

Patient's Medication Guide for Benlysta

Benlysta 120 mg powder for concentrate for solution for infusion
 Benlysta 400 mg powder for concentrate for solution for infusion
 Belimumab

Read all of this medication guide carefully before you start using this medicine.

- Keep this medication guide. You may need to read it again.
- If you have any further questions, ask your doctor.
- If any of the side effects gets serious, or if you notice any side effects not listed in this medication guide, please tell your doctor.

In this leaflet:

1. What Benlysta is and what it is used for
2. How Benlysta is used
3. Possible side effects

WHAT BENLYSTA IS AND WHAT IT IS USED FOR

Benlysta is a medicine used to treat lupus (systemic lupus erythematosus, SLE) in adults (18 years of age and over) whose disease is still highly active despite standard treatment. Benlysta is also used in combination with other medicines to treat adults with active lupus nephritis (lupus-related kidney inflammation).

Lupus is a disease in which the immune system (the system that fights infection) attacks your own cells and tissues, causing inflammation and organ damage. It can affect almost any organ in the body, and is thought to involve a type of white blood cells called B cells. Kidney inflammation is considered a common manifestation of lupus.

Benlysta contains belimumab (a monoclonal antibody). It reduces the number of B cells in your blood by blocking the action of a protein that helps B cells to live longer and is found in high levels in people with lupus.

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

HOW BENLYSTA IS USED

A nurse or doctor will give you Benlysta through a drip in your vein (intravenous infusion) over one hour.

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.

Medicine given before an infusion

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.

POSSIBLE SIDE EFFECTS

Like all medicines, Benlysta can cause side effects, although not everybody gets them.

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, and suicidal thoughts and suicide attempts can affect up to 1 in 100 users. Tell your doctor if you have a history of these conditions. You may find it helpful to talk to a relative or close friend if you feel depressed or have thoughts of harming yourself or committing suicide, and for them to tell you if they are worried about changes in your mood or behaviour. If you have distressing thoughts or experiences, or if you experience new or worsening symptoms at any time, **contact your doctor or go to a hospital straight away.**

Hypersensitivity reactions and infusion reactions

Benlysta can cause a reaction to the infusion or an allergic (hypersensitivity) reaction. These can affect 1 to 10 users in 100, and can occasionally be severe, and could be life-threatening. These reactions are more likely to happen on the day of, or day after, your first or second treatment with Benlysta.

If you get any of the following symptoms of a hypersensitivity or infusion reaction tell your doctor or nurse immediately or go to the Accident and Emergency (A&E) at your nearest hospital;

- swelling of the face, lips, mouth or tongue
- wheezing, difficulty in breathing or shortness of breath
- rash
- itchy raised bumps or hives

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.**

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 nurse immediately if you get any symptoms of an infection, for example:

- fever and/or chills
- cough, breathing problems
- diarrhoea, vomiting
- burning sensation while passing urine; urinating often
- warm, red or painful skin or sores on your body

Very common side effects

These may affect more than 1 in 10 people:

- bacterial infections, such as chest or bladder infections
- feeling sick, diarrhoea

Common side effects

These may affect up to 1 in 10 people:

- high temperature or fever;
- low white blood cell count;
- nose, throat, or stomach infection;
- pain in hands or feet;
- migraine;
- sleeplessness;
- depression;
- rash;
- itchy raised bumps or hives.

Uncommon side effects

These may affect up to 1 in 100 people:

- severe allergic reactions, sometimes with swelling of face or mouth causing difficulty in breathing;
- swelling of the face, lips and tongue;
- suicidal thoughts;
- suicidal attempts.

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

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



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For distribution by medical professionals only to patients prescribed with Benlysta.
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For further information, please consult your doctor or pharmacist
For reporting of adverse events please write to sg.drugsafety@gsk.com
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