

# ARCEOLE / ARCEOLE Set Multidose

Ophthalmic gas for endotamponade

## Patient Information Leaflet



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You have just had retinal surgery in which your ophthalmologist placed a gas bubble in your eye to hold it in place by internal tamponade.

This bubble is composed of one of the following 3 gases: **SF<sub>6</sub>** (sulfur hexafluoride), **C<sub>2</sub>F<sub>6</sub>** (Hexafluoroethane), **C<sub>3</sub>F<sub>8</sub>** (Octafluoropropane) and air. The choice of gas used was made by your ophthalmologist.

### CONTRAINDICATIONS

Because this gas bubble will remain in your eye for several weeks, you must wear the warning bracelet for at least 3 months.

During these 3 months, you must avoid any nitrous oxide anaesthesia and any activity that could lead to a pressure variation, as illustrated by the logos on the warning bracelet explained on the implant card. Failure to observe these contraindications can lead to loss of vision (blindness).

### 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 the gas bubble inside your eye that may occur are:

- An increase in pressure inside your eye that results in increased pain or headaches. Failure to treat this complication can lead to loss of vision.
- A tamponade time that is too short to fix your retina in place. This results in a risk of recurrence. This can result in poor visual recovery or impaired vision. This may require repeat surgery. Following the instructions given by your ophthalmologist on the position of your head is important in order to ensure an effective tamponade.
- Displacement of the gas bubble inside your eye, leading to inflammation or irritation and a risk of cataract. This can result in persistent blurring of your vision. Keeping your head in the position recommended by your ophthalmologist will limit this risk.
- A change in the quality of your distance 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 an ophthalmic gas in your eye.

Any serious incident, that occurs in relation to the implantation of **Arceole** or **Arceole Set Multidose** 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).

### PRECAUTIONS/WARNINGS

Your vision may be disturbed (feeling of blurred vision and/or seeing the gas bubble). This will fade as the bubble disappears.

Floating elements may pass through your visual axis. This is a consequence of the presence of the gas bubble beside the vitreous. Although sometimes annoying, this phenomenon is not serious.

You must position your head according to the surgeon's recommendations and avoid rubbing your eye to ensure that the device works properly.

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 operation is beneficial and to limit the risks of side effects or recurrence. Also, 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.