NOVARTIS

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

LUCENTIS®
10 mg/ml

Solution for injection
Pre-filled syringe for injection into the eye

Active ingredient:
Ranibizumab 10 mg/ml
Inactive and allergenic ingredients in the preparation: See section 6 'Further Information'.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Lucentis is used:
- For treatment of patients with neovascular (wet) age-related macular degeneration (AMD)
- For treatment of adult patients with visual impairment due to diabetic macular edema (DME)
- For treatment of proliferative diabetic retinopathy (PDR)
- For treatment of visual impairment due to macular edema secondary to retinal vein occlusion (RVO)
- For treatment of visual impairment due to choroidal neovascularizition (growth of new, abnormal blood vessels in the vascular layer of the eye) (CNV)
- For treatment of retinopathy of prematurity (ROP)

Therapeutic group: Eye medicines that contradict the growth of new blood vessels (anti-neovascularization).

Lucentis is used in adults for treatment of several eye diseases that cause vision impairment. These diseases result from damage to the retina (light-sensitive layer at the back of the eye) caused by the conditions that the medicine is intended to treat.

Lucentis is used in babies born prematurely for treatment of retinopathy of prematurity (ROP), a disease causing vision impairment due to damage to the back of the eye.

Lucentis specifically recognizes and binds to a protein called human vascular endothelial growth factor A (VEGF-A) present in the eye. In excess, the protein causes abnormal blood vessel growth and swelling in the eye, which can lead to impairment of vision in diseases such as neovascular (wet) age-related macular degeneration (AMD), vision impairment resulting from diabetic macular edema (DME), vision impairment resulting from proliferative diabetic retinopathy (PDR), vision impairment resulting from macular edema secondary to retinal vein occlusion (RVO), vision impairment resulting from choroidal neovascularizition (CNV), or visual impairment caused by retinal disease (retinopathy) in babies born prematurely (ROP). By binding to the protein, Lucentis can block its action and prevent this abnormal blood vessel growth and swelling.

In these diseases, Lucentis can help stabilize, and in many cases, improve your vision.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient ranibizumab or to any of the additional ingredients contained in the medicine (see section 6 'Further information')
- You have an infection in or around the eye
- You have pain or redness (severe intraocular inflammation) in the eye

Special warnings regarding use of the medicine
Consult your doctor before starting treatment with Lucentis.
- Lucentis is given as an injection into the eye. Occasionally, an infection in the internal portion of the eye, pain or redness (inflammation), detachment or tear of one of the layers in the back of the eye (retinal detachment or tear and retinal pigment epithelial detachment or tear) or clouding of the lens (cataract) may occur after Lucentis treatment. It is important to identify and treat such an infection or retinal detachment as soon as possible. Please tell your doctor immediately if you develop signs such as eye pain or an increased sense of discomfort, worsening eye redness, blurred or decreased vision, an increased number of small particles in your field of vision or an increased sensitivity to light.
- In some patients, the eye pressure may increase for a short period immediately after the injection. You may not notice this, therefore, your doctor may monitor this after each injection.
- Inform your doctor if you have a history of eye diseases or eye treatments, or if you have had a stroke or experienced transient signs of a stroke (weakness or paralysis of limbs or face, difficulty speaking or understanding). This information will be taken into account to evaluate if Lucentis is the appropriate treatment for you.

For more detailed information on side effects that could occur during Lucentis treatment, see section 4 'Side effects'.

Children and adolescents:
The preparation is not intended for children and adolescents.

Drug interactions:
If you are taking, or have recently taken, or if you may take other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Pregnancy and breast-feeding:
- Women who could become pregnant must use effective contraception during treatment and for at least three further months after the last injection of Lucentis.
- There is no experience of using Lucentis in pregnant women. Lucentis should not be used during pregnancy unless the potential benefit from treatment outweighs the potential risk to the unborn child. If you are pregnant, think you may be pregnant or are planning a pregnancy, discuss this with your doctor before treatment with Lucentis.
- Lucentis is not recommended for use while breast-feeding because it is not known whether it passes into breast milk. Consult with your doctor or pharmacist before Lucentis treatment.

Driving and using machines:
After treatment with Lucentis you may experience a temporary vision blurring. If this happens, do not drive or use machines until the vision blurring is over.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.
Lucentis will be administered to you as a single injection into the eye by your eye doctor, under local anesthesia.

The dosage and treatment regimen will be determined by the doctor only.

The pre-filled syringe is not suitable for administering to babies born prematurely.
For treatment in adults, the usual dosage of an injection is generally: 0.05 ml (which contains 0.5 mg of active ingredient).
The pre-filled syringe contains more than the recommended dose of 0.5 mg. Do not use the entire extractable volume. The excess volume should be expelled prior to injection. Injecting the entire volume of the pre-filled syringe could result in an overdose.
The interval between two doses injected into the same eye should be at least four weeks. All injections will be administered by your eye doctor.
Before the injection, your doctor will wash your eye carefully to prevent infection. Your doctor will also give you local anesthesia to reduce or prevent any pain you may experience with the injection.
The treatment in adults begins with one injection of Lucentis per month. The doctor will monitor the condition of your eye and, depending on how you respond to the treatment, will decide if and when you need to receive further treatment.
Detailed instructions on how to use Lucentis are provided in English at the end of the leaflet, in section 'How to prepare and administer Lucentis'.

Elderly (age 65 years and over)
Can be used in people aged 65 and over without dosage adjustment.

Do not exceed the recommended dose.
If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room, and bring the package of the medicine with you.
Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Before stopping Lucentis treatment
If you are considering stopping Lucentis treatment, go to your next appointment and discuss this with your doctor. The doctor will advise you and will decide how long you should be treated with Lucentis.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take the medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Lucentis may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.
Side effects related to use of Lucentis may be the result of the medicine itself or from the injection procedure, and mostly affect the eye.

Adult patients
<u>The most serious side effects are described below</u>:
Common serious side effects (effects that occur in 1-10 in 100 users): Detachment or tear of the layer in the back of the eye (retinal detachment or tear), resulting in flashes of light with floaters, progressing to a temporary loss of sight or clouding of the lens (cataract).
Uncommon serious side effects (effects that occur in 1-10 in 1,000 users): Blindness, infection of the eyeball (endophthalmitis) with inflammation of the inside of the eye.
The symptoms you might experience are pain or increased discomfort in the eye, worsening eye redness, blurred or decreased vision, an increased number of small particles in the field of vision or increased sensitivity to light. **Refer to the doctor immediately if you develop any of these side effects.**
<u>The most frequently reported side effects are described below</u>:
Very common side effects (effects that occur in more than 1 user in 10)
Visual side effects include:
Inflammation of the eye, bleeding in the back of the eye (retinal bleeding), visual disturbances, eye pain, small particles or spots in your field of vision (floaters), bloodshot eye, eye irritation, sensation of a foreign object in the eye, increased tear production, inflammation or infection of the eyelid margins, dry eye, redness or itching of the eye and increased eye pressure.
Non-visual side effects include: Sore throat, nasal congestion, runny nose, headache and joint pain.
<u>Other side effects which may occur following Lucentis treatment are described below</u>:
Common side effects (effects that occur in 1-10 in 100 users)
Visual side effects include: Decreased visual acuity, swelling of a section of the eye (uvea, cornea), inflammation of the cornea (the front part of eye), small marks on the surface of the eye, blurred vision, bleeding at the site of injection, bleeding in the eye, discharge from the eye with itching, redness and swelling (conjunctivitis), light sensitivity, eye discomfort, swelling of the eyelid, eyelid pain.
Non-visual side effects include: Urinary tract infection, low red blood cells count (with symptoms such as tiredness, breathlessness, dizziness, pale skin), anxiety, cough, nausea, allergic reactions such as rash, hives, itching and skin reddening.
Uncommon side effects (effects that occur in 1-10 in 1,000 users)
Visual side effects include: Inflammation and bleeding in the front part of the eye, pus sac on the eye, changes of the central part of the eye surface, pain or irritation at injection site, abnormal sensation in the eye, irritation of the eyelid.

Reporting side effects
If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.
Side effects can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

Avoid poisoning! This medicine and any other medicine must be kept in a safe place, out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the package and on the label of the pre-filled syringe. The expiry date refers to the last day of that month.
Storage conditions:
Store in the original package to protect from light.
Store refrigerated (2°C - 8°C).
Do not freeze.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
α,α-trehalose dihydrate, L-histidine HCl monohydrate, L-histidine, Polysorbate 20, Water for injection, Nitrogen.
What the medicine looks like and the contents of the package:
Lucentis is a solution for injection in a pre-filled syringe.
The pre-filled syringe contains 0.165 ml of a sterile, clear to slightly opalescent, colorless to pale yellow aqueous solution.
Each ml contains 10 mg ranibizumab.
One pre-filled syringe contains 0.165 ml, equivalent to 1.65 mg ranibizumab.
The package contains one transparent, glass, pre-filled syringe, with a grey rubber plunger stopper and a white cap.
The pre-filled syringe is packaged in a sealed tray and is intended for single use only.
Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.
Revised in March 2022 according to MOH guidelines.
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 136 75 31520

המידע הבא מיועד לאנשי הצוות הרפואי בלבד:
אנא עיינו גם בפרק 3 ’כיצד תשתמש בתרופה?’.

المعلومات التالية مخصصة لأفراد الطاقم الطبي فقط:
الرجاء الإمعان أيضاً في البند 3 "كيفية إستعمال الدواء؟".

The following information is intended for medical healthcare professionals only:
Please also read section 3 ‘How should you use the medicine?’.

כיצד להכין ולהזריק לוסנטיס
كيفية تحضير وحقن لوسينتيس
HOW TO PREPARE AND ADMINISTER LUCENTIS

המזרק המוכן לשימוש אינו מתאים למתן התרופה לטיפול בפגים.
المحقنة الجاهزة للإستعمال غير مناسبة لإعطاء الدواء لعلاج الخدج.
The pre-filled syringe is not suitable for administering to babies born prematurely.

Single-use pre-filled syringe for intravitreal use only.
Adults: Lucentis must be administered by a qualified ophthalmologist experienced in intravitreal injections.
Lucentis should be inspected visually for particulate matter and discoloration prior to administration.

The 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) and the availability of sterile paracentesis (if required). The patient’s medical history for hypersensitivity reactions should be carefully evaluated prior to performing the intravitreal procedure. Adequate anesthesia and a broad-spectrum topical microbicide to disinfect the periocular skin, eyelid and ocular surface should be administered prior to the injection, in accordance with local practice.
The pre-filled syringe is for single use only. The pre-filled syringe is sterile. Do not use the product if the packaging is damaged. The sterility of the pre-filled syringe cannot be guaranteed unless the tray remains sealed. Do not use the pre-filled syringe if the solution is discolored, cloudy or contains particles.
The pre-filled syringe contains more than the recommended dose of 0.5 mg. The extractable volume of the pre-filled syringe (0.1 ml) is not to be used in total. The excess volume should be expelled prior to injection. Injecting the entire volume of the pre-filled syringe could result in an overdose.
To expel the air bubble along with the excess medicinal product, slowly push the plunger until the edge below the dome of the rubber stopper is aligned with the black dosing line on the syringe (equivalent to 0.05 ml, i.e., 0.5 mg ranibizumab).
For the intravitreal injection, a 30G sterile injection needle should be used.

<u>To prepare Lucentis for intravitreal administration, please adhere to the instructions for use</u>:

Introduction

Read all the instructions carefully before using the pre-filled syringe.

The pre-filled syringe is for single use only. The pre-filled syringe is sterile. Do not use the product if the packaging is damaged. The opening of the sealed tray and all subsequent steps should be done under aseptic conditions.

Note: The dose must be set to 0.05 ml.

Pre-filled syringe description

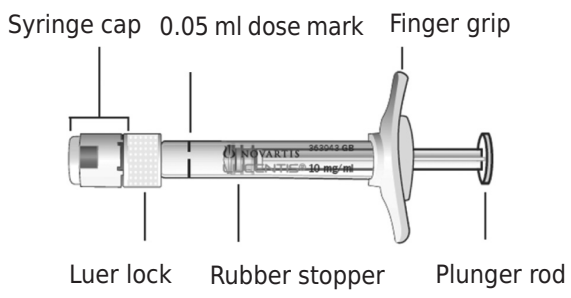

Figure 1

Prepare

1. Make sure that the pack contains:
   - a sterile pre-filled syringe in a sealed tray.
2. Peel the lid off the syringe tray and, using aseptic technique, carefully remove the syringe.

Check syringe

3. Check that:
   - the syringe cap is not detached from the Luer lock.
   - the syringe is not damaged.
   - the solution looks clear, colorless to pale yellow and does not contain any particles.
4. If any of the above is not true, discard the pre-filled syringe and use a new one.

Remove syringe cap

5. Snap off (do not turn or twist) the syringe cap (see Figure 2).

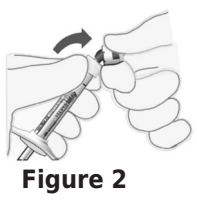

Figure 2

6. Dispose of the syringe cap (see Figure 3).

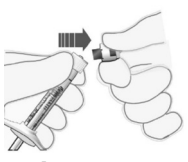

Figure 3

Attach needle

7. Attach a 30G x ½″ sterile injection needle firmly onto the syringe by screwing it tightly onto the Luer lock (see Figure 4).
8. Carefully remove the needle cap by pulling it straight off (see Figure 5).

Note: Do not wipe the needle at any time.

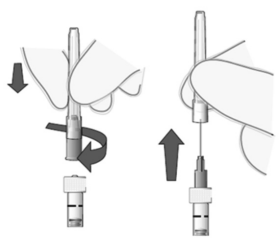

Figure 4 **Figure 5**

Dislodge air bubbles

9. Hold the syringe upright.
10. If there are any air bubbles, gently tap the syringe with your finger until the bubbles rise to the top (see Figure 6).

Figure 6

Set dose

11. Hold the syringe at eye level and carefully push the plunger until the **edge below the dome of the rubber stopper** is aligned with the dose mark (see Figure 7). This will expel the air and the excess solution and set the dose to 0.05 ml.

Note: The plunger rod is not attached to the rubber stopper – this is to prevent air being drawn into the syringe.

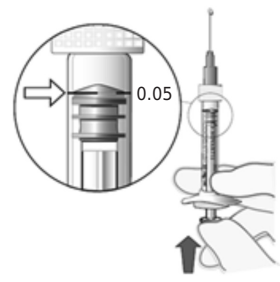

Figure 7

Inject

The injection procedure should be carried out under aseptic conditions.

12. 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 center of the globe.
13. Inject slowly until the rubber stopper reaches the bottom of the syringe to deliver the volume of 0.05 ml.
14. A different scleral site should be used for subsequent injections.
15. After injection, do not recap the needle or detach it from the syringe.
    Dispose of the used syringe together with the needle in a sharps disposal container or in accordance with local requirements.

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PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

LUCENTIS®
10 mg/ml

Solution for injection
Pre-filled syringe for injection into the eye

Active ingredient:
Ranibizumab 10 mg/ml
Inactive and allergenic ingredients in the preparation: See section 6 'Further Information'.

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed to treat you. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Lucentis is used:
- For treatment of patients with neovascular (wet) age-related macular degeneration (AMD)
- For treatment of adult patients with visual impairment due to diabetic macular edema (DME)
- For treatment of proliferative diabetic retinopathy (PDR)
- For treatment of visual impairment due to macular edema secondary to retinal vein occlusion (RVO)
- For treatment of visual impairment due to choroidal neovascularizition (growth of new, abnormal blood vessels in the vascular layer of the eye) (CNV)
- For treatment of retinopathy of prematurity (ROP)

Therapeutic group: Eye medicines that contradict the growth of new blood vessels (anti-neovascularization).

Lucentis is used in adults for treatment of several eye diseases that cause vision impairment. These diseases result from damage to the retina (light-sensitive layer at the back of the eye) caused by the conditions that the medicine is intended to treat.

Lucentis is used in babies born prematurely for treatment of retinopathy of prematurity (ROP), a disease causing vision impairment due to damage to the back of the eye.

Lucentis specifically recognizes and binds to a protein called human vascular endothelial growth factor A (VEGF-A) present in the eye. In excess, the protein causes abnormal blood vessel growth and swelling in the eye, which can lead to impairment of vision in diseases such as neovascular (wet) age-related macular degeneration (AMD), vision impairment resulting from diabetic macular edema (DME), vision impairment resulting from proliferative diabetic retinopathy (PDR), vision impairment resulting from macular edema secondary to retinal vein occlusion (RVO), vision impairment resulting from choroidal neovascularizition (CNV), or visual impairment caused by retinal disease (retinopathy) in babies born prematurely (ROP). By binding to the protein, Lucentis can block its action and prevent this abnormal blood vessel growth and swelling.

In these diseases, Lucentis can help stabilize, and in many cases, improve your vision.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient ranibizumab or to any of the additional ingredients contained in the medicine (see section 6 'Further information')
- You have an infection in or around the eye
- You have pain or redness (severe intraocular inflammation) in the eye

Special warnings regarding use of the medicine

Consult your doctor before starting treatment with Lucentis.

- Lucentis is given as an injection into the eye. Occasionally, an infection in the internal portion of the eye, pain or redness (inflammation), detachment or tear of one of the layers in the back of the eye (retinal detachment or tear and retinal pigment epithelial detachment or tear) or clouding of the lens (cataract) may occur after Lucentis treatment. It is important to identify and treat such an infection or retinal detachment as soon as possible. Please tell your doctor immediately if you develop signs such as eye pain or an increased sense of discomfort, worsening eye redness, blurred or decreased vision, an increased number of small particles in your field of vision or an increased sensitivity to light.
- In some patients, the eye pressure may increase for a short period immediately after the injection. You may not notice this, therefore, your doctor may monitor this after each injection.
- Inform your doctor if you have a history of eye diseases or eye treatments, or if you have had a stroke or experienced transient signs of a stroke (weakness or paralysis of limbs or face, difficulty speaking or understanding). This information will be taken into account to evaluate if Lucentis is the appropriate treatment for you.

For more detailed information on side effects that could occur during Lucentis treatment, see section 4 'Side effects'.

Children and adolescents:
The preparation is not intended for children and adolescents.

Drug interactions:
If you are taking, or have recently taken, or if you may take other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

Pregnancy and breast-feeding:
- Women who could become pregnant must use effective contraception during treatment and for at least three further months after the last injection of Lucentis.
- There is no experience of using Lucentis in pregnant women. Lucentis should not be used during pregnancy unless the potential benefit from treatment outweighs the potential risk to the unborn child. If you are pregnant, think you may be pregnant or are planning a pregnancy, discuss this with your doctor before treatment with Lucentis.
- Lucentis is not recommended for use while breast-feeding because it is not known whether it passes into breast milk. Consult with your doctor or pharmacist before Lucentis treatment.

Driving and using machines:
After treatment with Lucentis you may experience a temporary vision blurring. If this happens, do not drive or use machines until the vision blurring is over.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain regarding the dosage and treatment regimen of the preparation.
Lucentis will be administered to you as a single injection into the eye by your eye doctor, under local anesthesia.
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The pre-filled syringe contains more than the recommended dose of 0.5 mg. Do not use the entire extractable volume. The excess volume should be expelled prior to injection. Injecting the entire volume of the pre-filled syringe could result in an overdose.
The interval between two doses injected into the same eye should be at least four weeks. All injections will be administered by your eye doctor.
Before the injection, your doctor will wash your eye carefully to prevent infection. Your doctor will also give you local anesthesia to reduce or prevent any pain you may experience with the injection.
The treatment in adults begins with one injection of Lucentis per month. The doctor will monitor the condition of your eye and, depending on how you respond to the treatment, will decide if and when you need to receive further treatment.
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Elderly (age 65 years and over)
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Do not exceed the recommended dose.
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Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.

Before stopping Lucentis treatment
If you are considering stopping Lucentis treatment, go to your next appointment and discuss this with your doctor. The doctor will advise you and will decide how long you should be treated with Lucentis.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.
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4. SIDE EFFECTS

As with any medicine, use of Lucentis may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.
Side effects related to use of Lucentis may be the result of the medicine itself or from the injection procedure, and mostly affect the eye.

Adult patients
The most serious side effects are described below:

Common serious side effects (effects that occur in 1-10 in 100 users): Detachment or tear of the layer in the back of the eye (retinal detachment or tear), resulting in flashes of light with floaters, progressing to a temporary loss of sight or clouding of the lens (cataract).

Uncommon serious side effects (effects that occur in 1-10 in 1,000 users): Blindness, infection of the eyeball (endophthalmitis) with inflammation of the inside of the eye.

The symptoms you might experience are pain or increased discomfort in the eye, worsening eye redness, blurred or decreased vision, an increased number of small particles in the field of vision or increased sensitivity to light. **Refer to the doctor immediately if you develop any of these side effects.**

The most frequently reported side effects are described below:

Very common side effects (effects that occur in more than 1 user in 10)
Visual side effects include:
Inflammation of the eye, bleeding in the back of the eye (retinal bleeding), visual disturbances, eye pain, small particles or spots in your field of vision (floaters), bloodshot eye, eye irritation, sensation of a foreign object in the eye, increased tear production, inflammation or infection of the eyelid margins, dry eye, redness or itching of the eye and increased eye pressure.
Non-visual side effects include: Sore throat, nasal congestion, runny nose, headache and joint pain.
Other side effects which may occur following Lucentis treatment are described below:

Common side effects (effects that occur in 1-10 in 100 users)
Visual side effects include: Decreased visual acuity, swelling of a section of the eye (uvea, cornea), inflammation of the cornea (the front part of eye), small marks on the surface of the eye, blurred vision, bleeding at the site of injection, bleeding in the eye, discharge from the eye with itching, redness and swelling (conjunctivitis), light sensitivity, eye discomfort, swelling of the eyelid, eyelid pain.
Non-visual side effects include: Urinary tract infection, low red blood cells count (with symptoms such as tiredness, breathlessness, dizziness, pale skin), anxiety, cough, nausea, allergic reactions such as rash, hives, itching and skin reddening.

Uncommon side effects (effects that occur in 1-10 in 1,000 users)
Visual side effects include: Inflammation and bleeding in the front part of the eye, pus sac on the eye, changes of the central part of the eye surface, pain or irritation at injection site, abnormal sensation in the eye, irritation of the eyelid.

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If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult the doctor.
Side effects can be reported to the Ministry of Health by clicking the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il

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6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:
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The package contains one transparent, glass, pre-filled syringe, with a grey rubber plunger stopper and a white cap.
The pre-filled syringe is packaged in a sealed tray and is intended for single use only.

Registration Holder and Importer and its address: Novartis Israel Ltd., P.O.B 7126, Tel Aviv.

Revised in March 2022 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 136 75 31520

الأعراض الجانبية الأكثر شيوعاً التي تم التبليغ عنها مُفصلة فيما يلي:

أعراض جانبية شائعة جدا (أعراض تظهر لدى أكثر من مستعمل واحد من بين عشرة)
أعراض جانبية تتعلق بالرؤية وتشمل: إلتهاب العين، نزف في الجزء الخلفي من العين (نزف في الشبكية)، إضطرابات في الرؤية، ألم في العين، جزيئات أو بقع صغيرة في مجال الرؤية (أشياء عائمة)، إحمرار العين، تهيج العين، الشعور بجسم غريب في العين، زيادة إنتاج الدموع، إلتهاب أو تلوث حواف الجفن، جفاف العين، إحمرار أو حكة في العين وتزايد الضغط في العين.
أعراض جانبية لا تتعلق بالرؤية وتشمل: ألم في الحنجرة، إحتقان الأنف، رشح، صداع وألم في المفاصل.
أعراض جانبية أخرى التي قد تحدث بعد العلاج بـ لوسينتيس مُفصلة فيما يلي:
أعراض جانبية شائعة (أعراض تظهر لدى 1-10 مستعملين من بين 100)
أعراض جانبية تتعلق بالرؤية وتشمل: إنخفاض حدة الرؤية، إنتفاخ جزء من العين (العنبية، القرنية)، إلتهاب القرنية (الجزء الأمامي من العين)، علامات صغيرة على سطح العين، تشوش الرؤية، نزف في مكان الحقن، نزف في العين، إفراز من العين مع حكة، إحمرار وإنتفاخ (إلتهاب الملتحمة)، حساسية للضوء، إنزعاج في العين، إنتفاخ الجفن، ألم في الجفن.
أعراض جانبية لا تتعلق بالرؤية وتشمل: تلوث في المسالك البولية، إنخفاض تعداد كريات الدم الحمراء (مع أعراض مثل إرهاق، ضيق في التنفس، دوار، شحوب الجلد)، قلق، سعال، غثيان، ردود فعل تحسسية مثل طفح، شرى، حكة وإحمرار الجلد.
أعراض جانبية غير شائعة (أعراض تظهر لدى 1-10 مستعملين من بين 1,000)
أعراض جانبية تتعلق بالرؤية وتشمل: إلتهاب ونزف في الجزء الأمامي من العين، كيس من القيح على العين، تغيرات في الجزء المركزي لسطح العين، ألم أو تهيج في مكان الحقن، شعور شاذ في العين، تهيج الجفن.

التبليغ عن أعراض جانبية
إذا ظهر عرض جانبي، إذا تفاقمت إحدى الأعراض الجانبية أو عندما تعاني من عرض جانبي لم يذكر في هذه النشرة، عليك إستشارة الطبيب.
بالإمكان التبليغ عن أعراض جانبية لوزارة الصحة بواسطة الضغط على الرابط «تبليغ عن أعراض جانبية عقب علاج دوائي» الموجود على الصفحة الرئيسية لموقع وزارة الصحة (www.health.gov.il) الذي يوجهك إلى النموذج المباشر للتبليغ عن أعراض جانبية، أو عن طريق تصفح الرابط:
https://sideeffects.health.gov.il

5) كيفية تخزين الدواء؟

تجنب التسمم! يجب حفظ هذا الدواء وكل دواء آخر في مكان مغلق بعيداً عن متناول أيدي ومجال رؤية الأطفال و/أو الرضع، وذلك لتفادي إصابتهم بالتسمم.
لا تسبب التقيؤ بدون تعليمات صريحة من الطبيب.
لا يجوز إستعمال الدواء بعد إنقضاء تاريخ الصلاحية (exp. date) الذي يظهر على ظهر العلبة وعلى ملصقة المحقنة الجاهزة للإستعمال. يشير تاريخ الصلاحية إلى اليوم الأخير من نفس الشهر.

شروط التخزين:
يجب التخزين في العلبة الأصلية وذلك لحمايته من الضوء.
يجب التخزين في البراد (8 - 2 درجة مئوية).
لا يجوز التجميد.

6) معلومات إضافية

يحتوي الدواء بالإضافة للمركب الفعال أيضاً على:
α,α-trehalose dihydrate, L-histidine HCl monohydrate, L-histidine, Polysorbate 20, Water for injection, Nitrogen.
كيف يبدو الدواء وما هو محتوى العلبة:
لوسينتيس هو عبارة عن محلول للحقن ضمن محقنة جاهزة للإستعمال.
تحتوي المحقنة الجاهزة للإستعمال على 0.165 ملل من محلول مائي، معقم، رائق حتى ساطع قليلا، عديم اللون حتى أصفر شاحب.
يحتوي كل ملل على 10 ملغ رانيبيزوماب.
تحتوي محقنة واحدة جاهزة للإستعمال على 0.165 ملل، ما يعادل 1.65 ملغ رانيبيزوماب.
تحتوي العلبة على محقنة واحدة جاهزة للإستعمال، شفافة، زجاجية، ذات سدادة مكبس رمادية اللون من المطاط وغطاء أبيض.
المحقنة الجاهزة للإستعمال معبأة ضمن لويحة مغلقة ومخصصة للإستعمال لمرة واحدة فقط.
إسم صاحب الإمتياز والمستورد وعنوانه: نوفارتيس إسرائيل م.ض.، ص.ب. 7126، تل أبيب.
تم إعدادها في آذار 2022 بموجب تعليمات وزارة الصحة.
رقم سجل الدواء في سجل الأدوية الحكومي في وزارة الصحة: 136 75 31520
من أجل سهولة وتهوين القراءة، تمت صياغة هذه النشرة بصيغة المذكر. على الرغم من ذلك، فإن الدواء مخصص لكلا الجنسين.

LUC-PFS APL MAR22 V3