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 inhalation anesthetic circuits .

As it contains only calcium hydroxide as an absorbent, its use in procedures involving the use of 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 toxic compounds (See item 4.8 Precautions/warnings).

2 – Composition / Specification

2.1 Chemical Composition

Calcium Hydroxide (absorber);
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 %)
1344-09-8 – Sodium Silicate - Chemical formula: Na_2SiO_3 (≥ 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: SiO_2 (0.0 %)

2.2 Technical specification

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

3 – Product Description

Atrasorb PHARMA $_{FREE}$, CO2 absorber , is a chemical compound used as a filter for semi- closed or closed respiratory circuits in the medical field.

CO2 absorption area , in addition to preventing the formation of dust.

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

Atrasorb PHARMA FREE has a limited useful life, at the end of which it must be replaced so that there is no rebreathing of CO2 by the patient/user. For this purpose , it has an evolution indicator.

The indicator of the evolution of the use of Atrasorb PHARMA $_{FREE}$ is ethyl violet, which transforms the color of white lime into violet as the CO2 absorption capacity is exhausted .

Atrasorb PHARMA FREE has a moisture content of between 12 and 19% H2O (as specified by the United States Pharmacopoeia - USP). Its degree of hardness allows safe transportation, preventing the formation of dust .

Atrasorb PHARMA FREE packaging is hermetically sealed, ensuring its moisture content, enabling a 5-year product warranty.

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 a reservoir or canister suitable for depositing the product (Ex.: Anesthesia machines/systems with rebreathing).
The handling, use, monitoring and control of the product must be carried out by a qualified professional in the medical field, as well as 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 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, it must be changed when the violet coloration reaches 3/4 (three quarters) of the canister . If there is an indication of the CO2 (carbon dioxide) content in the air flow, the change must be made when the index reaches the level of 1 % CO2 .

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 the product (test performed with an air flow of 10 liters/minute with 4% CO_2 by 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 done by recording the time of use or by the maximum index of 1% CO_2 in the air flow if measurement by capnograph /gas analyzer is available, 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 Data Sheet).

ATTENTION

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 its own box). After this period, it must be discarded (see MSDS – Chemical Product Safety Data 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 it is not used immediately, its duration (CO_2 absorption capacity) will depend on factors such as:
- room temperature;
- incidence of light and sunlight;
- equipment sealing;
- loss of moisture from the product, which significantly interferes with its absorption capacity and quality of inhaled air.

ATTENTION

Each environment or mode of operation interferes differently with the product (Ex.: Use of high or low flow, temperature conditions of the surgical center, 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 inspired 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 the product . After this, it stops

absorbing CO2 and if it is left unattended for a long period, the absorber will return to its original color (the indicator will not work) as there is no chemical reaction and, therefore, it will not filter the CO2 . If you are using a gas analyzer , it will indicate CO_2 retention by the patient. The CO_2 absorber should then be replaced with a new one.

4.7 - Notes:

a) Minimal or low flow anesthesia

When using minimal or low flow anesthesia (between 0.5 and 1 liter/min) for long periods, it is common for humidity in the respiratory system hoses to increase. 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 the acceptable limits. This procedure unclogs the hoses and eliminates possible CO2 retention by the patient.

b) Flushing the system with nitrogen (N_2)

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

c) How to prevent water build-up in the system

Water accumulation in the flow sensors or the presence of water in the detection lines can cause false alarms. Water comes from two factors: exhaled gases that, when they come into contact with the environment due to the temperature difference, condense in the tubes, and the chemical reaction between the exhaled CO2 and the CO_2 absorber .

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

- More residual CO2 in the absorber to react and produce water;
- More humid exhaled gas in the patient circuit and absorber and if you are using a gas analyzer, it may indicate CO_2 retention by the patient even with new Atrasorb PHARMA FREE.

Solution:

- When replacing the absorber, empty the container water tank 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 into the flow sensors;
- Water condensation in the respiratory circuit tubes can be reduced by using an HME type filter in the patient's airway connection.

d) Canister

The canister is a container for housing the CO2 absorbing element (Atrasorb PHARMA FREE) of the valve filter. The canister has a transparent wall to allow viewing of the color of the CO2 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 cap .
The canister should not be left filled with a CO2 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 allows the reuse of exhaled gases without the patient rebreathing carbon dioxide (closed or semi-closed systems). For this, a CO2 absorbing element (Atrasorb PHARMA FREE) is used.

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 carbon dioxide absorption by the CO2 absorbing element involves the formation of water inside the canister , and also its heating.

The CO 2 absorbing element has a limited service life, at the end of which it must be replaced (see items 4.1 to 4.6).

ATTENTION

1 - Saturated Atrasorb PHARMA FREE (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 previously mentioned.

2 - The useful life of the Absorber is measured in liters of absorbed CO2 , which is approximately 7 to 8 hours or 190 liters per kilogram of the product. The Absorber used and kept at rest, after some time returns to its original color. If the canister is filled, it NO LONGER ABSORBS CO2 , CHANGES COLOR QUICKLY (useful life indicator) and CAUSES REINHALATION OF CO2 . Therefore, never use absorber 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 involving trichloroethylene and chloroform, as the reaction may lead to the formation of toxic products;
- CO_2 absorber 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;
- CO_2 absorber element is changed to levels below those specified by the manufacturer, some undesirable reactions may be produced, regardless of the type of CO2 absorber and anesthetics being used (sevoflurane , desflurane , halothane , enflurane and isoflurane) , such as:

CO_2 absorption capacity ;
- Rebreathing of CO2 by the patient;
- Absorption or decomposition of the anesthetic agent;
- Increased heat generation in the CO2 absorbing element, which in turn causes an increase in the temperature of the gas breathed by the patient.

These reactions can cause various harms to the patient, including poisoning with compound A, carbon monoxide, formaldehyde and methanol (which can be formed with the degradation of anesthetics due to low humidity or heat from the reaction), superficiality of the anesthetic plane and even 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 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 during the manufacturing process, within the requirements of the United States Pharmacopeia (USP), in the range of 12 to 19% (more commonly between 16 and 18%).

Atrasorb recommends replacing the CO2 absorbing 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

1 - The CO 2 absorber element contains calcium hydroxide (lime) and may cause irritation to the eyes, skin and respiratory system. When replacing the CO 2 absorber element , be careful not to spill it .

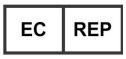
a) Empty the canister with the used CO2 absorbing element in an appropriate location ;
b **) Only** fill the canister with a new CO2 absorber element ;

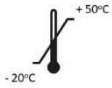
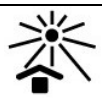
c) Make sure that when closing the filled canister , there is no dust or $CO2_{absorber}$ element particles preventing the system from sealing.

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.

Personal protective measures:
- Skin/eye protection: Tightly fitting safety glasses;
- Hand protection: Glove material: Nitrile rubber - Glove thickness: 0.11 mm;
- Respiratory protection - Required in case of dust formation: Recommended filter type: PFF2 filter.

5 – Symbol table

	Manufacturer
	Authorized representative in the European Community
	Date of manufacture
	Expiration date
	Non-sterile
	Batch

	Do not reuse
	Fragile, handle with care
	Consult 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
	Barcode
	Medical Device
	CE Marking

6 – Manufacturer data

Atrasorb Hospital Products Industry Ltd.
Address: 351 Piracicaba Avenue – Vila Nova São Roque

City: Sao Roque-SP

CNPJ: 05.691.570/0004-31

Contact: +55 11 5521-2076

Email: atrasorb@atrasorb.com.br

7 – Data from the European representative

EC REP **CINTERQUAL International Trade Solutions Ltd.**

Taxpayer/VAT number 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 MSDS (Chemical Product Safety Data Sheet) and at www.atrasorb.com.br

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

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