NOVARTIS

Lucentis 10 mg/ml solution for injection

(One ml contains 10 mg ranibizumab)

Patient Information Leaflet

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LUCENTIS 10 mg/ml solution for injection

Ranibizumab

Read all of this leaflet carefully before you are given LUCENTIS® 10 mg/ml solution for injection

Keep this leaflet. You may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

LUCENTIS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What LUCENTIS is and what it is used for
2. What you need to know before you are given LUCENTIS
3. How LUCENTIS is given
4. Possible side effects
5. How to store LUCENTIS
6. Contents of the pack and other information

1. WHAT LUCENTIS IS AND WHAT IT IS USED FOR

What LUCENTIS is

LUCENTIS is a solution which is given as an injection into the eye by your eye doctor under a local anesthetic.

The active substance of LUCENTIS is ranibizumab. LUCENTIS contains ranibizumab 10 mg per ml.

What LUCENTIS is used for

Adults:

Ranibizumab reduces the growth and the leakage of new blood vessels in the eye. LUCENTIS is used to treat damage to the retina caused by:

- growth of leaky, abnormal blood vessels. This is observed in diseases such as age-related macular degeneration (AMD) and proliferative diabetic retinopathy (PDR, a disease caused by diabetes). It may also be associated with choroidal neovascularisation (CNV) due to pathologic myopia (PM), angioid streaks, central serous chorioretinopathy or inflammatory CNV.

LUCENTIS can help to improve the damaged vision or stop it from getting worse.

Preterm infants:

LUCENTIS is used in babies born prematurely to treat retinopathy of prematurity (ROP), a disease causing vision impairment due to damage to the back of the eye (the retina) caused by abnormal growth of blood vessels.

2. WHAT YOU NEED TO KNOW BEFORE YOU ARE ADMINISTERED LUCENTIS

You should not be administered LUCENTIS

- If you are allergic (hypersensitive) to ranibizumab or any of the other ingredients of LUCENTIS.
- If you have, an infection in or around your eye.
- If you have pain or redness (severe intraocular inflammation) in your eye.
- If you are pregnant or breastfeeding.

Warnings and Precautions

LUCENTIS is given as an injection into the eye. An infection in the internal portion of the eye, pain or redness (inflammation), detachment or tear of the layer in the back of the eye (retinal detachment or tear), or clouding of the lens (cataract) may occur after LUCENTIS treatment.

It is important to identify and treat such a type of infection or retinal detachment as soon as possible.

Please tell your doctor immediately if you or your baby develop signs such as eye pain or increased discomfort, worsening eye redness, blurred or decreased vision, an increased number of small particles in your vision or increased sensitivity to light.

In some patients the eye pressure may increase for a short period directly after the injection. This is something you may not notice, therefore your doctor may monitor this after each injection.

Inform your doctor if you have already had a stroke or experienced transient signs of 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.

Pregnancy

You must not receive LUCENTIS when you are pregnant or planning to become pregnant. Do not become pregnant until at least three months after finishing a course of LUCENTIS treatment.

Breastfeeding

Do not breastfeed your baby if you are receiving LUCENTIS.

Ask your doctor, pharmacist or other healthcare provider for advice before taking any medicine.

Older patients (age 65 years and over)

LUCENTIS can be used for people of 65 years of age and over without adjusting the dose.

Children and adolescents (below 18 years of age)

Except for retinopathy of prematurity, LUCENTIS should not be used in children and adolescents below 18 years of age.

Driving and using machines

After LUCENTIS treatment you may experience some short term vision blurring. If this happens, do not drive or use machines until this resolves.

Other medicines and LUCENTIS

Always tell your healthcare provider if you are taking or have recently taken any other medicines. (This includes all complementary or traditional medicines).

3. HOW LUCENTIS IS GIVEN/ADMINISTERED

All LUCENTIS injections will be administered by your doctor. Your doctor will tell you how long your treatment with LUCENTIS will last. If you have the impression that the effect of LUCENTIS is too strong or too weak for you, tell your doctor or pharmacist.

***Adults*:**

Treatment of wet AMD, visual impairment due to DME or due to macular oedema secondary to RVO:

LUCENTIS is administered as a single injection into your eye. The interval between two doses should not be shorter than one month. The treatment is started with one injection of LUCENTIS per month. Your doctor will check the condition of your eye. Depending on how you respond to the treatment, your doctor will decide whether and when you need to receive the next injection of LUCENTIS.

If you are being treated for visual impairment due to DME or macular oedema secondary to RVO, your doctor may decide that you also need to be treated with laser for these conditions. If so, laser treatment can be administered together with LUCENTIS.

Babies born prematurely

LUCENTIS will be administered by an eye doctor as a single injection into your baby's eyes, usually under local anaesthetic. The usual dose of an injection is 0.02 ml (which contains 0.2 mg of active substance). The interval between two doses injected into the same eye should be at least four weeks. All injections will be administered by the eye doctor.

Before the injection, your baby's doctor will wash your baby's eyes carefully to prevent infection. The doctor will also give your baby a local anaesthetic to reduce or prevent any pain.

The treatment is started with one injection of LUCENTIS in each eye (some babies may only need treatment in one eye). The doctor will monitor the condition of your baby's eye(s) and, depending on how your baby responds to the treatment,

will decide if and when further treatment is needed.

If you are administered more LUCENTIS than you should

Since a healthcare provider will administer LUCENTIS, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

If you forget to attend an appointment

Contact your doctor or hospital as soon as possible to re-schedule your appointment.

4. POSSIBLE SIDE EFFECTS

LUCENTIS can cause side effects.

Not all side effects reported for LUCENTIS are included in this leaflet. Should your general health worsen or if you or your baby experience any untoward effects while receiving LUCENTIS, please consult your healthcare provider for advice.

With administration of LUCENTIS, there may be some side effects, mostly in the eye and due to the injection procedure. Occasionally an infection in the internal portion of the eye, detachment or tear of the layer in the back of the eye (retinal detachment or tear), or clouding of the lens (cataract) may occur in the two weeks after LUCENTIS treatment. Other side effects include pain or redness (inflammation) and increased eye pressure.

Some side effects can be serious and might need immediate medical attention:

- Signs of inflammation and/or eye infection 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
- Signs of a stroke, such as weakness or paralysis of limbs or face, difficulty speaking or understanding. If you experience any of these signs, please go to your nearest emergency room as immediate medical care is needed.

If you experience any of these, tell your doctor straight away.

The following side effects in the eye are frequent:

Tell your doctor if you notice any of the following:

Inflammation of the eye, blurred vision, temporary blindness, visual disturbance, eye pain, small particles or spots in your vision (floaters), bloodshot eye, eye irritation, a feeling of having something in the eye, increased tear production, inflammation or infection of the eyelid margins, dry eye, redness or itching of the eye, increased pressure inside of the eye. Seeing flashes of light with floaters and shadows progressing to a loss of sight, decreased sharpness of vision, swelling of a section of the eye (uvea, cornea), clouding of the lens, scratch on the cornea (front part of the eye), bleeding in the eye or at sight of injection, discharge of the eye with itching, redness and swelling (conjunctivitis), light sensitivity, eye discomfort, swelling of the eyelid, eyelid pain, blurred vision, inflammation of the cornea.

The following side effects in the eye are less frequent:

Blindness, sac of pus on the eye, pain or irritation at the site of injection, abnormal sensation in the eye, irritation of the eyelid, accumulation of blood in the front part of the eye, infection or inflammation of the inside of the eye.

If you notice any side effects not mentioned in this leaflet, please inform your doctor and pharmacist.

Other non-visual side effects:

Sore throat, nasal congestion, runny nose, headache and joint pain is frequent.

Stroke, flu, urinary tract (bladder) infection, low level of red blood cells (you may experience tiredness, breathlessness, dizziness, pale skin), anxiety, cough, nausea, allergic reactions (rash, hives, itching, skin reddening) are also frequent.

If any of the side effects affects you severely, tell your doctor:

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of LUCENTIS.

5. HOW TO STORE LUCENTIS

Store in a refrigerator (between 2 °C and 8 °C). Do not freeze.

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

Vials are for single use only. Any unused product or waste material should be disposed of in accordance with local requirements.

LUCENTIS must be kept out of the reach and sight of children**.**

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What LUCENTIS contains

The active substance of LUCENTIS is ranibizumab. LUCENTIS contains ranibizumab 10 mg per ml.

The other ingredients are: α,α-trehalose dehydrate; histidine hydrochloride, monohydrate; histidine; polysorbate 20; water for injection.

What LUCENTIS looks like and contents of the pack

0,23 ml LUCENTIS solution for injection in a glass vial (colourless type I glass) with chlorobutyl rubber stopper.

One pack contains one vial containing LUCENTIS and one filter needle.

The solution is clear, colourless to pale yellow to brown.

Holder of the Certificate of Registration

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