BENLYSTA

for injection

belimumab (rmc) 120 mg and 400 mg powder; belimumab (rmc) 200 mg in 1 mL solution

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you are given BENLYSTA.

This leaflet answers some common questions about BENLYSTA. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you being given BENLYSTA against the risks this medicine could have for you.

If you have any concerns about receiving this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.
You may need to read it again.

What BENLYSTA is used for?

BENLYSTA contains belimumab which 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).

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.

Before you are given BENLYSTA

Do not receive if:

You must not receive BENLYSTA if:

- you have ever had an allergic reaction to belimumab or any of the ingredients listed toward the end of this leaflet. (See "Ingredients"). Check with your doctor if this applies to you.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Tell your doctor if:

You must tell your doctor if you have or have had any of the following medical conditions:

- 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.
- you are pregnant , think you could be pregnant, or are planning to become pregnant. Your doctor will decide if you can be given BENLYSTA.
- you become pregnant while being treated with BENLYSTA.
- you are breast-feeding. 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 breast-feeding while you are being treated with BENLYSTA.

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
The recommended dose is 200 mg once a week, injected under your skin on the same day each week.

How it is 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 'What are the 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 can inject the same area of your body each week, but 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 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. 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

BENLYSTA is not recommended for use in children and adolescents under 18 years.

What do I do if I take too much? (Overdose)

If you use more BENLYSTA than you should:

If this happens, contact your doctor or nurse immediately who will monitor you for any signs or symptoms of side effects, and treat these symptoms if necessary. If possible show them the pack, or this leaflet.

Immediately telephone your doctor or Poisons Information Centre (In Australia call 131126. In New Zealand call 0800 POISON or 0800 764 766) for advice, if you think you or anyone else may have received too much BENLYSTA, even if there are no signs of discomfort or poisoning.

If you are not sure what to do, contact your doctor or pharmacist.

While you are using BENLYSTA

Things you must 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.

Things you must do

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.

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 or go to a hospital 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.

Tell your doctor 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.

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.

Things to be careful of

Be careful driving or operating machinery until you know how BENLYSTA affects you.

What are the side effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to use of BENLYSTA, even if the problem is not listed below.

Like other medicines, BENLYSTA can cause some side effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

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.

An allergy or reactions to the infusion or injection can occur.
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

Tell your doctor or a nurse immediately if you get any of the symptoms below:

These side effects can affect more than 1 in 10 patients

- Nausea
- Diarrhoea
- Infections

These side effects can affect between 1 in 10 and 1 in 100 patients

- high temperature or fever (pyrexia)
- rash, redness, itching or swelling of the skin where you have injected BENLYSTA solution for subcutaneous injection
- low white blood cell count
- nose, throat, chest, bladder or stomach infections
- pain in hands or feet
- depression

These side effects can affect between 1 in 100 and 1 in 1000 patients

- severe allergic reactions, sometimes with swelling of face or mouth causing difficulty in breathing (anaphylactic reactions)
- swelling of the face, lips and tongue (angioedema)
- suicidal thoughts
- suicidal behaviour
- rash, possibly with itchy raised bumps or hives (urticaria)

Other symptoms of infusion or injection related reactions and allergic (hypersensitivity) reactions include:

- low blood pressure (can cause light-headedness when you stand up) (hypotension)
- slow heart beat (bradycardia)
- difficulty breathing, shortness of breath (dyspnoea)

Tell your doctor or a nurse immediately if you get any of these symptoms.

If you notice any side effects not listed in this leaflet, please tell your doctor.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Storage

Keep this medicine where children cannot reach it, such as in a locked cupboard.

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

Store in the original package to protect BENLYSTA from light.

Do not leave in a car, on a window sill or in a bathroom.

Return any unused or expired medicine to your pharmacist.

Product description

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.

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.

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.

Ingredients

Powder for intravenous infusion
BENLYSTA contains the active ingredient belimumab.

BENLYSTA also contains citric acid monohydrate, sodium citrate dihydrate, sucrose and polysorbate 80. BENLYSTA is dissolved and diluted before being given to you.

Pre-filled pen (autoinjector) and pre-filled syringe solution for subcutaneous injection
Each 1mL pre-filled pen (autoinjector) and pre-filled syringe contains 200 mg belimumab.

The other ingredients are arginine hydrochloride, histidine, histidine hydrochloride monohydrate, polysorbate 80, sodium chloride, water for injections.

Sponsor

BENLYSTA is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston Street
Abbotsford, Victoria, 3067
Australia.

BENLYSTA is supplied in New Zealand by:

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland 1143
New Zealand

Where to go for further information
Pharmaceutical companies are not in a

position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

This leaflet was prepared on 20 August 2019

The information provided applies only to: BENLYSTA.

BENLYSTA:

120mg - AUST R 173077

400 mg - AUST R 173078

200 mg pre-filled autoinjector pen - AUST R 314922

200 mg pre-filled syringe - AUST R 314903

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