

CONSUMER INFORMATION
Product Monograph Part III

^{Pr}**MACUGEN***
pegaptanib sodium injection
0.3 mg/90 µL

Pfizer Canada Inc.

Submission Control No. 094022

The Consumer Information Section (Part III) of the Product Monograph for MACUGEN has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on May 2, 2005 and does not necessarily reflect the most current information for the product.

For the most up-to-date product information, please consult your health care professional.

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

INFORMATION FOR THE CONSUMER

PrMACUGEN* 0.3 mg (pegaptanib sodium injection)

Read all of this leaflet carefully before your treatment with MACUGEN begins.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What MACUGEN is and what it is used for
2. Before MACUGEN is used
3. How the injection of MACUGEN is administered
4. Possible side effects
5. Storing MACUGEN

MACUGEN 0.3 mg (pegaptanib sodium injection)

- The active substance is pegaptanib sodium. Each syringe contains 0.3 mg of pegaptanib sodium.
- The other ingredients are sodium chloride, sodium phosphate monobasic monohydrate, sodium phosphate dibasic heptahydrate, sodium hydroxide, hydrochloric acid and water for injections.

1. WHAT MACUGEN IS AND WHAT IT IS USED FOR

MACUGEN is an ophthalmic product, which means it is for eye treatment only. It is a solution for injection contained within a glass syringe. Your eye doctor will administer the injection.

Each box of MACUGEN contains one syringe (with a pre-fitted needle) inside a sealed pouch. A plastic plunger and a snap-on flange, that are used by your doctor when injecting the medicine, are contained within a separate pouch inside the box. The syringe will be used once and then thrown away.

MACUGEN is used for the treatment of the wet form of age-related macular degeneration (AMD). This disease leads to vision loss resulting from damage to the central part of the retina (called the macula), at the back of the eye. The macula enables the eye to provide the fine central vision that is needed for driving a car, reading fine print and other similar tasks.

In the wet form of AMD, abnormal blood vessels (known as choroidal neovascularization, or CNV) grow under the retina and macula. These new blood vessels may bleed and leak fluid, causing the macula to bulge or lift up, thus distorting or destroying central vision. Under these circumstances, vision loss may be rapid and severe. MACUGEN works by inhibiting the growth of these abnormal blood vessels and by stemming the bleeding and leakage. MACUGEN is used for the treatment of subfoveal CNV in AMD patients.

2. MACUGEN MUST NOT BE USED:

If you are hypersensitive (allergic) to pegaptanib sodium or any of the other ingredients of MACUGEN (see list of other ingredients under MACUGEN 0.3 mg) or

3. BEFORE MACUGEN IS USED, TELL YOUR DOCTOR IF:

- You have an eye infection in or around the eye.
- You suffer from liver or kidney problems (reduced function) or if you have to undergo haemodialysis treatment, because MACUGEN has not been studied in patients with these problems.
- You are pregnant or breastfeeding. There is no experience of using MACUGEN in pregnant or breast-feeding women. Discuss with your doctor if you are pregnant or planning to become pregnant or breast-feed. .
- You are taking or have recently taken any other medicines - including nonprescription (OTC [over-the-counter]), or natural health products.

3. HOW THE INJECTION OF MACUGEN IS ADMINISTERED

All injections of MACUGEN will be administered by your eye doctor.

Before the treatment is given your eye doctor may ask you to use antibiotic eye drops, or to wash your eyes carefully. Please follow these instructions carefully.

Before the injection, your eye doctor will give you some local anaesthetic (numbing medication). After that you should not feel the injection, which is a simple and rapid procedure. The injection is given into the vitreous of the eye, which is the jelly-like substance inside the eye.

MACUGEN is administered as a single injection into your eye at intervals of 6 weeks (ie. 9 times per year). Your eye doctor will schedule follow-up appointments to monitor your condition and will decide on the duration of treatment.

After each injection you might be asked to use antibiotic eye drops (or another type of antibiotic treatment) to guard against eye infection.

If you forget to attend an appointment:

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

4. POSSIBLE SIDE EFFECTS AND WHAT TO DO ABOUT THEM

Like all medicines, MACUGEN can have side effects. During clinical trials, the following side effects were recorded in the treated eye, most probably caused by the injection procedure (rather than by MACUGEN).

Side effects associated with the eye:

- eye infection
- increased or decreased intraocular pressure (pressure inside the eye)
- inflammation, irritation, discomfort, periorbital bleeding,
- conjunctival swelling, inflammation or haemorrhage (bloodshot eye),
- small particles in the field of vision (vitreous floaters or opacities)
- pupillary enlargement, eye strain
- bleeding, displacement or tear of the retina
- bleeding or displacement of the vitreous
- macular degeneration
- decreased vision
- cataract (clouding of the lens)
- eye movement disorder or disorder of the surface of the eye (cornea)
- increased sensitivity to light or appearance of flashing lights
- eyelid irritation, swelling, inflammation or drooping
- discharge, tear formation or dry eye
- lack of blood circulation to the retina

If you suffer any of the above, consult your (eye) doctor promptly.

If your eye doctor is not accessible for any reason, an alternate should be contacted immediately especially if you experience the following symptoms: increased eye discomfort, bloodshot eye, decreased vision, increased sensitivity to light or vitreous floaters.

Other side effects:

- headache
- nasal discharge

Driving and using machines: You may experience temporary visual blurring after

receiving MACUGEN. If you are affected you should not drive or use machines until this resolves.

If these or other side effects not mentioned in this leaflet are bothersome, please consult your eye doctor or pharmacist.

5. STORING MACUGEN

Keep MACUGEN out of the reach and sight of children.

MACUGEN should be stored at 2°C-8°C (in a refrigerator).

Do not freeze.

Store in the original box. Do not use after the expiry date on the box.

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