

ARCIOLANE 1300/5500

Silicone oil for endotamponade

Patient information leaflet



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You have just had retinal surgery to treat a retinal detachment in which your ophthalmologist placed a liquid silicone oil (ophthalmic oil) inside your eye to hold the retina in place by internal tamponade.

The silicone oil implanted is one of the following: **Arciolane 1300** or **Arciolane 5500**, differing in their viscosity. The choice of Arciolane type was made by your ophthalmologist according to your retinal detachment characteristics.

UNDESIRABLE SIDE EFFECTS

As with any surgery, there are risks associated with retinal surgery. These unwanted side effects should be explained to you by your ophthalmologist.

Complications related to having retinal detachment surgery with silicone oil such as Arciolane inside your eye that may occur include:

- An increase in pressure inside your eye that results in increased pain or headaches. Failure to treat this complication may lead to loss of vision.
- A decrease in pressure inside your eye may result in significant perturbation in vision.
- Blurred vision (sensation of visual fog) that may be linked to a damage of your cornea, in case of migration of the silicone oil in the anterior part of your eye (only few cases reported).
- Pain and/or difficulty to close your eyelid due to the presence of silicone oil under the conjunctiva.
- Redness or itching of your eye due to inflammation of ocular tissue or ocular bleeding.
- Presence of silicone bubbles in the visual axis due to the fragmentation of silicone oil that will result in a vision loss.
- Cataract (opacification of the natural lens inside your eye), resulting in decrease of your vision.

Also, if you have any of the following symptoms: significant loss or blurring of vision, increased eye pain, headaches, significant redness or itching of the eye, seek immediate medical attention from an ophthalmologist or emergency services, indicating that you have had surgery to place silicone oil in your eye.

Any serious incident, that occurs in relation to the implantation of **Arciolane 1300** or **Arciolane 5500**, should be reported to **ARCADOPHTA** and to the **Therapeutic Goods Administration** on the website <https://www.tga.gov.au/>

INTERACTION

- Your treatment does not contraindicate radiological examinations, including Magnetic Resonance Imaging (MRI).
- You should mention the presence of silicone oil into your eye in any ophthalmological consultation, in order for the physician to take it into account for treatment of other potential ocular condition, such as cataract.
- If you have been operated from cataract surgery with implantation of an intra-ocular lens (IOL), there is a risk of interaction if the IOL is highly hydrophobic that may lead to a replacement of your IOL.

PRECAUTIONS/WARNINGS

If you have a known hypersensitivity to silicone that your ophthalmologist has not been aware prior to the surgery, please contact your ophthalmologist immediately.

- You may experience visual disturbance or sensation of halos or floaters (dark filaments moving in your visual axis). Although sometimes annoying, this phenomenon is not serious as due to the presence of silicone oil in your eye.
- You may also experience pain or discomfort after surgery. In any case, you should avoid rubbing your eye, and seek medical advice if you worry about these signs.
- Depending on your age, your health and your disease, your ophthalmologist may ask for adapted medical surveillance. Follow their recommendations carefully so that the result of your surgery is beneficial and to limit the risks of side effects or recurrence. It is important to attend the post-operative follow-ups requested by your ophthalmologist, in particular to check that the pressure inside your eye is correct and the silicone oil works as expected.
- You must be advised that the silicone oil should be removed surgically when your retinal detachment is stabilized. In principle, the duration of implantation is not more than 6 months.