Package leaflet: Information for the patient

Lytenava 25 mg/mL solution for injection
bevacizumab gamma

▼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.
- 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 Lytenava is and what it is used for

What Lytenava is
Lytenava contains the active substance bevacizumab gamma, which belongs to a group of medicines called antineovascularisation agents.

What Lytenava is used for
Lytenava is used in adults to treat an eye condition called neovascular (wet) age-related macular degeneration (nAMD).
This eye condition is characterised by the abnormal formation and growth of blood vessels underneath the macula. The macula is the central part of the retina at the back of the eye and is responsible for clear vision. The abnormal growth and formation of blood vessels may leak fluid or blood into the eye and interfere with the macula's function.

How Lytenava works
Lytenava specifically binds to a protein called human vascular endothelial growth factor A (VEGF-A), which is present in the eye. In excess, this growth factor causes abnormal growth of blood vessels in the eye, which can reduce vision. By binding to this growth factor, Lytenava can block its actions and prevent abnormal growth. This can help to stabilise or improve your vision.

2. What you need to know before you use Lytenava

You must not receive Lytenava if you
- are allergic to bevacizumab gamma or any of the other ingredients of this medicine (listed in section 6)

- have an infection in or around your eye
- have an inflammation in your eye

Tell your doctor if any of these apply to you.

Warnings and precautions
Talk to your doctor before using Lytenava if you have:
- glaucoma, an eye condition usually caused by high eye pressure
- a history of seeing flashes of light or floater or a sudden increase in the size and number of floaters (small, dark shapes moving in the field of vision)
- had blocked blood vessels, caused by a blood clot, such as heart attack, stroke, blood clots formed in the deep veins of the legs or lungs
- had eye surgery in the last 4 weeks or an eye surgery is planned in the next 4 weeks
- ever had any eye diseases or eye treatments

Tell your doctor immediately if you have:
- sudden vision loss
- signs of an eye infection or inflammation, such as
  - worsening of eye redness or increased eye discomfort
  - increased number of floaters in your vision or sensitivity to light
  - eye pain
  - blurred or decreased vision

It is important to know:
- safety and efficacy of Lytenava given to both eyes at the same time has not been studied. Such use may increase risk of side effects.
- injections with Lytenava may cause a temporary increase in eye pressure within 60 minutes after injection. Your doctor will monitor this after each injection.
- your doctor will check for factors increasing risk of a tear or detachment of one of the layers at back of the eye

When some other medicines that work in a similar way to Lytenava are given, there is a risk for the formation of blood clots that can block blood vessels. This may lead to heart attack or stroke. As small amounts of the medicine enter the blood, there is a theoretical risk of such events following injection of Lytenava into the eye.

Please see section 4 (“Possible side effects”) for more detailed information on side effects that could occur during Lytenava therapy.

Children and adolescents under 18 years
The use of Lytenava in children and adolescents has not been established and is therefore not recommended.

Other medicines and Lytenava
Tell your doctor if you are using, have recently used, or might use any other medicines.

Pregnancy and breast-feeding
- Women who could become pregnant must use effective contraception during treatment and for at least three months after the last injection of Lytenava.
- There is no experience of using bevacizumab gamma in pregnant women. Lytenava is not recommended during pregnancy unless the potential benefit outweighs the potential risk to the unborn child. If you are pregnant, think you may be pregnant or planning to become pregnant, discuss this with your doctor before starting treatment with Lytenava.

- Lytenava is not recommended during breast-feeding because it is not known whether bevacizumab gamma passes into breast milk. Ask your doctor or pharmacist for advice before Lytenava treatment.

Driving and using machines
After Lytenava treatment you may experience some temporary vision blurring. If this happens, do not drive or use machines until this resolves.

Lytenava contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to use Lytenava

Lytenava is given as a single injection into your eye by your doctor. The usual dose of an injection is 0.05 mL (which contains 1.25 mg of bevacizumab gamma). The interval between two doses injected into the same eye should be about four weeks.

Before the injection, your doctor will wash your eye carefully to prevent infection. Your doctor will also give you a local anaesthetic to reduce or prevent any pain you might have with the injection.

The treatment starts with one injection of Lytenava every 4 weeks. After the first few treatments (about 3), your doctor will determine the frequency of further treatments by monitoring the condition of your eye, such as your vision and the health of your eye.

How long does Lytenava treatment last for
This is a long-term treatment, possibly continuing for months or years. Your doctor will check that the treatment is working during your regular scheduled visits. Your doctor may also check on your eyes between injections. If you have questions about how long you will receive Lytenava, talk to your doctor.

If you miss a dose of Lytenava
If you miss a dose, schedule a new appointment with your doctor as soon as possible.

Before stopping Lytenava treatment
If you are considering stopping Lytenava treatment, please go to your next appointment and discuss this with your doctor. Your doctor will advise you and decide how long you should be treated with Lytenava. Stopping treatment may increase your risk of vision loss and your vision may worsen.

If you have any further questions on the use of this medicine, ask your doctor.

4. Possible side effects

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

Side effects of Lytenava injection result from either the medicine itself or the injection procedure and mostly affect the eye.

Contact your doctor immediately if you have any of the following serious side effects:
- increased eye pressure that requires immediate intervention (uncommon, may affect up to 1 in 100 people)

- serious inflammation inside the eye often caused by infections, called endophthalmitis, or (uncommon, may affect up to 1 in 100 people)
- temporary blindness (uncommon, may affect up to 1 in 100 people)

Symptoms of these serious side effects are pain or increased discomfort in your eye, worsening eye redness, blurred or decreased vision, increased number of small particles in your vision or increased sensitivity to light.

Other possible side effects are:
Common (may affect up to 1 in 10 people)
- small particles or spots in your vision (vitreous floaters)
- eye pain
- bleeding in the protective layer covering the eye called conjunctiva (conjunctival haemorrhage)
- increased eye pressure

Uncommon (may affect up to 1 in 100 people)
- detachment or tear of one of the layers in the back of the eye (retinal pigment epithelial tear, vitreous detachment)
- bleeding in the eye
- inflammation of the iris, the coloured part of the eye (iritis)
- corneal scar
- inflammation or damage to the cornea, the clear layer covering the iris (keratopathy, punctate keratitis)
- perceived flashes of light in the field of vision (photopsia)
- eye discomfort
- scratching of the cornea (corneal abrasion)
- eye irritation
- itching of the eye (eye pruritus)
- dry eye
- red eye (ocular hyperaemia)
- iodine allergy

Reporting of side effects
If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system: 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 Lytenava

Your doctor, pharmacist, or nurse is responsible for storing this medicine and disposing of any unused product correctly. The following information is intended for healthcare professionals.

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 carton and vial label after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C – 8 °C). Do not freeze.
The unopened vial may be stored outside the refrigerator below 25 °C for up to 12 hours.

Keep the vial in the outer carton in order to protect from light.

6. Contents of the pack and other information

What Lytenava contains

- The active substance is bevacizumab gamma. Each mL contains 25 mg bevacizumab gamma. Each vial contains 7.5 mg of bevacizumab gamma in 0.3 mL solution. This provides a suitable amount to deliver a single dose of 0.05 mL containing 1.25 mg bevacizumab gamma.
- The other ingredients are sodium dihydrogen phosphate monohydrate, disodium hydrogen phosphate, α,α-trehalose dihydrate, polysorbate 20 (E432), water for injections.

What Lytenava looks like and contents of the pack
Lytenava 25 mg/mL solution for injection (injection) is colourless to slightly brown.

Pack containing one glass vial with butyl rubber stopper. The vial is for single use only.

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The following information is intended for healthcare professionals only:

The solution should be inspected visually upon removal from the refrigerator and prior to administration. If particulates or cloudiness are visible, the vial must not be used and appropriate replacement procedures must be followed.

The content of the vial is sterile and for single use only. Do not use if the packaging or vial are damaged or expired.

The vial contains more than the recommended dose of 1.25 mg. Injecting the entire volume of the vial could result in overdose. The excess medicinal product and any air bubbles should be carefully expelled from the syringe prior to injection. The injection dose must be set to the 0.05 mL dose mark (1.25 mg bevacizumab gamma).

Traceability
In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

Method of administration
Lytenava is provided in a single-use vial for intravitreal use only. Each vial should only be used for the treatment of a single eye.

Use aseptic technique to carry out the following preparation steps:
1. Prepare for intravitreal injection with the following recommended commercially available medical devices for single use (not provided):
    - 5 micron sterile filter needle, 18-gauge × 1½ inch (micro acrylic copolymer filter; polycarbonate/stainless steel 304 needle or equivalent)
    - 1 mL sterile silicone-free syringe with marking to measure 0.05 mL (polypropylene/polyethylene or equivalent)
    - Sterile injection needle, 30-gauge × ½ inch (polypropylene/ stainless steel or equivalent)
    - Alcohol swab
2. Before withdrawal, disinfect the outer part of the rubber stopper of the vial.
3. Place the 5 micron filter needle onto the 1 mL syringe using aseptic technique.
4. Push the filter needle into the centre of the vial stopper and ensure the tip of the needle remains within the Lytenava solution to minimise the potential for air bubbles.
5. Withdraw the entire content of Lytenava to ensure a full dose can be prepared in the syringe, keeping the vial in an upright position, slightly inclined to ease sufficient withdrawal.
6. Ensure that the plunger rod is drawn sufficiently back when drawing up Lytenava to provide for sufficient volume to prepare a 0.05 mL injection.
7. The filter needle should be discarded after withdrawal of the vial content and must not be used for the intravitreal injection.
8. Attach a 30-gauge × ½ inch sterile injection needle firmly onto the syringe by screwing it tightly onto the syringe hub. Carefully remove the needle cap by pulling it straight off. Do not wipe the needle at any time.
9. Hold the syringe with the needle pointing up. If there are any air bubbles, gently tap the syringe with your finger until the bubbles rise to the top.
10. Hold the syringe at eye level and carefully push the plunger rod until the plunger tip is aligned with the line that marks 0.05 mL on the syringe.

The intravitreal injection procedure should be carried out under aseptic conditions, which includes the use of surgical hand disinfection, sterile gloves, a sterile drape and a sterile eyelid speculum (or equivalent). Sterile paracentesis equipment should be available as a precautionary measure. The patient's medical history for hypersensitivity reactions should be carefully evaluated prior to performing the intravitreal procedure. Adequate anaesthesia and a broad-spectrum topical microbicide to disinfect the periocular skin, eyelid and ocular surface should be administered prior to the injection.

The injection needle should be inserted 3.5-4.0 mm posterior to the limbus into the vitreous cavity, avoiding the horizontal meridian and aiming towards the centre of the globe. The injection volume of 0.05 mL is then delivered slowly; a different scleral site should be used for subsequent injections.

Following intravitreal injection, patients should be instructed to report any symptoms suggestive of endophthalmitis (e.g. eye pain, redness of the eye, photophobia, blurring of vision) without delay.