

# Beovu®

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## 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.

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- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

## 1. Why am I receiving Beovu?

Beovu contains the active ingredient brolocizumab. Beovu is used to treat eye conditions in adults 1) neovascular (wet) age-related macular degeneration (AMD) or wet AMD, 2) diabetic macular oedema (DME).

For more information, see Section [1. Why am I receiving Beovu?](#) in the full CMI.

## 2. What should I know before I am given Beovu?

Do not use if you have ever had an allergic reaction to Beovu 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 am given Beovu?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with Beovu 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 will I be given Beovu?**

- Beovu is given by an ophthalmologist (eye doctor) as an injection into the eye under a local anaesthetic.
- The recommended dose is 6 mg (0.05 mL) of brolocizumab.

More instructions can be found in Section [4. How will I be given Beovu?](#) in the full CMI.

### **5. What should I know while I am given Beovu?**

<b>Things you must do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist</li></ul>
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	<p>you visit that you are using Beovu.</p> <ul style="list-style-type: none"> <li>• Tell your doctor if you experience signs of inflammation or infection or you become pregnant.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Do not drive or operate machinery if your vision is poor, either because of your disease or because of the treatment.</li> </ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• There are no known interactions between Beovu and alcohol.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Your ophthalmologist (eye doctor) will treat you with Beovu. There is no need to store this medicine at home.</li> </ul>

For more information, see Section [5. What should I know while I am given Beovu?](#) in the full CMI.

## 6. Are there any side effects?

**The most common side effects are:** eye irritation, clouding of the lens, dry eye, abnormal sensation in the eye, pain or irritation at the site of the injection, increased tear production, redness or itching of the eye,

small particles or spots in your vision (floaters), allergic reactions (rash, itching, redness of the skin).

**The most serious side effects are:** redness or worsening redness of the eye, eye pain, sensitivity to light, any vision changes, including sudden vision loss, seeing flashes of light with floaters (seeing spots or cobwebs), progressing to blurred vision or loss of sight, stroke and heart attack.

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](http://www.tga.gov.au/reporting-problems).

## Beovu®

**Active ingredient(s):** *brolocizumab(rbe)*

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### Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

- [1. Why am I receiving Beovu?](#)
- [2. What should I know before I am given Beovu?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given Beovu?](#)
- [5. What should I know while I am given Beovu?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I receiving Beovu?

**Beovu contains the active ingredient brolucizumab.**

It is a prescription medicine that is injected into the eye by your ophthalmologist (eye doctor) to treat eye conditions which may impact your vision. It belongs to a group of medicines called anti- neovascularization agents ("anti- VEGF").

**Beovu is used to treat eye conditions in adults** which may cause decreased vision such as:

- Wet age-related macular degeneration (wet AMD)
- Diabetic macular oedema (DME)

Beovu may slow down disease progression and thereby maintain, or even improve your vision.

If you have any questions about Beovu, how it works or why this medicine has been prescribed for you, ask your doctor.

Your doctor may have prescribed it for another reason. It is available only with a doctor's prescription.

This medicine is not addictive.

There is not enough information to recommend the use of this medicine for children or adolescents.

## 2. What should I know before I am given Beovu?

### Warnings

#### You must not be given Beovu if:

- you are allergic (hypersensitive) to brolocizumab, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- you have an active or suspected infection in or around the eye.
- you experience pain or redness in your eye.

#### Check with your doctor if you:

- have glaucoma.
- have a history of seeing flashes of light or floaters (dark floating spots) and if you have a sudden increase of size and number of floaters.
- have a prior history of eye diseases or eye treatments.
- if you have a history of sudden vision loss due to blockage of blood vessels in the back of the eye (retinal vascular occlusion) or inflammation of blood vessels in the back of the eye (retinal vasculitis) in the last year
- ever had a stroke or heart attack. Signs of a stroke may include weakness or numbness of limbs or face, difficulty speaking or swallowing. Signs of a heart

attack may include chest pain, which may spread to the neck and shoulders.

- had a surgery or surgery is planned on your eye within the previous or next four weeks.
- take any medicines for any other condition.

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, think you are pregnant or plan to become pregnant. Your doctor can discuss with you the risks and benefits involved. It is recommended that you use effective contraception during Beovu treatment and for at least one month after the last injection of Beovu.

**Talk to your doctor if you are breastfeeding or plan to breastfeed.** Beovu is not recommended during breast feeding and for at least one month after the last injection when stopping treatment with Beovu. It is not known whether Beovu passes into breast milk.

## **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.



Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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

## **4. How will I be given Beovu?**

### **How Beovu is given**

Beovu is given by your ophthalmologist (eye doctor) as an injection into your eye (intravitreal injection).

Before the injection, your doctor will use a disinfectant eyewash to clean your eye carefully, to prevent infection. Your doctor will also give you an eye drop (local anesthetic) to numb the eye to reduce or prevent any pain you might have with the injection.

Follow the directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor for help. It is important to see your doctor regularly when on treatment with Beovu.

### **How much is given**

The recommended dose is 6 mg (0.05 mL) of brolucizumab.

## **When it is given**

### **Wet AMD**

- You will be treated with one injection per month for the first three months.
- After that, you may get one injection every eight (2 months) to twelve weeks (3 months). The treatment interval between two doses should not be less than every eight weeks (2 months). Your doctor will determine your treatment interval based on the condition of your eye.

### **DME**

- You will be treated with one injection every six weeks for the first five injections.
- After that, you may get one injection every twelve or sixteen weeks (3 or 4 months). Your doctor will determine your treatment interval based on the condition of your eye; some patients may need treatment every eight weeks (2 months). The treatment interval between two doses should not be less than every eight weeks (2 months).

Follow the instructions provided and use Beovu until your doctor tells you to stop.

## **How long does Beovu treatment continue**

Beovu is used to treat chronic eye diseases, therefore this is a long-term treatment, possibly continuing for months or years. Your doctor will check that the treatment is having the desired effect during your

regularly scheduled visits. Your doctor may also check your eyes during a visit without an injection.

If you have questions about how long you will receive Beovu, talk to your doctor.

### **If a scheduled Beovu injection is missed**

If you miss an appointment for Beovu treatment, contact your doctor as soon as possible. Your doctor will decide when you should be given your next dose.

Missing an injection may reverse the visual improvement you may have experienced.

### **Before stopping Beovu treatment**

Speak with your doctor before stopping treatment.

Stopping treatment may increase your risk of vision loss and reverse the visual improvement you may have experienced.

### **If you are given too much Beovu**

If you are given more Beovu than you need, your doctor will check the pressure in your eye and may need to treat it if it is increased. If you are unwell after receiving Beovu contact your doctor.

## **5. What should I know while I am given Beovu?**

### **Things you must do**

**Tell your doctor immediately if you notice any of the following symptoms during or after Beovu is injected:**

- develop redness of the eye or worsening eye redness, eye pain, increased discomfort, any change in vision (such as sudden vision loss, blurred or decreased vision), an increased number of small particles also commonly referred to as floaters, seeing spots or cobwebs in your vision, increased sensitivity to light, nausea or vomiting, develop sudden vision loss, which could be a sign of retinal vascular occlusion. All of these could be symptoms of a serious eye condition and may result in your doctor discontinuing your treatment with Beovu.
- develop serious eye infection or eye disorder as it can sometimes develop after an injection into the eye.
- notice any bruising or unexplained bleeding. There is a theoretical increased risk of bleeding with this group of medicines (anti-VEGF).
- the systemic use of VEGF inhibitors, substances similar to those contained in Beovu, is potentially related to the risk of blood clots blocking blood vessels (arterial thromboembolic events), which may lead to heart attack or stroke. There is a theoretical risk of such events following injection of Beovu into the eye

- become pregnant while being treated with this medicine, tell your doctor immediately.

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

Furthermore it is important for you to know that:

- the safety and efficacy of Beovu when administered to both eyes at the same time has not been studied and use in this way may lead to an increased risk of experiencing side effects
- injections with Beovu may cause an increase in eye pressure (intraocular pressure) in some patients within 30 minutes of the injection. Your doctor will monitor this after each injection
- your doctor will check whether you have other risk factors that may increase the change of a tear or detachment of one of the layers at the back of the eye (retinal detachment or tear; and retinal pigment epithelial detachment or tear), in which case Beovu must be given with caution.

## **Things you must not do**

### **Driving or using machines**

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

Do not drive or operate machinery if your vision is poor, either because of your disease or because of the treatment. After your injection with Beovu, you may experience some temporary vision problems (example - blurry vision). If you are affected, do not drive, operate

machinery or do anything else that could be dangerous until your vision is normal.

## **Looking after your medicine**

The information on how to store Beovu is meant for your doctor, who will be storing, handling, and injecting Beovu.

If you have to store Beovu:

### **Pre-filled syringe**

- Keep it in a refrigerator (2°C to 8°C). Do not freeze it.
- Keep the pre-filled syringe in the sealed blister and in the outer carton in order to protect from light.
- Prior to use, the unopened blister may be kept at room temperature (25°C) for up to 24 hours.

### **Vial**

- Keep it in a refrigerator (2°C to 8°C). Do not freeze it.
- Keep the vial in the outer carton in order to protect from light.
- Prior to use, the unopened vial may be kept at room temperature (25°C) for up to 24 hours.

### **Do not store Beovu or any other medicines**

- in the bathroom or near a sink, or
- in the car or on window sills

**Keep the medicine where young children cannot reach it.**

## Getting rid of any unwanted medicine

You must not be given this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. If it has expired or is damaged, return it to your pharmacist for safe disposal.

### 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.

The side effects associated with the administration of Beovu are either due to the medicine itself or the injection procedure and mostly affect the eye.

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

#### Less serious side effects

Less serious side effects	What to do
<p><b>Injection site reactions such as:</b></p> <ul style="list-style-type: none"><li>• eye irritation, clouding of the lens, a feeling of having something in the eye, dry eye, abnormal sensation in the eye</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● eye discomfort, pain or irritation at the site of the injection, increased tear production, redness or itching of the eye, small particles or spots in your vision (floaters)</li> <li>● <b>allergic</b> reactions (rash, itching, redness of the skin)</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Eye infection symptoms such as:</b></p> <ul style="list-style-type: none"> <li>● bloodshot eye, bleeding in the eye (retinal haemorrhage, conjunctival haemorrhage), inflammation or infection of the eyelid margins, visual disturbance, blurred or decreased sharpness of vision, blindness (temporary or otherwise)</li> </ul>	<p><b>Tell your doctor as soon as possible if you notice any of these side effects</b></p>



<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● discharge of the eye with itching, redness and swelling (conjunctivitis)</li> <li>● small marks on the surface of the eye, swelling of a section of the eye ( uveitis, iritis, iridocyclitis, conjunctivitis), swelling or irritation of the eyelid, eyelid pain, sac of pus on the eye</li> <li>● detachment of one of the layers at the back of the eye (vitreous detachment)</li> <li>● tear of the retina at the back of the eye (retinal tear)</li> <li>● increase in eye pressure</li> </ul>	
<p><b>Worsening of eye inflammation or infection such as:</b></p> <ul style="list-style-type: none"> <li>● inflammation of blood vessels in the back of the eye (retinal vasculitis), redness or worsening redness of the eye (retinal</li> </ul>	<p><b>Tell your doctor immediately, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<p>vascular occlusion), eye pain, severe inflammation inside the eye (endophthalmitis), sensitivity to light, any vision changes, including sudden vision loss.</p> <ul style="list-style-type: none"> <li>• seeing flashes of light with floaters (seeing spots or cobwebs), progressing to blurred vision or loss of sight</li> </ul>	
<p><b>Nervous system disorders:</b></p> <ul style="list-style-type: none"> <li>• signs of a stroke, such as weakness or numbness of limbs or face, difficulty speaking or swallowing</li> </ul> <p><b>Heart disorders:</b></p> <ul style="list-style-type: none"> <li>• signs of a heart attack may include chest pain, which may spread to the neck and shoulders</li> </ul>	<p><b>Go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

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

Other side effects not listed here may also occur in some people. Some of these side effects (e.g. an increase in the pressure inside your eye) can only be found when your doctor does tests to check your progress.

## 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](http://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 Beovu contains

<b>Active ingredient (main ingredient)</b>	<b>Pre-filled syringe</b> contains <b>19.8 mg</b> brolucizumab as the active ingredient.  <b>Vial</b> contains <b>27.6 mg</b> brolucizumab as the active ingredient.
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<b>Other ingredients (inactive ingredients)</b>	sodium citrate  sucrose  polysorbate 80  water for injections
<b>Potential allergens</b>	This medicine contains sorbates.

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

## **What Beovu looks like**

### **Pre-filled syringe (Aust R 313681)**

Beovu is a solution for injection supplied in a glass pre-filled syringe. The pre-filled syringe contains 0.165 mL of a clear to slightly opalescent, colourless to slightly brownish-yellow aqueous solution.

Beovu is supplied as packs containing one single use sterile pre-filled syringe in a sealed tray.

### **Vial (Aust R 313680)\***

Beovu is a solution for injection supplied in a glass vial. The vial contains 0.230 mL of a clear to slightly opalescent, colourless to slightly brownish-yellow aqueous solution.

Beovu is supplied as packs containing one single use glass vial and one filter needle for withdrawal of the vial contents.

\*Not all presentations may be marketed.

## **Who distributes Beovu**

NOVARTIS Pharmaceuticals Australia Pty Limited

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54 Waterloo Road

Macquarie Park NSW 2113

Telephone 1-800-671-203

Web site: [www.novartis.com.au](http://www.novartis.com.au)

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