BENLYSTA

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the full CMI for further details.

1. Why am I being given BENLYSTA?

BENLYSTA contains the active ingredient belimumab. BENLYSTA is used to treat systemic lupus erythematosus (SLE) and lupus-related kidney inflammation (active lupus nephritis) in adults aged 18 years and over.

For more information, see Section 1. Why am I using BENLYSTA? in the full CMI.

2. What should I know before I am given BENLYSTA?

Do not use if you have ever had an allergic reaction to belimumab or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use BENLYSTA? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BENLYSTA and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How is BENLYSTA given?

- BENLYSTA powder for intravenous infusion will be given to you by a doctor or nurse into a vein as a drip over 1 hour.
- BENLYSTA solution for subcutaneous injection comes in a pre-filled syringe or pen and will be injected by you or your caregiver, as instructed by your doctor or nurse.

More instructions can be found in Section 4. How is BENLYSTA given? in the full CMI.

5. What should I know while using BENLYSTA?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using BENLYSTA. • Tell your doctor immediately if you get an infection, have memory loss, trouble thinking, difficulty talking or walking or loss of vision, feel low in mood, have mental health problems or have thoughts of harming yourself or committing suicide. • Women of child-bearing potential must use contraception while using BENLYSTA and for four months after the last dose.
Things you should not do	• Do not give this medicine to anyone else, even if their symptoms seem similar to yours. • Do not use BENLYSTA to treat other complaints unless your doctor says to.
Driving or using machines	• Be careful driving or operating machinery until you know how BENLYSTA affects you.
Looking after your medicine	• Keep BENLYSTA in a refrigerator (2°C- 8°C) until it is time to use. Do not freeze. • Store BENLYSTA in the original package to protect it from light and keep it where children cannot reach it.

For more information, see Section 5. What should I know while using BENLYSTA? in the full CMI.

6. Are there any side effects?

Side effects can occur, including allergic reactions to the infusion or injection, depression, suicide or infections. Tell your doctor or nurse immediately if you experience any of these symptoms or notice them worsening.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

BENLYSTA

Active ingredient: *belimumab*

Consumer Medicine Information (CMI)

This leaflet provides important information about using BENLYSTA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BENLYSTA.**

Where to find information in this leaflet:

1. Why am I being given BENLYSTA?

BENLYSTA contains the active ingredient belimumab. Belimumab belongs to a group of medicines called monoclonal antibodies.

BENLYSTA is used to treat lupus (systemic lupus erythematosus, SLE) in adults (18 years of age and over). BENLYSTA is also used to treat adults with lupus-related kidney inflammation (active lupus nephritis) who are receiving standard treatment.

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.

BENLYSTA binds to BLyS and limits the activity of BLyS.

You will be given BENLYSTA as well as your usual treatment for lupus.

Your doctor may have prescribed BENLYSTA for another reason.

BENLYSTA is not addictive.

2. What should I know before I am given BENLYSTA?

Warnings

Do not use BENLYSTA if:

- you are allergic to belimumab or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Check with your doctor if:

- you have had an allergic reaction (hypersensitivity) to foods, dyes, preservatives or any other medicines or injections. You may be given medicines before you are given BENLYSTA to help reduce any infusion reactions to BENLYSTA.
- you have a history of depression, suicidal thoughts or behaviour.
- you think you have an infection.
- you need a vaccination or have recently received a vaccination. Your doctor will decide if you can be given the vaccination.
- you have had cancer. Your doctor will decide if you can be given BENLYSTA.
- you are taking any other medicines, including medicines you buy without a prescription.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Your doctor will decide if you can be given BENLYSTA.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is likely that BENLYSTA can pass into breast milk. Your doctor will discuss with you whether you should stop being treated with BENLYSTA while you are breast-feeding or you should stop breastfeeding while you are being treated with BENLYSTA.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with BENLYSTA and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BENLYSTA.

4. How is BENLYSTA given?

How much is given

Powder for intravenous infusion

Your doctor 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.

Solution for subcutaneous injection

Always use this medicine exactly as your doctor or pharmacist has told you to. Check with your doctor or pharmacist if you are not sure.

BENLYSTA should be injected under your skin on the same day each week. If you have lupus nephritis, one dose may be 2 individual injections administered at least 5 cm apart.

Systemic lupus erythematosus (SLE):

The recommended dose is 200 mg once a week.

Lupus nephritis:

At the start of your treatment the recommended dose is 400 mg (two 200 mg injections in one day) once a week for 4 doses. After this, the recommended dose is 200 mg (one injection) once a week.

How is it given

Powder for intravenous infusion

A nurse or doctor will give you BENLYSTA into a vein (intravenously) as a drip (infusion). It usually takes 1 hour to give the drip.

You are usually given BENLYSTA on the first day of treatment then again 14 and 28 days later. After this, BENLYSTA is usually given once every 4 weeks.

Solution for subcutaneous injection

BENLYSTA comes in a pre-filled syringe or pre-filled pen. Your doctor or nurse will show you or your caregiver how to inject BENLYSTA. Your doctor or nurse may then decide that you or your caregiver may inject BENLYSTA. In this case you or your caregiver will get training on how to inject BENLYSTA and what the signs and symptoms of allergic reactions are - see Section 6. Are there any side effects?

You or your caregiver should inject BENLYSTA under your skin in your stomach area (abdomen) or upper leg (thigh). You or your caregiver should inject a different area of your body for each injection. Don't inject in exactly the same place every time. You should not inject BENLYSTA into areas where the skin is tender, bruised, red or hard.

BENLYSTA subcutaneous injection must not be injected into a vein (intravenously).

If you forget to take your BENLYSTA subcutaneous injection

If you miss a dose, inject the next dose as soon as possible. After that, you can go back to having your dose on the usual day or start a new weekly schedule from the day that the missed dose was injected. If you are unsure consult your doctor or nurse.

Medication given before an infusion

If you have had an allergic reaction to other medicines or injections, your doctor may decide to give you medicines which help to reduce any infusion reactions before you are given BENLYSTA. These may include a type of medicine called an anti-histamine and a medicine to prevent a high temperature. You will be checked closely and if you do have any reactions these will be treated.

Stopping treatment with BENLYSTA

Your doctor will decide if you need to stop being given BENLYSTA.

Use in children and adolescents

Your doctor will decide if you need to stop being given BENLYSTA is not recommended for use in children and adolescents under 18 years.

If you use too much BENLYSTA

If you think that you have used too much BENLYSTA you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26)** or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using BENLYSTA?

Things you should do

- Women of child-bearing potential must use an effective method of contraception while being treated with BENLYSTA and for at least 4 months after the last dose.
- Tell your doctor if you have any mental health problems. Symptoms of mental health problems can include, new or worse depression, new or worse anxiety, thoughts of hurting yourself or others, acting on dangerous impulses or other unusual changes in your behaviour or mood.

Call your doctor straight away:

- if you feel low in mood, have thoughts of harming yourself or committing suicide. You may find it helpful to tell a relative or close friend and ask them to read this leaflet. You should also ask them to tell you if they are worried about changes in your mood or behaviour. If you experience new or worsening symptoms at any time, contact your doctor or go to a hospital straight away.
- if you get an infection while you are being treated with BENLYSTA. Your doctor will want to check that your infection is being properly treated. Symptoms of an infection can include, fever, chills, headache, sore

throat, cough, diarrhoea, stinging or burning on passing urine, aching muscles and pain, redness, swelling or discharge at the site of the wound.

Remind any doctor, dentist or pharmacist you visit that you are using BENLYSTA.

Things you should not do

- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use BENLYSTA to treat any other complaints unless your doctor says to.

Progressive multifocal leukoencephalopathy (PML)

Tell your doctor immediately if you have memory loss, trouble thinking, difficulty with talking or walking, loss of vision, or similar problems that have lasted over several days.

If you had these symptoms prior to treatment with BENLYSTA tell your doctor immediately about any changes in these symptoms.

These could be symptoms of Progressive multifocal leukoencephalopathy (PML).

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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BENLYSTA affects you.

Looking after your medicine

Keep BENLYSTA in a refrigerator (2°C - 8°C) until it's time to use. Do not freeze.

Follow the instructions in the carton on how to take care of your medicine properly.

Store in the original carton and protect from heat and sunlight.

Solution for subcutaneous injection

The pre-filled syringe or pre-filled pen (autoinjector) must be administered within 12 hours once the pack is opened. Discard if not administered within 12 hours.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Some of these serious side effects may cause death, including serious infection, risk of cancer and mental effects such as depression, but it is not known if BENLYSTA causes these side effects. You should discuss risks of serious side effects with your doctor before commencing treatment with BENLYSTA.

Allergic reaction to the infusion or injection

Medicines of this type (monoclonal antibodies) can cause allergic (hypersensitivity) reactions, which can affect between 1 in 10 and 1 in 100 people, and can occasionally be severe. These reactions usually occur within 1 to 2 hours after starting the infusion. They are more likely to happen during the first treatment.

Allergic reactions can also occur later with BENLYSTA generally 5-10 days after a dose of medication (but can occur before or after that time) and include a combination of symptoms such as rash, nausea, fatigue, muscle aches, headache, and/or facial swelling. If you experience these symptoms, particularly if you experience a combination of such symptoms tell your doctor or nurse.

Depression and suicide

There have been reports of depression, suicidal thoughts and suicide attempts during treatment with BENLYSTA. Depression can affect up to 1 in 10 users, suicidal thoughts and suicide attempts can affect up to 1 in 100 users. If you experience any new or worsening symptoms such as low mood, suicidal thoughts or behaviour, contact your doctor or go to a hospital straight away.

Infections

BENLYSTA can cause infection which can be of different types including chest infection, kidney infection, infection of nose and throat, bowel infection etc. These can affect more than 1 in 10 users, which can be severe and can uncommonly cause death.

Tell your doctor or a nurse immediately if you get symptoms of an infection, for example:

- Fever
- Cough
- Breathing problems
- Diarrhoea
- Vomiting
- Burning sensation while passing urine

Less serious side effects

Less serious side effects	What to do
Administration site reactions • rash, redness, itching or swelling of the skin where you have injected BENLYSTA solution for subcutaneous injection** **Gastrointestinal system disorders** • diarrhoea* • nausea* **General disorders** • high temperature or fever (pyrexia)**	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• pain in hands and feet**	

Serious side effects

Serious side effects	What to do
Infections • nose, throat, chest, bladder or stomach infections** **Allergic or infusion/injection related reactions** • swelling of face or mouth causing difficulty in breathing (anaphylactic reactions)*** • swelling of the face, lips and tongue (angioedema)*** • rash, possibly with itchy raised bumps or hives (urticaria)*** • low blood pressure (can cause light-headedness when you stand up) (hypotension) • slow heart beat (bradycardia) • difficulty breathing, shortness of breath (dyspnoea) **Blood disorders** • low white blood cell count** **Psychiatric disorders** • depression** • suicidal thoughts or behaviour***	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

* Can affect more than 1 in 10 patients

**Can affect between 1 in 10 and 1 in 100 patients

***Can affect between 1 in 100 and 1 in 1000 patients

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What BENLYSTA contains

Active ingredient (main ingredient)	Belimumab
Other ingredients (inactive ingredients)	**Powder for infusion** • citric acid monohydrate • sodium citrate dihydrate • sucrose • polysorbate 80 **Pre-filled pen (autoinjector) and pre-filled syringe solution for subcutaneous injection** • arginine hydrochloride • histidine • histidine hydrochloride monohydrate • polysorbate 80 • sodium chloride water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What BENLYSTA looks like

Powder for intravenous infusion

BENLYSTA 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 delivers 120 mg of BENLYSTA.

Each 20 mL vial delivers 400 mg of BENLYSTA.

There is 1 vial in each pack.

BENLYSTA is dissolved and diluted before being given to you.

Pre-filled pen (autoinjector) solution for subcutaneous injection

BENLYSTA is supplied as a colourless to slightly yellow solution in a 1 mL siliconised, USP Type I glass syringe with 13mm, 27G, stainless steel needle assembled as an auto-injector.

Each 1mL pre-filled pen (autoinjector) contains 200 mg belimumab.

Pre-filled syringe solution for subcutaneous injection

BENLYSTA is supplied as a colourless to slightly yellow solution in a 1 mL siliconised, USP Type I glass syringe with 13mm, 27G, stainless steel needle assembled with a needle guard.

Each 1mL pre-filled syringe contains 200 mg belimumab.

BENLYSTA:

120 mg powder for infusion - AUST R 173077

400 mg powder for infusion - AUST R 173078

200 mg pre-filled autoinjector pen - AUST R 314922

200 mg pre-filled syringe - AUST R 314903

Who distributes BENLYSTA

GlaxoSmithKline Australia Pty Ltd

Level 4, 436 Johnston Street

Abbotsford, Victoria, 3067

Australia.

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