

**Product: Active Oxygen Gel**

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**REF** Reference number



Storage conditions

**LOT** Batch number



Use by date



Consult instructions for use



**Manufacturer**

Ardoz Healthcare BV, Kasteleinenkampweg 9 C, 5222 AX 's-Herthogenbosch, The Netherlands

**CE 0044**

**For OXYSAFE Gel Professional only:**



**Storage conditions**



**Single use device**

## **Instructions for use: Ardoz Active Oxygen gel**

Please read the IFU carefully prior to use

### **What is Ardoz Active Oxygen gel?**

Ardoz Active Oxygen gel is a product with a patented active oxygen technology. This technology becomes active at the moment of contact with the skin or mucous membranes.

### **How does the Ardoz Active Oxygen gel work?**

Ardoz Active Oxygen gel contains the patented Ardox-X® technology which becomes active at the moment of contact with the skin or mucous membranes. The technology is based on a stabilized hydrocarbon-oxoborate complex that generates a non-radical form of oxygen under the influence of saliva. The hydrocarbon-oxoborate complex functions as a matrix that releases active oxygen on the area that has to be treated. The oxygen-enriched micro-environment has a proven positive effect on the (infected) wound treatment, e.g. infected pockets.

### **For what purpose can the Ardoz Active Oxygen gel be used?**

Ardoz Active Oxygen gel is used for the treatment of periodontitis and peri-implantitis.

### **In which cases can the Ardoz Active Oxygen gel be used?**

Ardoz Active Oxygen gel is used in dentistry in case of pockets with a minimum depth of 5 mm and peri-implantitis. Ardoz Active Oxygen gel is used in dentistry in case of peri-implantitis.

### **In which case the Ardoz Active Oxygen gel can't be used?**

Ardoz Active Oxygen gel cannot be used in combination with metal implants or metal prosthesis, with the exception of titanium. Before using Ardoz Active Oxygen gel, first remove the prosthesis. Due to the fact that the Ardoz Active Oxygen gel reacts with metals, only plastic needles are suitable for the application of the Ardoz Active Oxygen gel.

### **How is the Ardoz Active Oxygen gel used?**

#### Dosage:

The dosage depends on the type of pocket and the depth of the pocket. The maximum dose per treatment is 3ml.

#### How is the Ardoz Active Oxygen gel used in dentistry in case of A pocket with a minimum depth of 5 mm?

- Place a plastic needle under the pocket and push the Ardoz Active Oxygen gel very slow out of the syringe until the Ardoz Active Oxygen gel that comes out of the pocket looks clean. Immediately after treatment of the pocket, the patient can have a warm and / or painful feeling for a short period of time, which should disappear almost immediately.
- Leave the Ardoz Active Oxygen gel in situ for 5 minutes.
- Then clean the pocket with physiological saline solution.
- Place a plastic needle under the pocket and push the Ardoz Active Oxygen gel out of the syringe very slowly until the Ardoz Active Oxygen gel that comes out of the pocket looks clean. Then leave the Ardoz Active Oxygen gel in the pocket.

- In exceptional cases, plugging of the needle may occur when capillary needles are used. In that case, use a new needle or a needle with a larger diameter.
- The gel can be applied multiple times, if necessary.

### **When is extra caution required with the Ardoz Active Oxygen gel?**

#### Possible reactions:

Ardoz Active Oxygen gel will increase the pressure locally. The patient may feel pain, which must disappear quickly. This pain can also be felt in the head. These symptoms are the result of the local pressure increase. Treat furcations with special care.

#### What to do if the pain doesn't disappear?

Fill a syringe with physiological saline solution and rinse the pocket until the pain disappears.

#### How to use in dentistry in case of peri-implantitis?

Place a plastic needle under the pocket and push the Ardoz Active Oxygen gel out of the syringe very slowly until the Ardoz Active Oxygen gel that comes out of the pocket looks clean. Then leave the Ardoz Active Oxygen gel in the pocket.

#### What should you pay attention to during a pregnancy?

Do not use during pregnancy/breastfeeding.

After periodontal surgery during which the Ardoz Active Oxygen gel has been used, the patient should continue with Ardoz Active Oxygen Mouthwash according to the manufacturer's instructions.

### **Additional information Ardoz Active Oxygen gel.**

The critical ingredient in the Ardoz Active Oxygen gel is the Ardox-X® technology; based on an oxygen donating complex. Contains Sodium Perborate. Medical device.

### **Appearance and packaging of the Ardoz Active Oxygen gel.**

Appearance: Ardoz Active Oxygen gel is an opaque, white gel.

Packaging: Ardoz Active Oxygen gel is packed in plastic syringes with a content of 1 ml. One outer packaging contains 3 syringes.

### **Any serious incident that occurs in relation to the use of the product must be reported to the manufacturer and to the competent authority.**

For any questions about this product, please contact Ardoz Healthcare, Kasteleinenkampweg 9C, 5222 AX 's-Hertogenbosch, +31 (0)73 627 07 40, info@ardoz.com