#### **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, walking, or seizures. Call your healthcare professional right away if you have any new or worsening experiences of the above symptoms. See SIDE EFFECTS, PML below.

#### **Suicidal thoughts, or suicide attempts, or harming yourself.**

Tell your healthcare professional right away if you have thoughts of harming yourself or committing suicide. See SIDE EFFECTS, Mental health problems and suicide, below.

Please also see the SERIOUS SIDE EFFECTS AND WHAT TO DO ABOUT THEM table below.

### **What BENLYSTA is used for:**

BENLYSTA injection is used with other medicines to treat:

- lupus (systemic lupus erythematosus / SLE) in patients aged 5 years and older, weighing 15 kg or more, and
- lupus-related kidney inflammation (active lupus nephritis) in adult patients.

### **How BENLYSTA works:**

BENLYSTA contains *belimumab* which belongs to a group of drugs called *monoclonal antibodies*.

Lupus is a disease of the immune system (the body system that fights infection). People with active lupus often have high levels of a protein called BLYS in their blood. BLYS plays a role in the functioning of white blood cells called B cells. The abnormal activity of B-cells in lupus may lead to damage affecting multiple organ systems. BENLYSTA binds to BLYS and limits the activity of BLYS. When given together with other drugs for lupus, BENLYSTA decreased lupus disease activity and lupus-related kidney inflammation more than the other drugs alone.

### **The ingredients in BENLYSTA are:**

Medicinal ingredients: belimumab

Non-medicinal ingredients: L-arginine hydrochloride, L-histidine, L-histidine monohydrochloride, polysorbate 80, sodium chloride, water for injections.

### **BENLYSTA comes in the following dosage forms:**

#### Autoinjector

Single dose, 1mL glass syringe in an autoinjector, containing 200 mg BENLYSTA.

The autoinjector is for use under the skin (subcutaneous injection) only and should not be given to you through a needle in your vein (not by intravenous infusion). See HOW TO TAKE BENLYSTA.

### **Do not use BENLYSTA if:**

- You have an allergic reaction (hypersensitivity) to BENLYSTA (also known as belimumab)
- You have an allergic reaction to any ingredient in BENLYSTA, including any non-medicinal ingredient (see the section *What are the ingredients in BENLYSTA*).

### **To help avoid side effects and ensure proper use, talk to your healthcare professional before you take BENLYSTA. Talk about any health conditions or problems you may have, including if you:**

- Have severe active central nervous system lupus.
- Have had an allergic reaction (hypersensitivity) to other drugs or shots/injections. You may be given medicines to help prevent reactions before you are given BENLYSTA.
- Have a current or long-term infection or if you often get infections. Your healthcare professional will decide if you can be given BENLYSTA.
- Have been diagnosed with cancer.
- Have memory loss, trouble thinking, difficulty with talking or walking, loss of vision, or similar problems.
- Have had mental health problems such as depression or thoughts of suicide. There have been reports of depression, suicidal thoughts and suicide attempts during treatment with BENLYSTA. If you feel depressed or have thoughts of harming yourself or committing suicide, contact your health professional or go to a hospital straight away. 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.

- Have recently received a vaccination (within the last 30 days) or if you think you may need a vaccination. If you are receiving BENLYSTA, you should not take live vaccines.
- 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 professional need to consider the risks and benefits of taking BENLYSTA while you are pregnant. Follow your healthcare professional'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 professional 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/benlysta-belimumab/>.

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

**Other warnings you should know about:**

The combination of BENLYSTA with other medicines that affect your B cells may make your immune system less effective and could increase your risk of serious infection.

**Patients of Black African Heritage:** Tell your healthcare professional if you are of black ethnicity. It is not known if BENLYSTA is effective in treating SLE in people of Black ethnicity.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with BENLYSTA:** biologic drugs or monoclonal antibodies that may affect your immune system.

**How to take BENLYSTA:**

Your BENLYSTA comes in an autoinjector.

You or your caregiver will get training on what the signs and symptoms of allergic reactions are (see SIDE EFFECTS AND WHAT TO DO ABOUT THEM).

Your healthcare professional will show you or your caregiver how to inject BENLYSTA. Your healthcare professional may then decide that you or your caregiver may inject BENLYSTA. Do not try to inject BENLYSTA yourself until you have been shown the right way to give the injections by your health care provider. Please see the BENLYSTA AUTOINJECTOR INSTRUCTIONS FOR USE, in your package of BENLYSTA.

BENLYSTA should be injected under your skin in your stomach area (abdomen) or upper leg (thigh). It should be injected in a different area of your body each injection. Don't inject in exactly the same place every time. (If you have lupus nephritis, you may need 2 injections to complete your dose; leave at least 2 inches between each injection). You should not give injections into areas where the skin is tender, bruised, red, or hard.

Each autoinjector contains a single injection; discard any unused portion after injection.

Always use this medicine exactly as your healthcare professional has told you to. If you have questions or do not understand the INSTRUCTIONS FOR USE, talk to your healthcare professional.

For children under 10 years of age: BENLYSTA must be injected by a healthcare professional or trained caregiver.

**Usual dose:**

Lupus (systemic lupus erythematosus)

Adults and children (5 to 17 years of age and weighing 50 kg or more): The recommended dose is 200 mg (one injection under your skin) once a week.

Children (5 to 17 years of age and weighing 30 to 50 kg): The recommended dose is 200 mg (one injection under your skin) every 10 days.

Children (5 to 17 years of age and weighing 15 kg to less than 30 kg): The recommended dose is 200 mg (one injection under your skin) every 2 weeks.

Lupus Nephritis

Adults only: At the start of your treatment the recommended dose is 400 mg (two injections under your skin) once a week for four weeks. After this the recommended dose is 200 mg (one injection under your skin) once a week.

The autoinjector is not recommended for use in children under 18 years of age with active lupus nephritis.

**Overdose:**

If you think that you or a person you are caring for have taken too much BENLYSTA, contact your healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

**Missed Dose:**

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 schedule from the day that the missed dose was injected.

**Possible side effects from using BENLYSTA:**

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.

Very common side effects in BENLYSTA studies (either IV infusion or subcutaneous injection) include:

- nausea, diarrhea, fever, headache, infections, injection site pain\*/redness\*/itching/swelling\*/bruising\*.  
*\*subcutaneous injection only*

Common side effects in BENLYSTA studies (either IV infusion or subcutaneous injection) 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 reactions, changes in lab tests including: decreased white blood cell count (leucopenia/neutropenia), white blood cells in urine

(leukocyturia), low potassium (hypokalemia).

**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 heart beat, muscle pain, joint pain, dizziness, nausea, fatigue, and headache. Tell your healthcare professional if you have any of these signs or symptoms. Please refer to the table below for more information.

**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 professional 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

You should not start taking BENLYSTA if you have an infection unless your healthcare professional says it is okay.

**Progressive Multifocal Leukoencephalopathy (PML):** Progressive multifocal leukoencephalopathy (PML) is a serious and life threatening 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 professional 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 professional immediately about any changes in these symptoms. It is advisable that your healthcare professional refer you to a neurologist or an appropriate specialist.

**Cancer:** BENLYSTA may decrease your immunity. Medicines that affect the immune system may also increase your 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 professional if these feelings change or get worse when using BENLYSTA.

**Serious side effects and what to do about them**

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>Very Common</b>			
<b>Infections, which may become serious and may cause death:</b> <ul style="list-style-type: none"> <li>• fever</li> <li>• chills</li> <li>• pain or burning with urination or urinating often</li> <li>• bloody diarrhea</li> <li>• coughing up mucus</li> </ul>		X	
<b>Common</b>			
<b>Depression:</b> <ul style="list-style-type: none"> <li>• new or worse depression</li> <li>• new or worse anxiety</li> <li>• trouble sleeping (insomnia)</li> <li>• other unusual changes in your behaviour or mood</li> </ul>			X
<b>Uncommon</b>			
<b>Severe allergic and infusion/injection reactions:</b> <ul style="list-style-type: none"> <li>• severe allergic reactions, sometimes with swelling of face or mouth causing difficulty in breathing</li> <li>• swelling of the face, lips and tongue</li> <li>• rash, possibly with itchy raised bumps or hives</li> <li>• low blood pressure (can cause light-headedness when you stand up)</li> <li>• slow heart beat</li> <li>• difficulty breathing, shortness of breath</li> </ul>			X
<b>Suicidal thoughts, or suicide attempts:</b> <ul style="list-style-type: none"> <li>• thoughts of suicide or dying</li> </ul>			X

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<ul style="list-style-type: none"> <li>thoughts of hurting yourself or others</li> <li>attempting to commit suicide or acting on other dangerous impulses</li> </ul>			
<b>Rare</b>			
<b>Progressive multifocal leukoencephalopathy (PML):</b> <ul style="list-style-type: none"> <li>memory loss, trouble thinking, confusion, difficulty talking, swallowing or walking, loss of vision, seizures</li> </ul>		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

#### Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting ([canada.ca/drug-device-reporting](http://canada.ca/drug-device-reporting)) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

#### Storage:

- Store BENLYSTA in the fridge at 2° to 8°C. Keep BENLYSTA refrigerated until 30 minutes before using it. Do not freeze it. Keep BENLYSTA in the original carton to protect from light. Do not shake it. Do not use it if it was dropped on a hard surface. Do not remove the autoinjector cap until right before the injection.
- Discard if not administered within 12 hours. Safely throw away medicine that is out of date or no longer needed.
- Keep out of reach and sight of children.

#### If you want more information about BENLYSTA:

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada Drug Product Database website: (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug->

[product-database.html](#)); the manufacturer's website [www.gsk.ca](http://www.gsk.ca), or by calling 1-800-387-7374.

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## BENLYSTA (belimumab injection)

### INSTRUCTIONS FOR USE – Autoinjector

#### READ THESE SECTIONS FIRST

#### BENLYSTA (belimumab injection) Autoinjector

These INSTRUCTIONS FOR USE should be read together with the PATIENT MEDICATION INFORMATION in your BENLYSTA package. Contact your healthcare professional if you have any questions about BENLYSTA.

Your healthcare professional will teach you how to use the BENLYSTA autoinjector, following these instructions. The autoinjector is for use **under the skin** (subcutaneous injection) **only**. Ask your healthcare professional if you have any questions about how to use BENLYSTA.

Follow these instructions on how to use the autoinjector. Failure to follow these instructions may affect proper function of the autoinjector. You should also receive training on how to use the autoinjector.

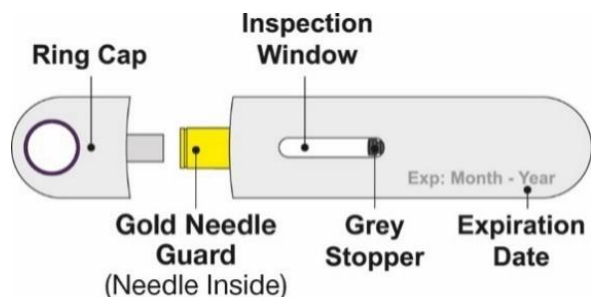
#### Important Storage Information

- Keep refrigerated until 30 minutes prior to use.
- Keep in the carton to protect from light.
- Keep out of reach of children.
- Keep away from heat and sunlight.
- **Do not** freeze. If the autoinjector has been frozen, **do not** use the autoinjector even if it is thawed.
- Do not use and **do not** place back in the refrigerator if left out at room temperature for more than 12 hours.

#### Important Warnings

- The autoinjector should be used only once and then discarded.
- **Do not** share your BENLYSTA autoinjector with another person.
- **Do not** shake.
- **Do not** use if dropped onto a hard surface.
- **Do not** remove the ring cap until right before the injection.

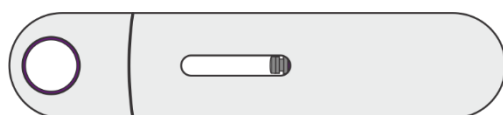
Figure A. BENLYSTA autoinjector parts



## 1. Gather supplies

- Remove one sealed tray containing an autoinjector from the refrigerator.
- Place any remaining autoinjectors back into the refrigerator.
- Find a comfortable, well-lit and clean surface and place the following supplies within reach:
  - BENLYSTA autoinjector
  - Alcohol swab (not included)
  - Gauze pad or cotton ball (not included)
  - Empty container with a tight-fitting lid for autoinjector disposal (not included)
- Do not perform the injection if you do not have all the supplies listed (see also Figure B).

**Figure B. Supplies needed for the injection**



**BENLYSTA autoinjector**



**Alcohol swab**  
*(not included)*

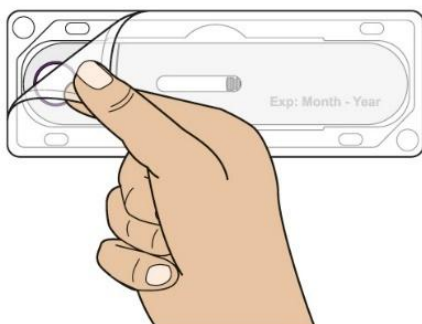


**Gauze pad or cotton wool ball**  
*(not included)*

## Take out the autoinjector

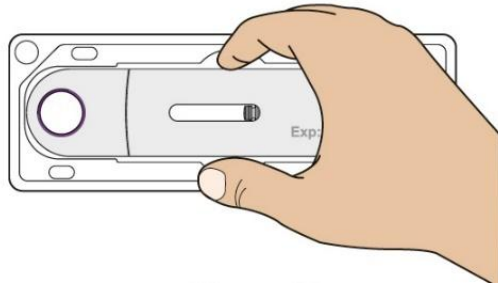
- Peel back the film from the corner of the tray (see Figure C).

**Figure C. Peel back film from tray**



- Holding the middle of the autoinjector (near the inspection window), carefully take the autoinjector out of the tray (see Figure D).

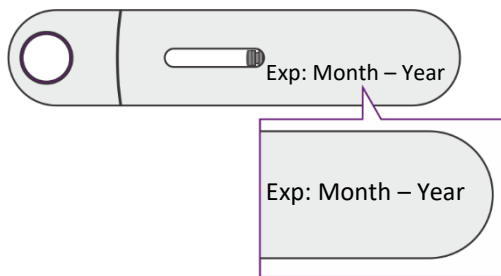
**Figure D. Take out autoinjector from the tray**



**Check expiration date**

- Check the expiration date on the autoinjector (see Figure E).

**Figure E. Check expiry date**



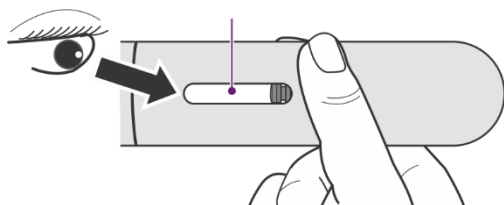
- **Do not** use if the expiration date has passed.
- 2. Prepare and inspect the autoinjector**
- Allow the autoinjector to sit at room temperature for 30 minutes (see Figure F).
  - Do not warm the autoinjector in any other way. For example, do not warm in a microwave oven, hot water or direct sunlight.
  - Do not remove the ring cap during this step.

**Figure F. Wait 30 minutes**



- Look in the inspection window to check that the BENLYSTA solution is colourless to slightly yellow in colour (see Figure G).
- It is normal to see one or more air bubbles in the solution.
- Do not use if the solution looks cloudy, discoloured or has particles.

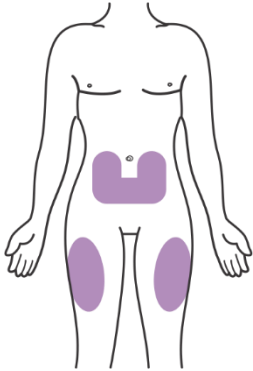
**Figure G. Inspect the BENLYSTA solution**  
**BENLYSTA solution**



### **3. Choose and clean the injection site**

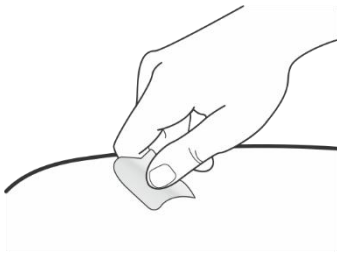
- Choose an injection site (abdomen or thigh) as seen in Figure H.
- Avoid injecting into the same site each time and areas where the skin is tender, bruised, red, or hard.
- If you need 2 injections to complete your dose, leave at least 2 inches between each injection if using the same site.
- Do not inject within 2 inches of the belly button.

**Figure H. Choose an injection site**



- Wash your hands.
- Clean the injection site by wiping it with an alcohol swab. Allow the skin to air dry (see Figure I).
- Do not touch this area again before giving the injection.

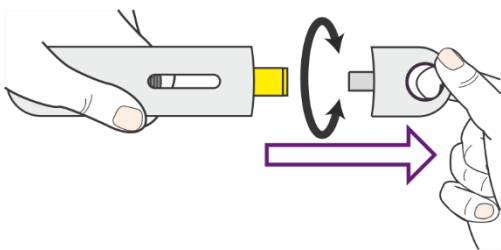
**Figure I. Clean the injection site**



**4. Prepare for the injection**

- Remove the ring cap right before the injection.
- Remove the ring cap by pulling or twisting it off. The ring cap may be twisted off in either a clockwise or counter-clockwise direction (see Figure J).
- Do not put the ring cap back onto the autoinjector.

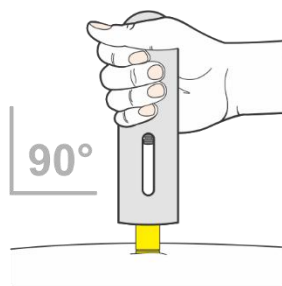
**Figure J. Remove ring cap**



### 5. Position the BENLYSTA autoinjector

- Hold the autoinjector comfortably so that you can view the inspection window. This is important so that you can confirm a complete dose (see Figure K).
- If needed, firm the injection site by pulling or stretching the skin.
- Position the autoinjector straight over the injection site (90 degree angle). Make sure the gold needle guard is flat on the skin.

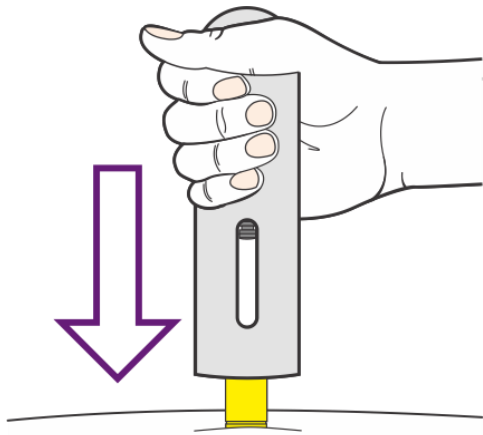
Figure K. Position the autoinjector



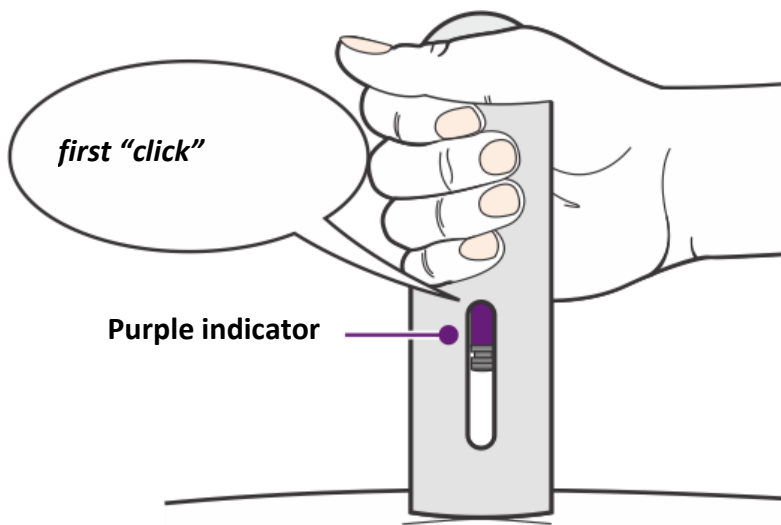
### 6. Inject BENLYSTA and Inspect

- Firmly press the autoinjector all the way down onto the injection site and hold in place (see Figure L). This will insert the needle and start the injection.
- You may hear a "first click" at the start of the injection and see the purple indicator start to move through the inspection window (see Figure M).
- Continue to hold the autoinjector down until you see that the purple indicator has stopped moving. You may hear a "second click" a few seconds before the purple indicator stops moving (see Figure N).
- The injection may take up to 15 seconds to complete.
- When the injection is complete, lift the autoinjector from the injection site.
- There may be a small amount of blood at the injection site. If needed, press a cotton ball or gauze pad on the injection site.
- **Do not** rub the injection site.

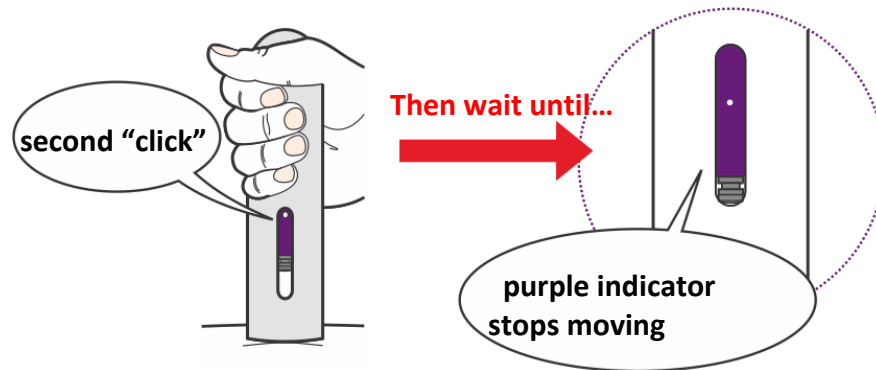
**Figure L. Hold the autoinjector down**



**Figure M. Start the injection**



**Figure N. Complete the injection**



**7. Inspect the Skin and Dispose of the used Autoinjector**

- Dispose of the used autoinjector and ring cap in an empty container with a tight-fitting lid.
- Ask your healthcare professional for instructions on how to properly dispose of a used autoinjector or container of used autoinjectors. Always keep used autoinjectors or the container of used autoinjectors out of the reach of children.
- Do not recycle or throw the used autoinjector or container of used autoinjectors in household trash.

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