

Package leaflet: Information for the user

Benlysta 200 mg solution for injection in pre-filled pen

belimumab

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Benlysta is and what it is used for
2. What you need to know before you use Benlysta
3. How Benlysta is used
4. Possible side effects
5. How to store Benlysta
6. Contents of the pack and other information
Step-by-step instructions for using the pre-filled pen

1. What Benlysta is and what it is used for

Benlysta as a subcutaneous injection is a medicine used to treat lupus (systemic lupus erythematosus, SLE) in adults (18 years of age and older) whose disease is still highly active despite standard treatment.

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*.

Benlysta contains **belimumab** (*a monoclonal antibody*). It reduces the number of B cells in your blood by blocking the action of BLYS, 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.

2. What you need to know before you use Benlysta

Do not use Benlysta

- if you are **allergic** to belimumab or any of the other ingredients of this medicine (*listed in section 6*).

➔ **Check with your doctor** if this may apply to you.

Warnings and precautions

Talk to your doctor before you use Benlysta:

- if you have a current or long-term **infection** or if you often get infections. Your doctor will decide if you can be given Benlysta
- if you are planning to have a **vaccination** or have had a vaccination within the last 30 days. Some vaccines should not be given just before or during treatment with Benlysta
- if your lupus affects your **kidneys** or **nervous system**
- if you are **HIV positive** or have **low immunoglobulin** levels
- if you have, or have had, **hepatitis B or C**
- if you have had an **organ transplant**, or a **bone marrow** or **stem cell transplant**
- if you have had **cancer**.

→ **Tell your doctor** if any of these may apply to you.

Depression and suicide

There have been reports of depression, suicidal thoughts, and suicide attempts including suicide during treatment with Benlysta. Tell your doctor if you have a history of these conditions. If you experience new or worsening symptoms at any time:

→ **Contact your doctor or go to a hospital straight away.**

If you feel depressed or 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 might ask them to tell you if they are worried about changes in your mood or behaviour.

Look out for important symptoms

People taking medicines that affect their immune system may be more at risk of infections, including a rare but serious brain infection called progressive multifocal leukoencephalopathy (PML).

→ **Read the information ‘Increased risk of brain infection’ in section 4 of this leaflet.**

To improve the traceability of this medicine, you and your healthcare provider should record the Benlysta lot number. It is recommended that you make a note of this information in case you are asked for it in the future.

Children and adolescents

Do not give Benlysta as a subcutaneous injection to children or adolescents younger than 18 years of age.

Other medicines and Benlysta

Tell your doctor if you are taking any other medicines, if you have recently taken or might take any other medicines.

In particular tell your doctor if you are being treated with medicines that affect your immune system:

- cyclophosphamide (a medicine to treat some cancers and autoimmune disorders)
- any medicine that affects your B cells (to treat cancer or inflammatory diseases).

→ **Tell your doctor.** Using such medicines in combination with Benlysta may make your immune system less effective. This could increase your risk of a serious infection.

Pregnancy and breast-feeding

Contraception in women of childbearing potential

- **Use an effective method of contraception** while you are being treated with Benlysta and for at least 4 months after the last dose.

Pregnancy

Benlysta is not usually recommended if you are pregnant.

- **Tell your doctor if you are pregnant**, think you may be pregnant, or are planning to have a baby. Your doctor will decide if you can use Benlysta.
- **If you become pregnant** while being treated with Benlysta, tell your doctor.

Breast-feeding

Tell your doctor if you are breast-feeding. It is likely that Benlysta can pass into breast milk. Your doctor will discuss with you whether you should stop treatment with Benlysta while you are breast-feeding, or if you should stop breast-feeding.

Driving and using machines

Benlysta can have side effects which may make you less able to drive or use machines.

Important information about the contents of Benlysta

This medicine contains less than 1 mmol sodium (23 mg) per dose, so it is essentially 'sodium-free'.

3. How Benlysta is used

How much to use

Adults (18 years of age and older)

The recommended dose is 200 mg (complete contents of one pen) once a week, injected under your skin on the same day each week.

If you wish to change your dosing day:

Take a dose on the new day (even if it is less than a week since your last dose). Continue with the new weekly schedule from that day.

Injecting Benlysta

Your doctor or nurse will show you or your caregiver how to inject Benlysta. Your first injection with the Benlysta pre-filled pen will be supervised by your doctor or nurse. After you have been trained on how to use the pen, your doctor or nurse may decide that you can give yourself the injection, or your caregiver can give it to you. Your doctor or nurse will also tell you what signs and symptoms to look out for when using Benlysta, because serious allergic reactions can occur (see '*Allergic reactions*' in section 4).

You inject Benlysta under your skin in your stomach area (abdomen) or upper leg (thigh).

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

Instructions for using the pre-filled pen are given at the end of this leaflet.

If you use more Benlysta than you should

If this happens, immediately contact your doctor or nurse, 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.

If you forget to use Benlysta

Inject the missed dose as soon as you remember. Then continue with your normal weekly schedule as usual or start a new weekly schedule starting from the day you inject the missed dose.

If you do not notice that you have missed a dose until it is already time for your next dose, then just inject this next dose as planned. It is not necessary to inject two doses on the same day.

Stopping treatment with Benlysta

Your doctor will decide if you need to stop using Benlysta.

4. Possible side effects

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

Allergic reactions — get medical help immediately

Benlysta can cause a reaction to the injection, or an allergic (*hypersensitivity*) reaction.

These are common side effects (may affect up to 1 in 10 people). They can occasionally be severe (uncommon, affecting up to 1 in 100 people), and could be life-threatening. These severe reactions are more likely to happen on the day of your first or second treatment with Benlysta, but can be delayed and occur several days afterwards.

Tell your doctor or nurse immediately, or go to the Emergency department of your nearest hospital, if you get any of the following symptoms of an allergic or injection-related reaction:

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

Rarely, less severe delayed reactions to Benlysta can also occur, usually 5 to 10 days after an injection. They include symptoms such as rash, feeling sick, tiredness, muscle aches, headache, or facial swelling.

If you experience these symptoms, particularly if you get two or more of them together:

→ Tell your doctor or nurse.

Infections

Benlysta can make you more likely to get infections, including infection of the urinary tract and airways. These are very common and may affect more than 1 in 10 people. Some infections can be severe and can uncommonly cause death.

If you get any of the following symptoms of an infection:

- 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.

→ Tell your doctor or nurse immediately.

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 people, suicidal thoughts and suicide attempts can affect up to 1 in 100 people. If you feel depressed, have thoughts about harming yourself or other distressing thoughts, or if you are depressed and notice that you feel worse or develop new symptoms:

→ Contact your doctor or go to a hospital straight away.

Increased risk of brain infection

Medicines that weaken your immune system, such as Benlysta, may put you at higher risk of getting a rare but serious and life-threatening brain infection called *progressive multifocal leukoencephalopathy* (PML).

Symptoms of PML include:

- memory loss
- trouble in thinking

- difficulty with talking or walking
 - loss of vision.
- **Tell your doctor immediately** if you have any of these symptoms, or similar problems that have lasted over several days.

If you already had these symptoms before you started treatment with Benlysta:

- **Tell your doctor immediately** if you notice any changes in these symptoms.

Other possible side effects:

Very common side effects

These may affect **more than 1 in 10** people:

- bacterial infections (*see 'Infections' above*)
- feeling sick, diarrhoea.

Common side effects

These may affect **up to 1 in 10** people:

- high temperature or fever
- low white blood cell count (can be seen in blood tests)
- nose, throat or stomach infection
- pain in hands or feet
- migraine
- injection site reactions, for example: rash, redness, itching or swelling of the skin where you have injected Benlysta.

Uncommon side effects

These may affect **up to 1 in 100** people:

- itchy, bumpy rash (hives), skin rash.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme website:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store..

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Benlysta

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C).

Do not freeze.

Store in the original package in order to protect from light.

A single Benlysta pre-filled pen can be stored at room temperature (up to 25°C) for a maximum of 12 hours – as long as it is protected from light. Once removed from the refrigerator, the pen **must be used within 12 hours or discarded**.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Benlysta contains

The active ingredient is belimumab.

Each 1 ml pre-filled pen contains 200 mg belimumab.

The other ingredients are arginine hydrochloride, histidine, histidine monohydrochloride, polysorbate 80, sodium chloride, water for injections. See 'Important information about the contents of Benlysta' in section 2 for further information.

What Benlysta looks like and contents of the pack

Benlysta is supplied as a 1 ml colourless to slightly yellow solution in a single use pre-filled pen.

Available in packs of 1 or 4 pre-filled pens in each pack and multipacks comprising 12 pre-filled pens (3 packs of 4 pre-filled pens).

Not all pack sizes may be marketed.

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Detailed information on this medicine is available on the European Medicines Agency web site:

<http://www.ema.europa.eu>.

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Step-by-step instructions for using the pre-filled pen

Once-Weekly

Follow these instructions on how to use the pre-filled pen correctly. Failure to follow these instructions may affect proper function of the pre-filled pen. You should also receive training on how to use the pre-filled pen.

Benlysta is for use **under the skin only** (*subcutaneous*).

To improve the traceability of this medicine, you and your healthcare provider should record the Benlysta lot number. It is recommended that you make a note of this information in case you are asked for it in the future.

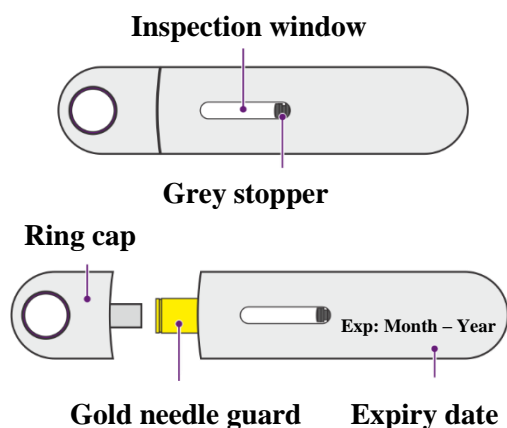
Storage

- Keep refrigerated until 30 minutes before use.
- Keep in the carton in order to protect from light.
- Keep out of the sight and reach of children.
- **Do not** freeze.
- **Do not** use if left out at room temperature for more than 12 hours.

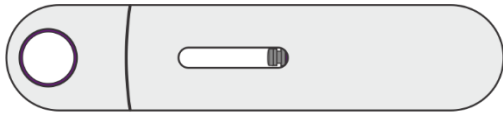
Warnings

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

Benlysta pre-filled pen parts



Supplies you need for the injection



Benlysta pre-filled pen



Alcohol swab
(not included)



Gauze pad or cotton wool ball
(not included)

1. Gather and check supplies

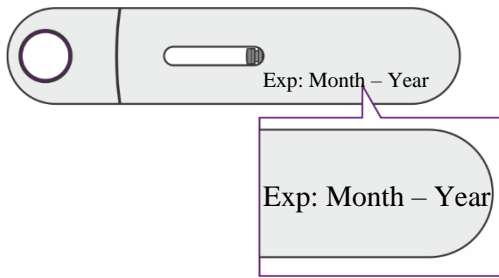
Gather supplies

- Remove one sealed tray containing a pre-filled pen from the refrigerator.
- Find a comfortable, well-lit and clean surface and place the following supplies within reach:
 - Benlysta pre-filled pen
 - alcohol swab (not included in the pack)
 - gauze pad or cotton wool ball (not included in the pack)
 - container with a tight-fitting lid for pen disposal (not included in the pack).
- **Do not** perform the injection if you do not have all the supplies listed.

Check the expiry date

- Peel back the film of the tray and remove the pre-filled pen.
- Check the expiry date on the pre-filled pen. (Figure 1)

Figure 1



Do not use if the expiry date has passed

2. Prepare and inspect the pre-filled pen

Allow to come to room temperature

- Leave the pen at room temperature for 30 minutes. (*Figure 2*) Injecting cold Benlysta may take longer and may be uncomfortable.

Figure 2



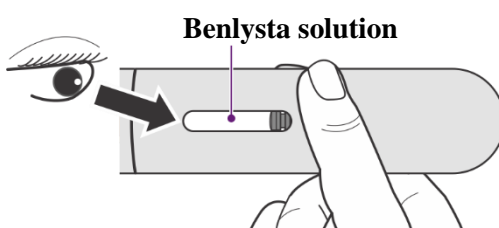
- **Do not** warm the pen in any other way. For example, do not warm it in a microwave oven, hot water or direct sunlight.
- **Do not** remove the ring cap during this step.

Inspect the Benlysta solution

- Look in the inspection window to check that the Benlysta solution is colourless to slightly yellow in colour. (*Figure 3*)

It is normal to see one or more air bubbles in the solution.

Figure 3



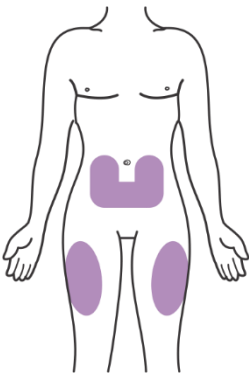
- **Do not** use if the solution looks cloudy, discoloured or has particles.

3. Choose and clean the injection site

Choose the injection site

- Choose an injection site (abdomen or thigh) as seen in *Figure 4*.

Figure 4



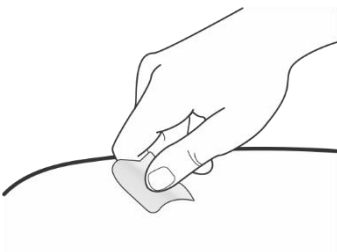
- **Do not** inject into the exact same site each time. This is to avoid the skin becoming hardened.
- **Do not** inject in areas where the skin is tender, bruised, red or hard.
- **Do not** inject within 5 cm (2 inches) of the navel (belly button).

Clean the injection site

- Wash your hands.

Clean the injection site by wiping it with an alcohol swab (*Figure 5*). Allow the skin to air dry.

Figure 5



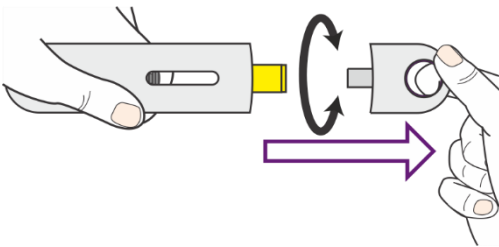
Do not touch this area again before giving the injection.

4. Prepare for the injection

Remove the ring cap.

- **Do not** remove the ring cap until immediately before the injection.
- Remove the ring cap by pulling or twisting it off. The ring cap may be twisted off either clockwise or anti-clockwise. (*Figure 6*)

Figure 6

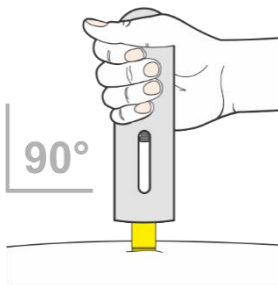


- **Do not** put the ring cap back onto the pen.

Position the pen

- Hold the pen comfortably so that you can view the inspection window. This is important so that you can confirm a complete dose. (*Figure 7*)

Figure 7



- If needed, firm the injection site by pulling or stretching the skin.
- Position the pen straight over the injection site (at a 90° angle). Make sure the gold needle guard is flat on the skin.

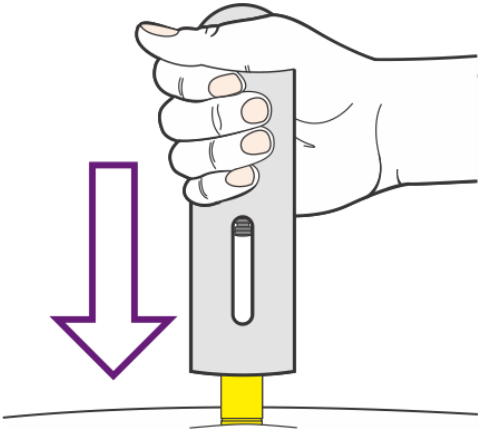
5. Inject Benlysta

Start the injection

- Firmly press the pen all the way down onto the injection site and hold in place. (*Figure 8*)

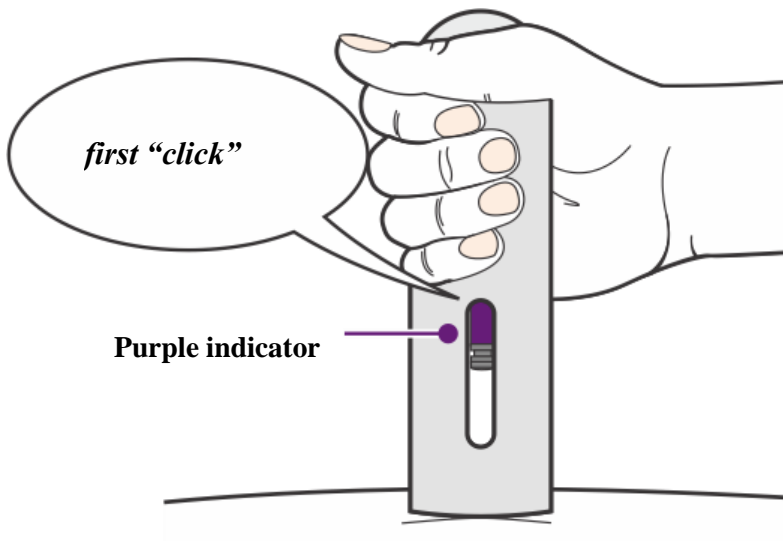
This will insert the needle and start the injection.

Figure 8



You may hear a first “click” at the start of the injection. You will see the purple indicator start to move through the inspection window. (*Figure 9*)

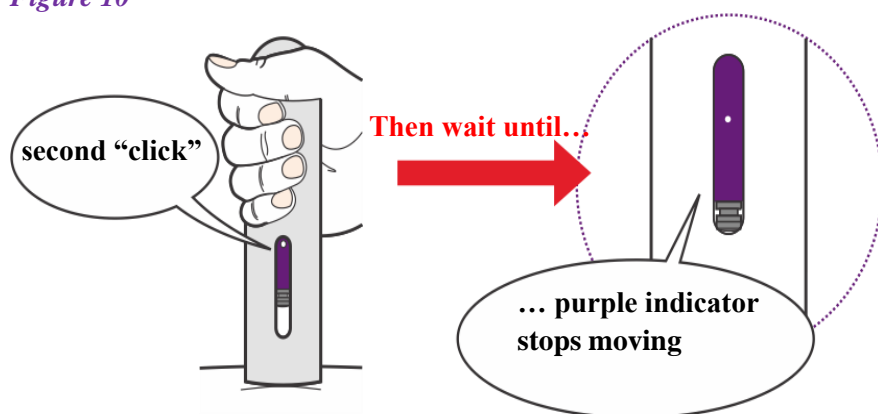
Figure 9



Complete the injection

Continue to hold the pen down until the purple indicator has stopped moving. You may hear a second “click” a few seconds before the purple indicator stops moving. (*Figure 10*)

Figure 10



The injection may take up to 15 seconds to complete.

- When the injection is complete, lift the pen from the injection site.

6. Dispose and inspect

Dispose of the used pen

- Do not put the ring cap back onto the pen.
- Dispose of the used pen and ring cap in a container with a tight-fitting lid.
- Ask your doctor or pharmacist for instructions on how to properly dispose of a used pen or container of used pens.
- **Do not** recycle or throw the used pen, or container of used pens, in household waste.

Inspect 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.