

Byooviz™

Ranibizumab (rbe)

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Byooviz.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the final page. More recent information on the medicine may be available.

You should ensure that you speak to your pharmacist or doctor to obtain the most up-to-date information on the medicine. You can also download the most up-to-date leaflet from www.medsafe.govt.nz

Those updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the risks of you being given Byooviz against the benefits they expect it will have for you.

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

Keep this leaflet.

You may need to read it again.

What Byooviz is used for

Byooviz is used to treat problems with your vision due to damage to the retina (light-sensitive layer at the back of the eye) caused by growth of leaky, abnormal blood vessels (choroidal neovascularisation, CNV), in diseases that may cause decreased vision such as:

- Wet age related macular degeneration (wet AMD)
- Diabetic macular edema (DME), or edema due to retinal vein occlusion (RVO) where fluid accumulates into the back of the eye
- Proliferative diabetic retinopathy (PDR)
- CNV secondary to pathologic myopia (PM)
- CNV due to causes such as angioid streaks, post-inflammatory retinochoroidopathy, central serous chorioretinopathy, and inflammatory CNV

Byooviz contains the active substance ranibizumab, which is part of an antibody.

Antibodies are proteins which specifically recognise and bind to other unique proteins in the body. Ranibizumab binds selectively to a protein called human vascular endothelial growth factor A (VEGF-A), which is present in the retina. Byooviz reduces both the growth and the leakage of new

blood vessels in the eye, abnormal processes that contribute to several eye diseases that may cause decreased vision.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

It is available only with a doctor's prescription.

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

Before you are given Byooviz

When you must not be given it

You must not be given Byooviz if you have an allergy to:

- any medicine containing ranibizumab
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin. If you think you may be allergic,

ask your doctor for advice.

You must not be given this medicine if you have or suspect you may have an infection in or around your eye or if you have any pain or redness in your eye.

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 disposal.

If you are not sure whether you should be given this medicine, talk to your doctor.

Before you are given it

Tell your doctor if you have allergies to any other medicines, foods, dyes or preservatives.

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you have the potential to become pregnant.

It is recommended that you use effective contraception during Byooviz treatment and for at least three months after finishing a course of Byooviz treatment.

Tell your doctor if you are breast-feeding or planning to breast-feed. Byooviz is not recommended during breast-feeding as it is not known whether Byooviz passes into breast milk.

Tell your doctor if you have ever had a stroke or have

experienced short-lasting signs of a stroke (weakness or paralysis of limbs or face, difficulty speaking or understanding), known as a TIA (“mini-stroke”). This information will be taken into account to evaluate if Byooviz is the appropriate treatment for you.

Your doctor can discuss with you the risks and benefits involved.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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 when you are given this medicine.

How Byooviz is given

Single-use vial for intravitreal use only.

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

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 Byooviz.

How much is given

The usual dose is 0.05mL (which contains 0.5mg of medicine). The time between two doses injected into the same eye should not be shorter than one month.

The treatment is started with one injection per month. Depending on how you respond to treatment, your doctor will decide whether and when you need to receive the next injection of Byooviz

How it is given

Byooviz is given as a single injection into your eye. Before the injection, you will receive an eye drop to numb the eye. You will receive a broad spectrum antibiotic eye drop before the injection to kill any germs on the eye and on the skin around the eye.

After the Byooviz injection, your doctor may perform some additional tests to make sure there are no complications. Eye injections like those with Byooviz can increase eye pressure. This is something you would not notice.

When it is given

Your doctor will decide when you will be given Byooviz.

How long to continue treatment

Continue treatment with this medicine for as long as your doctor tells you.

If you forget a treatment

If you miss a Byooviz treatment, you need to contact your doctor to arrange another appointment as soon as possible.

If you stop Byooviz treatment, your eye disease may get worse.

If you are given too much (overdose)

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

While you are being given Byooviz

Things you must do

If you experience any problems during the treatment, tell your doctor.

If you notice any changes after you have been given Byooviz, inform your doctor immediately.

Tell your doctor immediately if you develop signs of inflammation and/or infection of the eye such as redness of the eye, eye pain, sensitivity to light and/or vision changes, seeing flashes of light with floaters (seeing cobwebs), progressing to a loss of sight or blurred vision.

A serious eye infection or eye disorder can sometimes develop after an injection into the eye.

If you are treated for visual impairment due to macular oedema in diabetes or in RVO tell your doctor if you think that the effect of the treatment is being lost.

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

Things you must not do

Do not drive or operate machinery if your vision is poor, either because of your disease or because of the treatment.

This medicine may cause short-term problems with vision in some people. If you are affected, do not drive, operate machinery or do anything else that could be dangerous until your vision is normal.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with Byooviz.

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- eye irritation, clouding of the lens, a feeling of having something in the eye, dry eye, abnormal sensation in the eye
- eye discomfort, pain or irritation at the site of the injection, increased tear

production, redness or itching of the eye, seeing spots or cobwebs (floaters)

- sore throat, nasal congestion, runny nose, headache, joint pain, flu, fatigue, breathlessness, dizziness, pale skin, anxiety, cough, nausea, allergic reactions (rash, hives, itching, skin reddening).

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- bloodshot eye, bleeding in the eye or at the site of injection, inflammation or infection of the eyelid margins, vision change, blurred or decreased sharpness of vision, blindness (temporary or otherwise), bleeding of the eye
- discharge of the eye with itching, redness and swelling (conjunctivitis)
- scratches on the cornea (front part of the eye), swelling of a section of the eye (cornea, uvea), swelling or irritation of the eyelid, eyelid pain, sac of pus on the eye, inflammation of the cornea, accumulation of blood in the front part of the eye, infection or inflammation of the inside of the eye
- symptoms of a urinary tract infection, including burning, stinging, pain or increased urgency to pass water.

The above list includes serious

side effects which may require medical attention. Serious side effects are rare.

Tell your doctor immediately if you experience any of the following:

- signs of inflammation and/or infection of the eye such as redness of the eye, eye pain, sensitivity to light and/or vision changes.
- seeing flashes of light with floaters (seeing cobwebs), progressing to blurred vision or loss of sight.

Go to your nearest emergency room immediately if you experience signs of a stroke, such as weakness or paralysis of limbs or face, difficulty speaking or understanding.

If you experience any of these signs, immediate medical care is needed.

The above are serious side effects which might need immediate medical attention.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above 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.

After you are given Byooviz

Storage

It is unlikely you will have to

store Byooviz at home.

If you do have to store it: 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 it from light.
- Prior to usage, the unopened vial may be kept at room temperature not exceeding 30°C for up to 1 month.

Do not store Byooviz or any other medicine in the bathroom or near a sink.

Do not leave it in the car or on a window sill.

Heat and dampness can destroy some medicines.

Keep the medicine where children cannot reach it.

Each Byooviz vial and associated needles are to be used for one injection only and then discarded.

Product description

What it looks like

Byooviz is a solution for injection supplied in a clear, colourless glass vial. The vial contains 0.23mL of a sterile, clear, colourless to pale yellow aqueous solution.

Vial + filter needle + injection needle pack:

Byooviz is supplied as packs containing one glass vial containing 0.23mL of solution, one filter needle for withdrawal of the vial contents, and one injection needle.

Vial only*:

Byooviz is supplied as packs containing one glass vial of ranibizumab.

* Not all pack types may be marketed.

Ingredients

Byooviz contains 2.3mg ranibizumab as the active ingredient.

It also contains:

- trehalose dihydrate
- histidine hydrochloride monohydrate
- histidine
- polysorbate 20
- water for injections.

Distributor

Byooviz is distributed in New Zealand by:

Sponsor:

SAMSUNG BIOEPIS NZ LIMITED
TMF Group, Level 11, 41 Shortland Street, Auckland 1010 New Zealand

Distributor:

Biogen NZ Biopharma Limited
Auckland
New Zealand
Telephone: +64 800 852 289

This leaflet was prepared in:

16 March 2023