

Instructions for use OZONOSAN Vacuum bottle

EN



REF 3202
OZONOSAN Vacuum bottle 250ml
with latex-free plug, 12ml sodium citrate and Microbubble System



REF 3200
OZONOSAN Vacuum bottle 250ml
with latex-free plug and Microbubble System

Product

The vacuum bottle is a collection container and consists of a pharmaceutical glass container with a latex-free plug, a rising tube made of polypropylene PP with Microbubble System for the finest distribution of the ozone-oxygen mixture, a protective cap and a disposable hanging device.

REF 3202 contains 12ml of sodium citrate as anticoagulant.

The vacuum bottle is sterilized, evacuated and tested for sterility and pyrogenicity in accordance with Ph. Eur. checked. Moisture droplets in the REF 3200 bottle consist of sterile water, which is added to the bottle for sterilization purposes.

Label with scale (for reference only).

Classification: Medical device class IIb according to Directive 93/42/EEC

Intended Use

As part of ozone-oxygen therapy for the temporary intake of autologous blood.

Indications

For the complementary treatment of dry age-related macular degeneration, in addition to the current standard therapy.

The use of the product for the treatment of other diseases is not justified by sufficient clinical data.

Treatment Schedule

In the first seven (7) weeks, major autohemotherapy (MAH) 2x weekly; then MAH 2x per month for three (3) months; then 1x MAH per month up to a total treatment period of twelve (12) months. After 6 to 9 months, the effect may wear off, so the therapist may want to repeat the therapy, taking into account the patient's individual risk factors. There is no clinical evidence for the effectiveness of this repeated procedure.

Precautions

Container is made of glass. Be careful fragile! Container must not be pressurized.

Observe hygiene guidelines and legal regulations!

This IFU applies only in conjunction with the operating manual of the ozone generator used. The instructions of the device manufacturers must be observed!

Only use suitable hangers for the vacuum bottle, do not use damaged hangers again!

If the cap is damaged, there is a risk that there is no sterility – do not use it!

For reinfusion, only use transfusion equipment equipped with a particle filter!

For single use. Reuse poses a potential patient risk or a risk of infection for the user. The general hygiene guidelines when working with blood must be observed.

Storage

Do not use the product after the expiration date. Do not expose to direct sunlight and protect from moisture.

Disposal

When disposing of the products, the local regulations must be observed.

Mandatory user training

Before use, the user must have completed mandatory user training on the correct and intended use of the product. To do this, contact the manufacturer, Hänsler Medical or its authorized sales partner.

Composition of sodium citrate solution (only REF 3202)

Ingredients per 1,000mL of water for injections:

Tri-sodium citrate dihydrate 31.3g

Citric acid anhydrous 0.192g

mmol/L: Na⁺ 319.3mmol/L, Citrate³⁻ 107.4mmol/L

pH-value 6 to 8

Legend symbols, abbreviations



Sterile product.
Sterilized with steam



Free of latex



Not for reuse



Article reference



Expiry date



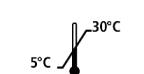
Batch designation



Manufacturer



Follow the instructions for use



Temperature range



Protect from moisture



Protect from light



fragile



Medical device



Notified Body

Abbreviations used:

MAH = Major autohemotherapy

IFU = Instructions for use

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Major autohemotherapy (MAH) following the guidelines of ozone therapy¹ and the hygiene guidelines

Principle:

50 to 100ml of the patient's own blood is enriched with the same amount of ozone/oxygen mixture and reinfused as a drip infusion.

Required consumables

Please note that the consumables are disposable!

- 1 OZONOSAN vacuum bottle 250ml with 12ml sodium citrate and Microbubble System (REF 3202)
alternatively 1 OZONOSAN vacuum bottle 250ml with Microbubble System (REF 3200) and additional 10ml ampoule of sodium citrate as anticoagulant, as well as size 1 (G19) single-use cannula for drawing up sodium citrate.
- 1 transfusion set with particle filter;
- 1 perfusion set 1.1mm (butterfly) or 0.8mm for blood sampling;
- 1 transfer filter set for ozone introduction with bacteria filter and roll clamp;
- 1 50ml disposable syringe (ozone resistant, siliconized)
- Fixation plasters (individually packed); swabs (shrink-wrapped, sterile) or hand disinfectant and sterile cell or gauze swabs.

Preparing the OZONOSAN Vacuum bottle

1. Remove the protective cap on the vacuum bottle; it is best to press away from bottom to top with both thumbs. Disinfect the plug on the vacuum bottle with skin disinfectant by rubbing or spraying (exposure time > 1 min).
2. Close the roller clamp on the transfusion set and insert the needle into the bottle plug at the point marked with the large circle (see Figure 1).
3. When using a vacuum bottle without sodium citrate solution (REF 3200): Connect the cannula size 1 to the transfusion set and draw the desired amount of sodium citrate from the ampoule via the cannula into the transfusion set by briefly opening the roller clamp slightly. Make sure that the roll clamp is closed in time to avoid vacuum loss. Discard used cannula and ampoule.
4. Get 50ml of ozone/oxygen mixture from the ozone generator with the disposable syringe according to instructions.
5. Connect the roller clamp to the transfer filter set and connect the filled 50ml syringe. Do not insert the transfer filter set into the plug of the bottle yet.
6. Go to the patient with the prepared vacuum bottle with transfusion set and transfer filter set with syringe.

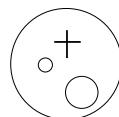


Figure 1: Latex-free plug with markings (view from above)

Patient Handling

1. Connect the perfusion set to the transfusion set.
2. Apply a tourniquet, puncture the vein, slowly open the roll clamp on the transfusion set and take 50 to 100ml of blood. Hygiene regulations must be observed for blood sampling Fehler! Textmarke nicht definiert.
3. Shortly before the desired blood volume is reached, reduce the roller clamp on the transfusion set to drip speed, do not close it completely.
4. Insert the transfer filter set into the bottle plug with the roller clamp closed at the cross marking (see Figure 1), open the roller clamp until small bubbles bubble through the blood. The vacuum in the infusion bottle draws in the ozone/oxygen mixture from the syringe and distributes it evenly in tiny bubbles. The roller clamps on the transfer filter set and, on the transfusion, set remain slightly open.
To administer another 50 ml syringe with ozone/oxygen mixture, close the roll clamp on the transfer filter set immediately and connect another filled 50 ml syringe of ozone/oxygen mixture.
5. Gently swirl the bottle, do not shake and hang it on the infusion stand for infusion, remove the tourniquet and fully open all roller clamps. Remove the 50 ml syringe from the transfer filter set so that the system can be ventilated.
6. Regulate the drip speed to 60 - 90 drops per minute after approx. 1 minute.

Contraindications and side effects

Contraindications for the MAH

Patients under 18 years of age
Glucose-6-phosphate dehydrogenase deficiency (Acute hemolytic anemia, favism)
Hyperthyroidism if not adjusted
Pregnant or breastfeeding women
Leukemia

Known side effects of MAH

„Flush“, i.e. blushing with increased pulse
Allergic reactions with shortness of breath

Additional contraindications to the use of sodium citrate

Allergic reaction to fruit acids / citrate intolerance
Hypocalcemia
Electrolyte disturbance
Coagulation disorders
Hepatic insufficiency
Renal failure

Known side effects of Sodium Citrate at high doses

Metabolic alkalosis
Electrolyte disorders
Respiratory acidosis
Blood clotting disorders

Manufacturer



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¹ Renate Viebahn-Hänsler, Olga Sonia León Fernández, Ziad Fahmy: „Ozone in medicine: The low-dose ozone concept. Guidelines and treatment strategies“, Ozone: Sci Eng 34, 408-424 (2012). <http://www.tandfonline.com/doi/full/10.1080/01919512.2012.717847#.U90hPFbB4v4>