EYDENZELT®

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.

1. Why am I using EYDENZELT?

EYDENZELT contains the active ingredient aflibercept (rch). EYDENZELT is used to treat eye conditions in adults

- neovascular (wet) age-related macular degeneration (also known as wet AMD)
- visual impairment due to macular oedema after central retinal vein occlusion (also known as CRVO)
- visual impairment due to macular oedema after branch retinal vein occlusion (also known as BRVO)
- diabetic macular oedema (DME), which is a swelling of the retina occurring in patients with diabetes.
- visual impairment due to myopic choroidal neovascularisation (also known as myopic CNV).

For more information, see Section 1. Why am I using EYDENZELT? in the full CMI.

2. What should I know before I use EYDENZELT?

Do not use if you have ever had an allergic reaction to aflibercept 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 use EYDENZELT? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with EYDENZELT 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 do I use EYDENZELT?

EYDENZELT is given by an ophthalmologist (eye doctor) as an injection into your eye usually under a local anaesthetic. In adult patients, the usual dose of EYDENZELT 2 mg is 0.05 mL or 50 microlitres; More instructions can be found in Section 4. How do I use EYDENZELT? in the full CMI.

5. What should I know while using EYDENZELT?

Things you should do	• Remind any doctor, dentist, or pharmacist you visit that you are using EYDENZELT. • Tell your doctor if you experience signs of infection, inflammation or you become pregnant.
Driving or using machines	• Patients may experience temporary visual disturbances after an intravitreal injection with EYDENZELT. Do not drive or use machinery after your injection as you may experience some temporary problems with vision.
Drinking alcohol	• There are no known interactions between EYDENZELT and alcohol.
Looking after your medicine	• Your ophthalmologist (eye doctor) will treat you with EYDENZELT. It is unlikely you will have to store EYDENZELT at home.

For more information, see Section 5. What should I know while using EYDENZELT? in the full CMI.

6. Are there any side effects?

The most common side effects include visual disturbance including blurred vision or dark spots, eye pain including injection site pain, perception of having something floating in the eye (floaters) or sensation that something is in the eye and increased tear production. Serious side effects such as severe eye pain, deterioration of eyesight, hazy vision, allergic reaction, chest pain and difficulty speaking or swallowing.

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.

EYDENZELT ®

Active ingredient(s): *Aflibercept (rch)*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I using EYDENZELT?
2. What should I know before I use EYDENZELT?
3. What if I am taking other medicines?
4. How do I use EYDENZELT?
5. What should I know while using EYDENZELT?
6. Are there any side effects?
7. Product details

1. Why am I using EYDENZELT?

EYDENZELT contains the active ingredient aflibercept (rch).

EYDENZELT is a type of treatment known as anti-vascular endothelial growth factor (anti-VEGF).

EYDENZELT contains the active ingredient aflibercept, which specifically recognises and binds to Vascular Endothelial Growth Factor-A (VEGF-A) and Placental Growth Factor (PlGF) proteins. By blocking these proteins, EYDENZELT can stop the growth and leakage of abnormal blood vessels and swelling of the retina in the eye, which in turn can help restore your eyesight or stop it from getting worse.

EYDENZELT is used to treat eye conditions in adults for:

- neovascular (wet) age-related macular degeneration (wet AMD)
- diabetic macular oedema (DME)
- visual impairment due to macular oedema after central retinal vein occlusion (CRVO)
- visual impairment due to macular oedema after branch retinal vein occlusion (BRVO)
- visual impairment due to myopic choroidal neovascularisation (myopic CNV)

In these conditions, EYDENZELT can help to prevent the eyesight from becoming worse or may improve it.

Proteins VEGF-A and PlGF play an important part in the development of new blood vessels in your eye which contributes to the progression of wet AMD or myopic CNV and the development of swelling (macular oedema) due to either CRVO, BRVO or DME.

EYDENZELT is used in patients with neovascular (wet) age-related macular degeneration (wet AMD), which is a condition in which abnormal blood vessels grow in the back of the eye (retina). These blood vessels can leak blood and fluid into the retina and damage it leading to vision loss.

EYDENZELT is used to treat diabetic macular oedema (DME) which is a swelling of the retina occurring in patients with diabetes due to leaking of fluid from blood vessels within the retina. When the macula swells with fluid, central vision becomes blurry.

EYDENZELT is used to treat CRVO which is caused by a blockage in the main blood vessel that transports blood away from the retina, in the back of your eye. The blockage stops blood from flowing in and out of the retina which causes swelling (macular oedema) and can damage your eyesight.

EYDENZELT is used to treat BRVO which is caused by a blockage in one or more branches of the main blood vessel that transports blood away from the retina, in the back of your eye. The blockage stops blood from flowing in and out of the retina which causes swelling (macular oedema) and can damage your eyesight.

EYDENZELT is used to treat Myopic CNV which is a severe form of myopia (short sightedness) which leads to extremely elongated eyes with additional defects in some layers in the back of the eye. This triggers the abnormal formation of new blood vessels which can cause bleeding and eventually may lead to loss of vision.

2. What should I know before I use EYDENZELT?

EYDENZELT should only be given to you by a doctor.

Warnings

Do not use EYDENZELT if:

- You are allergic to aflibercept, 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 <u>must not</u> be given this medicine if you have or are suspected of having:

- an infection in or around your eye
- severe inflammation of the eye (pain or redness)

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

Do not give this medicine to children under the age of 18 years. There is not enough information to recommend the use of EYDENZELT for children or adolescents.

Check with your doctor if you:

- had any prior issues or problems with injections into your eyes.
- have glaucoma (injection with EYDENZELT may trigger an increase in eye pressure in some patients within 60 minutes of injections and your doctor may monitor this after each injection).

- have ever had a stroke or experienced transient signs of a stroke (known as a "TIA" or "mini-stroke")
- have previously had or are planning to have an eye surgery within the past or next four weeks.

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

If you are pregnant or plan to become pregnant or have the potential to become pregnant, please talk to your doctor.

Your doctor will discuss the risks and benefits involved. It is recommended that you use effective contraception during EYDENZELT treatment and for at least three months after the last injection of EYDENZELT.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

EYDENZELT is not recommended during breast-feeding as it is not known whether EYDENZELT 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.

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

4. How will I be given EYDENZELT?

How much to use

EYDENZELT is given by your ophthalmologist (eye doctor) as an injection into your eye under a local anaesthetic.

Follow all 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 given to you, ask your doctor for help.

Make sure that you do not wear any makeup on the day of your EYDENZELT appointment.

On the day of your injection, your doctor or nurse will get you ready for your EYDENZELT treatment.

How much is given

- The recommended dose of EYDENZELT is 2 mg aflibercept, equivalent to 0.05 mL.
- The time between two doses into the same eye should be no shorter than one month.

If you are being treated for wet AMD:

- The injection is given once a month for the first 3 months followed by one injection every 2 months.
- Your doctor will check the condition of your eye. Depending on how you respond to the treatment, your doctor may decide to gradually increase or adjust the treatment interval for your next injection.

If you are being treated for DME:

- The injection is given once a month for the first 5 months followed by one injection every 2 months. Treatment interval may be kept at every 2 months or adjusted to your condition, based on your doctor's examination. Your doctor will decide on the schedule for follow up examinations.

If you are being treated for impaired vision due to macular oedema caused by CRVO or BRVO:

- You will start your treatment with monthly injections. After the first 3 injections, your doctor will determine the most appropriate treatment schedule for you based on your vision and test results at each visit. If considered appropriate, your doctor may decide to gradually increase or adjust the treatment interval for your next injection.

If you are being treated for myopic CNV:

- You will start your treatment with one injection and you will receive additional injections only if, during subsequent examinations, your doctor finds that your disease persists.

When it is given

- Your doctor will decide when you will be given EYDENZELT.

How it is given

- A doctor experienced in giving eye injections will inject EYDENZELT into your eye under sterile conditions. Before the injection your doctor will use a disinfectant eyewash to clean your eye carefully to prevent infection. Your doctor may also give you a local anaesthetic to reduce or prevent any pain you might have with the injection.
- After the EYDENZELT injection is given, your doctor may perform some additional tests to make sure there are no complications. Eye injections like those with EYDENZELT can increase the pressure inside your eye.

How long to continue treatment

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

Your doctor will arrange your next EYDENZELT appointment. Make sure you keep all of your scheduled appointments.

Your doctor may decide to stop your treatment with EYDENZELT if your vision is not showing benefits.

If you forget an appointment

If you miss a treatment with EYDENZELT, contact your doctor to make a new appointment for an examination and injection as soon as possible.

If you stop treatment with EYDENZELT, your vision may get worse.

If you are given too much EYDENZELT

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

EYDENZELT is given to you under medical supervision.

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have been given too much EYDENZELT.

Do this even if there are no signs of discomfort or poisoning.

5. What should I know while using EYDENZELT?

Things you should do

Tell your doctor if you experience any problems during the treatment, especially if you are being given EYDENZELT injections into both of your eyes at the same time.

You may be more likely to experience side effects if you receive an injection to both of your eyes at the same time.

Call your doctor straight away if you:

Develop signs or symptoms of an infection in the eye or other complications; such as eye pain or increased discomfort, worsening eye redness, blurred or decreased vision, increased sensitivity to light.

It is important to have any symptoms diagnosed and treated as soon as possible. A serious eye infection or eye disorder can sometimes develop after an injection into the eye.

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

Things you should not do

Driving or using machines

Do not drive or use machinery after your EYDENZELT injection as you may experience some temporary problems with vision.

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

It is unlikely you will have to store EYDENZELT. EYDENZELT will be stored by healthcare professionals at the hospital ward in a refrigerator at a temperature between 2-8° C.

If you do have to store it:

- Store at 2°C to 8°C. (Refrigerate. Do not freeze). Protect from light. Prior to usage, the unopened vial or pre-filled syringe blister pack may be stored at room temperature (25°C) for up to 24 hours.
- Keep the pre-filled syringe in its blister pack and carton in order to protect from light.
- Keep the vial in its carton in order to protect from light.

Do not store EYDENZELT or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.

Heat and damp can destroy some medicines

Each EYDENZELT pre-filled syringe is to be used for one injection only and then discarded.

Each EYDENZELT vial and associated filter needle are to be used for one injection only and then discarded.

Do not use this medicine after the expiry date.

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.

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
Eye disorders: • visual disturbance including blurred vision or dark spots • eye pain including injection site pain • perception of having something floating in the eye (floaters) or sensation that something is in the eye • increased tear production	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Serious side effects

Serious side effects	What to do
Eye disorders: • deterioration of eyesight • swelling of the eyelid of the injected eye • signs or symptoms of infection and/or inflammation of the eye • severe eye pain • sudden decrease in sharpness of vision in the injected eye which may be caused by tearing or detachment of the retina (the inner layer of the back of the eye) • damage to or swelling of the cornea (the transparent front part of the eye) • hazy vision (clouding of the lens) • flashes of light and a sudden increase in floaters in the eye • bloodshot eye caused by bleeding from small blood vessels in the outer layers of the eye or bleeding at the injection site **Immune system disorders:** • rash, itching, hives on the skin • severe allergic reaction, such as sudden signs of rash, itching or hives on the skin; swelling of the face, lips, tongue or other parts of the body; shortness of breath, wheezing or difficulty breathing **Blood clot related disorders:** • signs of a stroke, such as weakness or numbness of limbs or face, difficulty speaking or swallowing. • signs of heart attack, such as chest pain which may spread to the neck and shoulders.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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

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

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.

One vial and one prefilled syringe delivers a dose of 2 mg aflibercept in 0.05 mL.

What EYDENZELT contains

Active ingredient (main ingredient)	40 mg/mL aflibercept (rch)
Other ingredients (inactive ingredients)	Polysorbate 20 Histidine Histidine hydrochloride monohydrate, Sodium chloride Trehalose Water for injections
Potential allergens	N/A

This medicine MUST NOT be used if you are allergic to any of these ingredients.

What EYDENZELT looks like

EYDENZELT is a clear to slightly opalescent, colorless to very pale brownish yellow, iso-osmotic solution, supplied as a single dose in a glass vial or pre-filled syringe for the treatment of one eye.

Who distributes EYDENZELT

Celltrion Healthcare New Zealand Limited

Level 1, 46 Stanley Street

Parnell

Auckland 1010, New Zealand

Phone: 0800 838 899

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