

ILUVIEN®

(ee-loo-vee-un)

Fluocinolone Acetonide 190 mcg Intravitreal Implant in Applicator

CONSUMER MEDICINE INFORMATION

What is in this leaflet

This leaflet answers some common questions about Iluvien.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of your taking this medicine 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 Iluvien is used for

Iluvien is a tiny tube that is inserted into the eye and releases very small amounts of the active ingredient, fluocinolone acetonide, for up to 3 years. Fluocinolone acetonide belongs to a group of medicines called corticosteroids.

Iluvien is used to treat vision loss associated with diabetic macular oedema when other available treatments have failed to help. Diabetic macular oedema is a condition that affects some people with diabetes, and causes damage to the light-sensitive layer at the back of the eye responsible for central vision, the macula. The active ingredient helps to reduce the inflammation and the swelling that builds up in the macula in this condition. Iluvien can therefore help to improve the

damaged vision or stop it from getting worse.

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.

This medicine is available only with a doctor's prescription.

Before you are given it

When you must not receive it

You must not be given Iluvien:

- If you are allergic (hypersensitive) to fluocinolone acetonide or any of the other ingredients of Iluvien listed at the end of this leaflet (see **Product Description**).

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 have an infection of any kind in or around your eye.
- If you have glaucoma (high pressure inside your eye that caused damage to the optic nerves).

Before you are given it

Your doctor must know about all of the following before you are given this medicine.

Tell your doctor if:

- You are taking any medicines to thin the blood.
- You have had herpes simplex infection in your eye in the past (an ulcer on the eye that has been there a long time).
- You have higher than normal pressure in the eye, with or without it affecting your sight.
- You have had previous cataract surgery.
- You are pregnant or planning to become pregnant. There is no experience of using Iluvien in pregnant women; therefore the potential risks are unknown.
- You are breast-feeding or planning to breast-feed. Iluvien is not recommended during breast-feeding because it is not known whether Iluvien passes into human milk.

If you have not told your doctor about any of the above, tell them before Iluvien is administered.

Children and adolescents (below 18 years of age)

The use of Iluvien in children and adolescents has not been studied and is therefore not recommended.

Taking or being given other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

These medicines may be affected by Iluvien or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medications.

Your doctor and pharmacist have more information on medicines to be careful with or avoid after Iluvien has been injected.

How it is given

The Iluvien implant will be given by your eye doctor as a single injection into your eye. Afterwards, your doctor will monitor your vision regularly.

Before the injection, your doctor will use antibiotic eye drops and wash your eye carefully to prevent infection. Your doctor will also give you a local anaesthetic to prevent any pain that the injection might cause.

The injection of ILUVIEN into both eyes at the same time has not been studied and is not recommended. Your doctor should not inject ILUVIEN into both eyes at the same time.

How much is given

One implant of Iluvien is inserted into the eye and releases very small amounts of the active ingredient for up to 3 years.

If the effect of the implant wears off and your doctor recommends it, another implant may be injected into your eye.

The injection of Iluvien into both eyes at the same time has not been studied and is not recommended. Your doctor should not inject Iluvien into both eyes at the same time.

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

If you are given too much (Overdose)

As this medicine is administered directly by your doctor, overdose is unlikely. Your doctor will decide on

any necessary measures to avoid any problems.

After you are given it

Things you must do

If you experience any problems after the injection, tell your doctor.

Iluvien is given as an injection into the eye.

In rare cases, the injection can cause an infection in your eye.

Contact your eye doctor as soon as possible if you experience any of the following signs of inflammation or infection in your eye:

- Hazy or decreased vision
- Eye pain
- Worsening redness of your eye
- A feeling of spots in front of your eye
- Increased sensitivity to light after your injection

In rare cases, Iluvien may also cause changes to the retina.

Contact your eye doctor as soon as possible if you experience:

- Flashing lights
- Partially blocked vision.

Injection with Iluvien may also cause the following:

- Increase in pressure inside your eye
- Clouding of your eye's natural lens (cataract)

It is important to identify and treat these as soon as possible.

Your doctor may ask you to use antibiotic eye drops in order to prevent any possible eye infection. Please follow the instructions carefully.

In some patients eye pressure may increase with the possible development of glaucoma. This is something you may not notice; therefore you must be monitored by your doctor with visits to the clinic. You may require medication or a procedure to treat the increased eye pressure.

In the majority of patients who have not yet had an operation for cataracts, a clouding of the eye's natural lens (a cataract) may develop gradually (within months to longer than a year) after treatment with Iluvien. If this

occurs your vision will gradually decrease, and you are likely to need an operation to remove the cataract. Your doctor will help you to decide when is the most appropriate time to perform this operation, but you should be aware that until you are ready for your operation your vision may be as bad or worse than it was before you received your Iluvien injection.

There is a potential for the Iluvien implant to move from the back to the front of the eye. There is an increased risk of this if you have had previous cataract surgery. A sign that the implant may have moved to the front of the eye could be distorted vision or other visual disturbance, or you may notice a change in the appearance of your eye at the front. Please tell your doctor if you notice anything unusual that may lead you to suspect the implant has moved.

Keep all of your scheduled appointments that your doctor makes for you.

Things to be careful of

Be careful driving or operating machinery until you know how Iluvien affects you.

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

Side Effects

Tell your doctor, nurse, or pharmacist as soon as possible if you do not feel well after being given Iluvien.

Like all medicines, Iluvien can cause side effects, mostly in the eye, although not everybody gets them.

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

- increased eye pain, discomfort or irritation
- worsening redness of your eye
- Sudden increase in floaters (spots or specks in your vision)
- decreased vision

- bleeding in the eye

Occasionally the injection may cause an infection inside the eye, pain or redness in the eye, or a detachment or tear of the retina. It is important to identify and treat these as soon as possible.

Other side effects may include:

- increased eye pressure
- clouding of the eye's natural lens (a cataract).
- blurred vision
- worsening vision

Increased pressure in the eye which damages the optic nerve (glaucoma) may be more likely if the pressure inside your eye is higher than average before treatment.

Your doctor will discuss the risks of this with you before treatment. The symptoms you might experience and what you should do if you experience these symptoms are described in the section **After you are given it**.

Do not be alarmed by this list of possible 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 anything else that is making you feel unwell.

Other side effects not listed above may also 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.

Storage

It is unlikely you will have to store Iluvien at home. Your medicine will be stored by the doctor or pharmacy. If you do have to store it please:

Keep Iluvien out of the reach and sight of children.

Do not use Iluvien after the expiry date which is stated on the carton and inner wrap after EXP.

The expiry date refers to the last day of that month.

Keep your medicine in a cool dry place where the temperature stays below 25°C. Do not refrigerate or freeze.

Keep the preloaded applicator with 25-gauge needle in the sealed tray. **Once the sealed tray is opened, it must be used immediately.**

1 single pack containing 1 Iluvien Intravitreal Implant in Applicator.

This leaflet was prepared by Specialised Therapeutics Limited.

Last revised: July 2020.

Product Description

What it looks like

Iluvien consists of a tiny light brown tube (approximately 3.5 mm x 0.37 mm) which is preloaded in an applicator system. The preloaded applicator is placed in a polycarbonate tray and sealed with a peelable lid. Each sealed tray is provided in a carton which includes the product information.

Ingredients

The active substance is fluocinolone acetonide.

Each intravitreal implant contains 190 micrograms fluocinolone acetonide.

The other ingredients are:

- Excipients: Polyvinyl Alcohol, water for injection
- Drug delivery system (implant): PMDA/ODA copolymer tubing, MED-1137 RTV silicone adhesive, polyvinyl alcohol, water for injection

Iluvien does not contain gluten, tartrazine or any other azo dyes.

Sponsor

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Please check with your doctor or pharmacist for the latest Consumer Medicine Information.