1 - Product

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

Indications
CO2 absorber (carbon dioxide) in pills for medical use,in anesthetic circuits by closed or semi-closed inhalation method.

As it contains only calcium hydroxide as an absorber, 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 (absorbent);
Sodium silicate (binder);
Ethyl Violet (Indicator);
Water (product humidification 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: Na2SiO3 (≥ 1.5% - ≤ 2.5%)
2390-59-2 – Ethyl Violet - Chemical formula: C31H42N3Cl (≤ 0.03%)
1310-58-3 - Potassium hydroxide - Chemical formula: KOH (0.0%)
7631-86-9 - Silica - Chemical formula: SiO2 (0.0%)

2.2 Technical specification

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

3 – Product Description

The Atrasorb PHARMA FREE, absorber ofCO2 is a chemical compound used as a filter for semi-closed or closed respiratory circuits in the medical field.

Its pyramidal or half sphere format provides better compaction in the reservoir and consequently a greater area of absorption ofCO2, 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 (CO2) through a chemical filtering process.

Atrasorb PHARMA FREE has a limited shelf life, at the end of which it must be replaced so that there is no rebreathing ofCO2 by the patient / user. For this, it has an indicator of evolution.

The evolution indicator of the use of Atrasorb PHARMA FREE is ethyl violet, which transforms the color of white lime into violet as the absorption capacity ofCO2.

Atrasorb PHARMA FREE has a moisture composition between 12 to 19% $H_{two}O$ (as specified by the United States Pharmacopoeia - USP). Its degree of hardness allows for safe transport, avoiding the formation of dust.

The packaging of Atrasorb PHARMA FREE is hermetically closed, ensuring its moisture content, enabling the product's 5-year warranty.

Presentation forms:
The packaging consists of Plastic Containers (available for quantities of 1.0, 4.0, 4.3, 4.5, 5.0, 15.0, 16.0, 17.0, 18.0, 20.0 kg) with marked product identification label and lids differentiated by the color yellow (PHARMA FREE), 50 kg barrels and Big Bags of up to 1000 kg with product identification affixed to the packaging.

4 – Instructions for Use

4.1 -When in systems with semi-closed or closed circuit of absorption ofCO_2 that contains a reservoir or canister suitable for depositing the product (Ex.: Anesthesia machines/Systems with rebreathing).
The handling, use, follow-up and control of the product must be carried out by a qualified professional in the medical field, as well as the verification of 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 major vibrations;
- Temperature range between -20° C to +50° C;
- Relative humidity between 10 to 90% (without condensation).

The expiry date of the product, shown on the batch identification label on the package label, must be observed to avoid its use after its useful life.

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 theCO_2 (carbon dioxide) in the air flow, the exchange takes place when the index reaches the level of 1% of 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% ofCO_2 in volume, in an anesthesia machine with servo-controlled artificial respiration), keeping in mind that, between periods of use, the lime returns to a white color, depending on the time between periods. The control must be done by recording the time of use or by the maximum index of 1% of CO_2 in the air flow if measuring by capnograph / gas analyzer is available, which is the most efficient means of control.

4.4 -Once the maximum filtering limit has been reached, the product must be removed from the canister and discarded (see FISPQ – Safety Data Sheet for Chemical Products).

ATTENTION

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

4.5 -After opening the package, it is recommended that it be used within a maximum of 30 days and that the container remain protected from heat and light (preferably stored in its own box). After this period, it must be discarded (see FISPQ – Safety Data Sheet for Chemical Products).

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 it is not used immediately, 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 inhaled air quality.

ATTENTION

Each environment or mode of operation interferes differently with the product (Ex.: Use of high or low flow, operating room temperature conditions, 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 CO2 concentration in the inspiration gas reaches 1% (7.6 mmHg).

c) As already specified, the absorber element has a useful life (CO2 absorption capacity) of approximately7 (seven) to 8 (eight) hours or 190 liters of CO2 per kilogram of product. After that, it stops absorbing CO2 and if it is at rest for a long period, the absorber will return to its original color (the indicator will not work) because there is no chemical reaction and, therefore, it will not filter the CO2. If you are using a gas analyzer, it will indicate CO2 retention by the patient. The CO2 Absorber must then be replaced with a new one.

4.7 - Comments:

a) Minimal or low flow anesthesia

When using anesthesia with minimal or low flows (between 0.5 and 1 liter/min.) for long periods, it is common to also increase the humidity in the respiratory system hoses. Disconnect the 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 clears the hoses and eliminates possible retention of CO2 by the patient.

b) System flushing with nitrogen (N_{two})

During induction and after anesthesia, gases remaining in the respiratory system (and in the patient's lungs) contain about 79% nitrogen (N2). If the anesthetic procedure to be used is minimal or low flow, press the direct O2 flow button to eliminate this nitrogen (N2).

c) How to prevent water buildup 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 temperature difference, there is condensation in the tubes and the chemical reaction between the exhaled CO2 and the CO2 absorber.

Under conditions of lower fresh gas flow, more water will accumulate due to less gas exhaustion, and there will be:

- More residual CO2 in the absorber to react and produce water;
- More humid exhaled gas in the patient and absorber circuit and if you are using a gas analyzer, it may indicate CO2 retention by the patient even with the new Atrasorb PHARMA FREE.

Solution:

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

d) canister

The canister is a container to allocate the CO2 absorber element (Atrasorb PHARMA FREE) of the valve filter.
The canister has a transparent wall to allow viewing the color of the CO2 absorber element inside.
The exchange and/or filling is carried out by emptying and/or filling the canister with the CO2 absorber element up to the level of the canister lid.
The canister must not be filled with an unused CO2 absorber element for about 7 days or more (observe internal procedures and the equipment manufacturer's instructions for equipment cleaning and maintenance).

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

e) Replacing the CO2 Absorber Element (Atrasorb PHARMA FREE)

The valve filter makes it possible to reuse expired gases without rebreathing carbon dioxide by the patient (closed or semi-closed systems). For this, a CO2 absorber element (Atrasorb PHARMA FREE) is used.

The CO2 absorber element is a consumable, granulated material that is placed inside the canister to absorb carbon dioxide from expired gases, through a chemical filtering process.

The chemical reaction of carbon dioxide absorption by the CO2 absorber element results in the formation of water inside the canister, and also in its heating.

The CO2 absorber element has a limited useful life, at the end of which it must be replaced (see items 4.1 to 4.6).

ATTENTION

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

2 -Absorber life is measured in liters of CO2 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 DOES NOT ABSORB CO2 ANYMORE, CHANGES COLOR QUICKLY (lifetime indicator) and CAUSES CO2 REINHALATION. Therefore, never use absorber packaging to store used Atrasorb PHARMA FREE, nor mix new absorber with used absorber.

4.8 - Precautions / warnings

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

- Do not wash the CO2 absorber element with dry gas or basal or continuous flow of oxygen for a long time, outside the periods of use, as this causes the humidity to change;

- When changing the humidity of the CO2 absorber element to levels lower than those specified by the manufacturer, some undesirable reactions can be produced, regardless of the type of CO2 absorber and anesthetics being used (sevoflurane, desflurane, halothane, enflurane and isoflurane), such as as:

- Reduction in the ability to absorb CO2;
- CO2 rebreathing by the patient;
- Absorption or decomposition of the anesthetic agent;
- Increased heat generation in the CO2 absorber element which in turn causes an increase in the temperature of the gas breathed by the patient.

These reactions can cause several 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 reaction heat), superficiality of the anesthetic plane and to burns in 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 concentration of anesthetic in inspiration, immediately replace the absorber;

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

Atrasorb recommends replacing the CO2 absorber element, regardless of color, if the anesthesia machine remains unused for a period of 7 days or more (see item 4.6 of this Instruction).

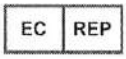
ATTENTION

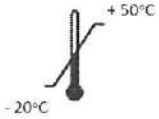
The absorbing elementCO2contains calcium hydroxide (lime) and may cause irritation to eyes, skin and respiratory system. When replacing the heat absorbing elementCO2, be careful not to spill it.

1)Empty canister with absorber elementCO2used, in an appropriate place;
2)Only fill the canister with a heat absorbing element.CO2new;
3)Make sure that when closing the filled canister, there are no dust or particles from the heat absorber element.CO2preventing system sealing.

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

5 - Table of symbols

	Manufacturer
	Authorized representative in the European Community
	Manufacturing date
	Expiration date
	not sterile
	Batch
	Does not reuse
	Fragile, handle with care
	Consult the 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 from heat
	bar code
	Medical Device

6 - Manufacturer data

Atrasorb Industria de Produtos Hospitalares Ltda.

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City:São Roque-SP

CNPJ: 05.691.570/0004-31

Contact: +55 11 5521-2076

Email:retardarb@atrasorb.com.br

7 - Data of the European representative

EC REP **CINTERQUAL Soluções de Comercio Internacional Ltd.**

Tax number / VAT No. 507288041

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

8 - Other information

For more information about the product (risks, protection and first aid measures, handling, storage, etc.) can also be found in the FISPQ (Safety Data Sheet for Chemical Products) of the product and inwww.atrasorb.com.br.