PACKAGE LEAFLET

Package leaflet: Information for the user

Verteporfin 15 mg powder for solution for infusion
verteporfin

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Verteporfin is and what it is used for

What Verteporfin is
Verteporfin contains the active substance verteporfin, which is activated by light from a laser in a treatment called photodynamic therapy. When you are given an infusion of Verteporfin, it is distributed within your body through the blood vessels, including the blood vessels at the back of the eye. When the laser light is shone into the eye, Verteporfin is activated.

What Verteporfin is used for
Verteporfin is used to treat the wet form of age-related macular degeneration and pathological myopia.

These diseases lead to vision loss. Vision loss is caused by new blood vessels (choroidal neovascularisation) that damage the retina (the light-sensitive membrane that lines the back of the eye). There are two types of choroidal neovascularisation: classic and occult.

Verteporfin is used for the treatment of predominantly classic choroidal neovascularisation in adults with age-related macular degeneration, and also for the treatment of all types of choroidal neovascularisation in adults with pathological myopia.

2. What you need to know before you are given Verteporfin

You should not be given Verteporfin
- if you are **allergic** to verteporfin or any of the other ingredients of this medicine (listed in section 6).
- if you have **porphyria** (a rare condition that may increase sensitivity to light).
- if you have any severe **liver problems**.

If any of these apply to you, **tell your doctor. You should not be given Verteporfin.**

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given Verteporfin
- **If you experience any infusion-related problems or symptoms during or following the treatment** such as chest pain, sweating, dizziness, rash, breathlessness, flushing, irregular heart

beat or seizure, please tell your doctor or nurse immediately, as the infusion may need to be stopped and your condition may need to be treated urgently. Infusion-related problems may also include sudden loss of consciousness.
- **If you have any liver problems or a blockage of your bile duct**, please tell your doctor before starting Verteporfin therapy.
- **If, during the infusion, Verteporfin goes outside the vein**, and especially if the affected area is exposed to light, this can cause pain, swelling, blistering and a change in skin colour in the area of the leakage. If this happens, the infusion needs to be stopped and the skin treated with cold compresses and thoroughly protected from light until the skin colour returns to normal. You may need to take a painkiller.
- **You will be sensitive to bright light for 48 hours after the infusion.** During that time, avoid exposure to direct sunlight, bright indoor lights such as in tanning salons, bright halogen lighting, high power lighting as used by surgeons or dentists, or light from light-emitting medical devices such as pulse oximeters (used to measure oxygen in blood). If you have to go outdoors during daylight in the first 48 hours after treatment, you must protect your skin and eyes by wearing protective clothing and dark sunglasses. Sunscreens offer no protection. Normal indoor lighting is safe.
- **Do not stay in the dark** because exposure to normal indoor lighting will help your body to eliminate Verteporfin more quickly.
- **If you experience any eye problems after the treatment,** such as a vision loss, talk to your doctor.

Other medicines and Verteporfin
Tell your doctor, nurse or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor or pharmacist if you are taking any of the following medicines, as they may increase your sensitivity to light:
- tetracyclines or sulphonamides (used to treat bacterial infection),
- phenothiazines (used to treat psychiatric disorders, or nausea and vomiting),
- sulfonylurea (used to treat diabetes),
- medicines used to lower blood sugar,
- thiazide diuretics (used to reduce high blood pressure),
- griseofulvin (used to treat fungal infection),
- calcium channel blockers (used to treat high blood pressure, angina and abnormal heart rhythms),
- antioxidants such as beta-carotene or medicines that can remove or inactivate free radicals (such as dimethylsulfoxide (DMSO), formate, mannitol and alcohol),
- vasodilators (used to widen blood vessels resulting from smooth muscle relaxation),
- or, if you are undergoing radiation therapy,

Pregnancy, breast-feeding and fertility
- There is very little experience of using this medicine in pregnant women. It is important to tell your doctor if you are pregnant, if you think you may be pregnant or if you plan to become pregnant. You should only be given Verteporfin if your doctor considers it absolutely essential.
- Verteporfin passes into human milk in low amounts. Please tell your doctor if you are breastfeeding. He/she will decide whether you should be given Verteporfin. It is recommended that, if you are given Verteporfin, you do not breastfeed for 48 hours after administration.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines
After Verteporfin treatment you may have some vision problems, such as abnormal or decreased vision, which may be temporary. If this happens to you, do not drive or use any tools or machines until your vision improves.

Verteporfin contains small amounts of butylated hydroxytoluene (E321)
This ingredient is irritant to eyes, skin and mucous membranes. **If you come into direct contact with Verteporfin, you must therefore wash it off thoroughly with water.**

3. How to use Verteporfin

Treatment with Verteporfin is a two-step process

- First your doctor or the pharmacist will prepare the Verteporfin infusion solution. It will be administered by your doctor or nurse into a vein using a drip (intravenous infusion).

- The second step is the activation of Verteporfin in the eye 15 minutes after the start of the infusion. Your doctor will put a special contact lens onto your eye and treat your eye using a special laser. It takes 83 seconds to deliver the laser dose required to activate Verteporfin. During this time, you will have to follow your doctor's instructions and keep your eyes still.

If necessary, Verteporfin therapy can be repeated every 3 months, up to 4 times per year.

Use in children
Verteporfin is a treatment for adults only and not indicated for the use in children.

If you are given more Verteporfin than you should be
Overdose of Verteporfin may prolong the time during which you are sensitive to light and you may need to follow the protection instructions given in section 2 for longer than 48 hours. Your doctor will advise you.

Overdose of Verteporfin and light in the treated eye may result in severe vision decrease.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some side effects could be serious:

Common (may affect up to 1 in 10 people)
- **Eye disorders**: severe decrease of vision (loss of 4 lines or more within 7 days of treatment), visual disturbances such as blurred, hazy or fuzzy vision, flashes of light, decreased vision, and a change in the field of vision in the treated eye such as grey or dark shadows, blind spots or black spots.
- **General disorders:** Hypersensitivity (allergic reactions), syncope (fainting), headache, light-headedness, breathlessness.

Uncommon (may affect up to 1 in 100 people)
- **Eye disorders**: bleeding of the retina or into the vitreous humour (the clear gel-like substance that fills the eyeball behind the lens), swelling or fluid retention in the retina and displacement of the retina in the treated eye.
- **Infusion site side effects**: as with other types of injections, some patients experienced bleeding at the infusion site, change in skin colour and hypersensitivity. If this happens to you, there will be increased sensitivity to light in that part of the skin until the green discolouration disappears.
- **General disorders**: rash, hives, itching

Rare (may affect up to 1 in 1,000 people)
- **Eye disorders**: lack of blood circulation to the retina or choroids (the vascular layer of the eye)

in the treated eye.
- **General disorders**: feeling unwell.

Not known (frequency cannot be estimated from the available data)
- **Eye disorders**: tear in the coloured layer of the retina, swelling or fluid retention in the macula.
- **General disorders**: vasovagal reactions (fainting), sweating, flushing, or changes in blood pressure. On rare occasions the vasovagal and hypersensitivity reactions may be severe and potentially include seizures.
- **Heart attack** has been reported, particularly in patients with a history of heart disease, sometimes within 48 hours after treatment with Verteporfin. In the event of suspected heart attack, seek medical attention immediately.
- **Localised death of skin tissue (necrosis).**

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

Other side effects:

Common (may affect up to 1 in 10 people)
- **Infusion site side effects**: as with other types of injections, some patients experienced pain, swelling, inflammation, and weeping from the infusion site.
- **General disorders**: feeling sick (nausea), sunburn-like reactions, tiredness, infusion-related reaction, primarily presented as chest pain or back pain, and increased cholesterol levels.

Uncommon (may affect up to 1 in 100 people)
- **General disorders**: pain, increased blood pressure, increased sensation, and fever.

Not known (frequency cannot be estimated from the available data)
- **Infusion site side effects**: as with other types of injections, some patients experienced blistering.
- **General disorders**: changes in heart rate. Infusion-related reaction, which may radiate to other areas, including but not limited to, the pelvis, shoulders or rib cage.

Reporting of side effects
If you get any side effects, talk to your doctor, nurse or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Verteporfin

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial after "EXP". The expiry date refers to the last day of that month.

Do not store above 25°C. Keep the vial in the outer carton in order to protect from light.

Chemical and physical in-use stability has been demonstrated for 4 hours at 25°C. From a microbiological point of view, the medicine should be used immediately. If not used immediately, the in-use storage time and conditions prior to use are the responsibility of the user and would normally not last longer than 4 hours below 25°C protected from light.

6. Contents of the pack and other information

What Verteporfin contains
- The active substance is verteporfin. Each vial contains 15 mg of verteporfin. After reconstitution, 1 ml contains 2 mg of verteporfin. 7.5 ml of reconstituted solution contains 15 mg of verteporfin.
- The other ingredients are dimyristoyl phosphatidylcholine, egg phosphatidylglycerol, ascorbyl palmitate, butylated hydroxytoluene (E321) and lactose monohydrate.

What Verteporfin looks like and contents of the pack
This medicine is supplied as a dark green to black powder in a clear glass vial. The powder is reconstituted in water prior to use to form an opaque dark green solution.

Verteporfin is available in packs containing 1 vial of powder.

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Ziegelhof 23-24
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The following information is intended for healthcare professionals only:

Reconstitute Verteporfin in 7.0 ml water for injections to produce 7.5 ml of a 2.0 mg/ml solution. Reconstituted Verteporfin is an opaque dark green solution. It is recommended that reconstituted Verteporfin be inspected visually for particulate matter and discoloration prior to administration. For a dose of 6 mg/m^2 body surface (the dose recommended for the treatment) dilute the required amount of Verteporfin solution in dextrose 50 mg/ml (5 %) solution for infusion to a final volume of 30 ml. Do not use sodium chloride solution. Use of a standard infusion line filter with hydrophilic membranes (such as polyethersulfone) of a pore size of not less than 1.2 µm is recommended.

For storage conditions, please see section 5 of this leaflet.

The vial and any unused portion of reconstituted solution should be discarded after single use.

If material is spilled, it should be contained and wiped up with a damp cloth. Eye and skin contact should be avoided. Use of rubber gloves and eye protection is recommended. Any unused medicine or waste material should be disposed of in accordance with local requirements.