1 – Product

Carbon dioxide absorber in pills - **Atrasorb PHARMA FREE**

Indications
CO_2 (carbon dioxide) absorber in pills for medical use, in closed or semi-closed anesthetic circuits for inhalation method .

As it only contains calcium hydroxide as an absorbent, its use in procedures using halogenated anesthetics, such as sevoflurane , desflurane , halothane , enflurane and isoflurane is more recommended, as the absorption reaction is less exothermic, greatly reducing the formation of compounds toxic (See item 4.8 Precautions / warnings).

2 – Composition / Specification

2.1 Chemical Composition

Calcium Hydroxide (absorber);
Sodium silicate (binder);
Ethyl Violet (Indicator);
Water (humidification of the product and primary absorption of carbon dioxide).

CAS Number/Formula:
1305-62-0 – Calcium Hydroxide (hydrated lime) - Chemical formula: $Ca(OH)_2$ (≥ 68.0 % - ≤ 75.0 %)
1327-36-2 – Sodium Silicate - Chemical formula: Na_2SiO_3 (≥ 1.5 % - ≤ 2.5 %)
2390-59-2 – Ethyl Violet - Chemical formula: $C_{31}H_{42}N_3Cl$ (≤ 0.03%)
1310-58-3 – Potassium Hydroxide – Chemical formula: KOH (0.0%)
7631-86-9 – Silica – Chemical formula: SiO_2 (0.0%)

2.2 Technical specification

- Grain size: 4.5mm pill (2.36 to 4.75 mm mesh) / 3.5mm and 2.5mm pill (2.36 to 4.00 mm mesh);
- Grain shape: semi-spherical pills;
- Humidity: 12 to 19% (depending on the application);
- Color: white to slightly yellowish or grayish;
- Post-saturation indicator: color change from white to violet.

3 – Product Description

Atrasorb PHARMA FREE, CO_2 absorber, is a chemical compound used as a filter for semi-closed or closed respiratory circuits in the medical field.

Its pyramidal or half-sphere shape provides better compaction in the reservoir and consequently a larger CO_2 absorption area, in addition to preventing the formation of dust.

When used in filters, combined or not, it allows the reuse of expired gases without rebreathing carbon dioxide (CO_2) through a chemical filtration process.

Atrasorb PHARMA FREE has a limited useful life, after which it must be replaced so that there is no rebreathing of CO_2 by the patient/user. For this purpose, it has an evolution indicator.

The indicator of progress in the use of Atrasorb PHARMA FREE is ethyl violet, which transforms the color of white lime into violet as the CO_2 absorption capacity is exhausted.

The Atrasorb PHARMA FREE has a moisture composition between 12 and 19% H_2O (as specified by the United States Pharmacopeia - USP). Its degree of hardness allows safe transportation, preventing the formation of dust.

The Atrasorb PHARMA FREE packaging is hermetically closed, guaranteeing its moisture content, enabling the product to be guaranteed for 5 years.

Presentation forms:
The packaging consists of Plastic Containers with a demarcated product identification label and lids differentiated by the color yellow. For Barrels and Big Bags, the product identification is affixed to the packaging.

4 – Instructions for Use

4.1 - When in systems with a semi-closed or closed CO_2 absorption circuit that contains an appropriate reservoir or canister for depositing the product (Ex.: Rebreathing anesthesia machines/systems).
The handling, use, monitoring and control of the product must be carried out by a qualified medical professional, as well as checking the environmental conditions for the procedures.

Handling and storage:
- In the packaging itself, in a covered environment without exposing the packaging to the elements;
- Avoid mechanical shocks or large vibrations;
- Temperature range between -20º C to +50º C;
- Relative humidity between 10 and 90% (without condensation).

The product's expiration date, shown on the batch identification label on the packaging label, must be observed to avoid using it after its useful life.

If the packaging is damaged or accidentally opened before use, the product must be discarded (see MSDS – Chemical Product Safety Data Sheet).

4.2 - In the case of continuous use of lime, the change must be made when the violet color reaches 3/4 (three quarters) of the canister . If there is an indication of the CO_2 (carbon dioxide) content in the air flow, the change takes place when the index reaches the level of 1% CO_2.

4.3 - In the case of intermittent use, the average time of use is 7 (seven) to 8 (eight) hours or 190 liters of CO_2 per kilogram of product (test carried out with an air flow of 10 liters/minute with 4% CO_2 in volume, in an anesthesia machine with servo-controlled artificial respiration), remembering that, between periods of use, the lime returns to its white color, depending on the time between periods. Control must be carried out by recording the time of use or by the maximum index of 1% of CO_2 in the air flow if measurement is available using a capnograph / gas analyzer, which is the most efficient means of control.

4.4 - Once the maximum filtration limit has been reached, the product must be removed from the canister and discarded (see MSDS – Chemical Product Safety Information Sheet).

ATTENTION

The material to be discarded after use must be properly identified and segregated, to avoid misuse.

4.5 - After opening the packaging, it is recommended that it be used within a maximum of 30 days and that the container remains protected from heat and light (preferably stored in the box itself). After this period, it must be discarded (see MSDS – Chemical Product Safety Information Sheet).

4.6 - After filling the canister (appropriate container) until its effective use, we inform you of the following:

a) The normal procedure is to fill the canister and use it immediately.

b) When its immediate use does not occur, its duration (CO_2 absorption capacity) will depend on factors such as:
- room temperature;
- incidence of luminosity and solar rays;
- equipment sealing;
- loss of moisture from the product, which significantly interferes with the absorption capacity and quality of inhaled air.

ATTENTION

Each environment or mode of operation interferes differently with the product (e.g., use of high or low flow, temperature conditions in the operating room, leaks in the circuit, etc.), therefore, Atrasorb PHARMA FREE must be replaced in the breathing system at least once every seven days or when the CO_2 concentration in the inspiration gas reaches 1% (7.6 mmHg).

c) As already specified, the absorbing element has a useful life (CO_2 absorption capacity) of approximately 7 (seven) to 8 (eight) hours or 190 liters of CO_2 per kilogram of product. After this, it stops absorbing CO_2 and if it is left standing for a long period, the absorber will return to its original color (the indicator will not act) as there is no chemical reaction and, therefore, it will not filter the CO_2. If you are using a gas analyzer, it will indicate CO_2 retention by the patient. The CO_2 Absorber must then be replaced with a new one.

4.7 - Comments:

a) Minimal or low flow anesthesia

When anesthesia with minimal or low flows (between 0.5 and 1 liter/min) is used for long periods, it is common to also increase the humidity in the respiratory system hoses. Disconnect inspiratory and expiratory hoses and valves and clean them before and after long-term procedures.
The valves contain a space for this accumulation of water, empty the hoses and valves if this accumulation of water exceeds acceptable limits. This procedure unclogs the hoses and eliminates possible retention of CO_2 by the patient.

b) Flushing the system with nitrogen (N_2)

During induction and after anesthesia, the gases that remain in the respiratory system (and in the patient's lungs) contain about 79% nitrogen (N_2). If the anesthetic procedure to be used is minimal or low flow, press the direct O_2 flow button to eliminate this nitrogen (N_2).

c) How to prevent water from accumulating in the system

Accumulation of water in the flow sensors or water in the detection lines can cause false alarms. The water comes from two factors: the exhaled gases that, when they come into contact with the environment due to the difference in temperature, cause condensation in the tubes and the chemical reaction between the exhaled CO_2 and the CO_2 absorber.

In conditions of lower fresh gas flow, there will be a greater accumulation of water due to less gas exhaustion and there will be:

- More residual CO_2 in the absorber to react and produce water;
- More humid exhaled gas in the patient circuit and absorber and if using a gas analyzer, this may indicate CO_2 retention by the patient even with the new Atrasorb PHARMA FREE.

Solution:

- When replacing the absorber, empty the water tank of the container and the circuit tubes;
- Make sure that the water condensed in the breathing circuit tubes remains below the flow sensors and that there is no infiltration into the flow sensors;
- Water condensation in the respiratory circuit tubes can be reduced by using the HME type filter when connecting the patient's airways.

d) Canister

The canister is a container to house the CO_2 absorbing element (Atrasorb PHARMA FREE) of the valve filter.
The canister has a transparent wall to allow viewing the color of the CO_2 absorbing element inside.
The exchange and/or filling is carried out by emptying and/or filling the canister with the CO_2 absorbing element up to the level of the canister lid.

The canister must not be filled with a CO_2 absorbing element without use for approximately 7 days or more (observe internal procedures and the equipment manufacturer's instructions for cleaning and maintaining equipment).

We recommend that the canister be washed with water and neutral soap weekly, to ensure its durability and perfect functioning, despite being autoclavable .

e) CO_2 Absorber Element (Atrasorb PHARMA FREE)

The valve filter makes it possible to reuse exhaled gases without the patient rebreathing carbon dioxide (closed or semi-closed systems). For this, a CO_2 absorbing element (Atrasorb PHARMA FREE) is used.

The CO_2 absorbing element is a consumable, granulated material that is placed inside the canister to absorb carbon dioxide from exhaled gases, through a chemical filtration process.

The chemical reaction of absorption of carbon dioxide by the CO_2 absorbing element results in the formation of water inside the canister, and also in its heating.

The CO_2 absorbing element has a limited useful life, after which it must be replaced (see items 4.1 to 4.6).

ATTENTION

1 - The saturated Atrasorb PHARMA FREE (purple or violet color) returns to its initial color (white) after a few hours of rest. However, its efficiency is reduced by more than 90%. Therefore, replace the saturated Atrasorb PHARMA FREE as mentioned previously.

2 - The useful life of the Absorber is measured in liters of CO_2 absorbed, which is approximately 7 to 8 hours or 190 liters per kilogram of product. The Absorber used and kept at rest, after some time returns to its original color, if the use canister is filled it NO LONGER ABSORBES CO_2, CHANGES COLOR RAPIDLY (indicator of useful life) and CAUSES CO_2 REBREATHING. Therefore, never use absorbent packaging to store used Atrasorb PHARMA FREE, nor mix the new absorber with the used absorber.

4.8 - Precautions / warnings

- Do not use in procedures using trichloroethylene and chloroform, as the reaction can lead to the formation of toxic products;

- Do not wash the CO_2 absorbing element with dry gas or basal or continuous flow of oxygen for a long time, outside of periods of use, as this causes the humidity to change;

- When the humidity of the CO_2 absorber element is changed to levels lower than those specified by the manufacturer, some undesirable reactions may be produced, independent of the type of CO_2 absorber and anesthetics being used (sevoflurane, desflurane, halothane, enflurane and isoflurane), such as:

- Reduction in CO_2 absorption capacity;
- Rebreathing of CO_2 by the patient;
- Absorption or decomposition of the anesthetic agent;
- Increased heat generation in the CO_2 absorbing element, which in turn causes an increase in the temperature of the gas breathed by the patient.

These reactions can cause various damages to the patient, among which it is worth mentioning, intoxication with compound A, carbon monoxide, formaldehyde and methanol (possible to be formed with the degradation of anesthetics due to low humidity or heat of the reaction), superficiality of the anesthetic plane and even burns to the respiratory tract.

- In cases of suspected low humidity in the product, unusual increase in temperature during the washing procedure or delay in increasing the anesthetic concentration during inspiration, immediately replace the absorber;

- Never add water to the absorber to try to correct the drop in humidity, as this may cause a decrease in absorption capacity due to excessive moisture content. The product's humidity is controlled in the manufacturing process, within the requirements of the United States Pharmacopeia (USP), in the range of 12 to 19% (more common between 16 to 18%).

Atrasorb recommends replacing the CO_2 absorbing element, regardless of color, if the anesthesia device remains unused for a period of 7 days or more (see item 4.6 of this Instruction).

ATTENTION

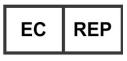
1 - The CO_2 absorbing element contains calcium hydroxide (lime) and can cause irritation to the eyes, skin and respiratory system. When replacing the CO_2 absorber element, be careful not to spill it.

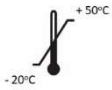
a) Empty the canister with used CO_2 absorbing element, in an appropriate location;
b) Fill the canister only with a new CO_2 absorbing element;
c) Make sure that when closing the filled canister, there is no dust or particles from the CO_2 absorber element preventing the system from sealing.

2 - In the event of a serious incident occurring with the medical device, it must be immediately reported to the manufacturer and the competent authority of the member state in which the users and/or patients are established.

Individual protection measures:
- Skin/eye protection: Well-fitting safety glasses;
- Hand protection: Glove substance: Nitrile rubber - Glove thickness: 0.11 mm;
- Respiratory protection - Necessary in case of dust formation: Recommended Filter Type: PFF2 Filter.

5 – Symbol table

	Manufacturer
	Authorized representative in the European Community
	Manufacturing date
	Expiration date
	Non-sterile
	Batch

	Do not reuse
	Fragile, handle with care
	See instructions for use
	Corrosive. May cause burns severe skin and eye damage
	Careful
	Causes skin sensitization and skin and eye irritation
	Correct stacking direction
	Maximum stacking
	Storage Temperature Range
	Protect against moisture
	Protect against heat
	bar code
	Medical Device
	CE marking

6 – Manufacturer data

Atrasorb Industria de Produtos Hospitalares Ltda.

Address: Avenue Piracicaba, 351 – Vila Nova São Roque

City: São Roque-SP

Vat number: 05.691.570/0004-31

Contact: +55 11 5521-2076

Email: atrasorb@atrasorb.com.br

7 – European representative details

EC REP **CINTERQUAL Soluções de Comercio Internacional Ltda**

Tax number / VAT nº 507288041

Address: Avenida Defensores de Chaves, 4, 1000-117 – Lisbon – Portugal. Telephone: +351 215838500

8 – Other information

For more information about the product (risks, protective and first aid measures, handling, storage, etc.) can also be found in the product's FISPQ (Chemical Product Safety Information Sheet) and at www.atrasorb.com.br

The CE marking indicates that the product complies with applicable European Union Directives.

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