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 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 (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 %);
1344-09-8 – 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 fórmula: KOH (0.0 %);
7631-86-9 – Sílica – Chemical fórmula: SiO 2 (0.0 %).

2.2 Physicochemical characteristics

-Grain size: 4.5mm pill (2.36 to 4.75mm mesh) / 3.5mm and 2.5mm pill (2.36 to 4.75mm mesh)
from 2.36 to 4.00 mm);
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.
Note: The total mass of the contents may vary depending on the density of the soda lime granules. This variation is within specifications and does not compromise the effectiveness of carbon dioxide absorption or the safety of the device during use.

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 exhaled gases without rebreathing carbon dioxide (CO_2) through a chemical filtration process.

Atrasorb PHARMA FREE has a limited shelf life, after which it must be replaced to prevent CO_2 rebreathing by the patient/user. It has a progress 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 CO_2 absorption capacity is exhausted.
Atrasorb PHARMA FREE has a moisture content of 12 to 19% H2O (as specified by the United States Pharmacopeia - USP). Its degree of hardness allows for safe transportation, preventing dust formation.

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 (e.g., 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 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 and +50º C;
- Relative humidity between 10 and 90% (without condensation).

The product's expiration date is shown on the batch identification label on the packaging and 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 SDS – 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 CO_2 (carbon dioxide) content in the air flow, the change must be made 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 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 a capnograph /gas analyzer is available, which is the most efficient means of control.

4.4 - Once the maximum filtration limit is reached, the product must be removed from the canister and discarded (see SDS – 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 remain protected from heat and light (preferably stored in its own box). After this period, it must be discarded (see SDS – 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;
- sealing of the equipment;
- loss of moisture from the product, which significantly interferes with the absorption capacity and quality of the 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 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 CO_2 concentration $_{in}$ the inspired gas reaches 1% (7.6 mmHg).

c) As already specified, the absorber 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 left unattended for a long period, the absorber will return to its original color (the indicator will not activate) as there is no chemical reaction and, therefore, will not filter the CO_2. If a gas analyzer is being used, it will indicate CO_2 retention by the patient. The CO_2 absorber must then be replaced with a new one.

4.7 - Observations

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 moisture in the respiratory system hoses to increase. Disconnect inspiratory and expiratory hoses and valves and clean them before and after long procedures.
The valves contain a space for this water accumulation. Empty the hoses and valves if this water accumulation exceeds acceptable limits. This procedure unclogs the hoses and eliminates possible CO_2 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 flow or low flow, press the direct O_2 flow button to eliminate this nitrogen (N_2).

c) How to prevent water buildup in the system

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

Under conditions of lower fresh gas flow, greater water accumulation will occur due to lower 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 you are using a gas analyzer, it may indicate CO_2 retention by the patient even with the new Atrasorb PHARMA FREE.

Solution:

- When replacing the absorber, empty the container's water reservoir and the circuit tubes.
- Ensure 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 CO_2 absorbing element (Atrasorb PHARMA FREE) of the valve filter.
The canister has a transparent wall to allow viewing of 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 should not be left 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 mild soap weekly, to ensure its durability and perfect functioning, despite being autoclavable.

e) Replacement of the CO_2 absorbing 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 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 carbon dioxide absorption by the CO_2 absorbing element results in the formation of water inside the canister and also in heating it.

The CO_2 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 - Saturated Atrasorb PHARMA FREE (purple or violet) returns to its original color (white) after a few hours of standing. However, its effectiveness is reduced by more than 90%. Therefore, replace the saturated Atrasorb PHARMA FREE as previously mentioned.

2 - The absorber's useful life is measured in liters of absorbed CO_2, which is approximately 7 to 8 hours or 190 liters per kilogram of product. A used absorber that is left unused returns to its original color after some time. If the canister is filled, it NO LONGER ABSORBS CO_2, CHANGES COLOR QUICKLY (useful life indicator) and CAUSES CO_2 REINHALATION. Therefore, never use absorber packaging to store used Atrasorb PHARMA FREE, nor mix new absorbers with used absorbers.

4.8 - Precautions/warnings

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

- Do not wash the CO_2 absorber element with dry gas or basal or continuous oxygen flow 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, regardless 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 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 of 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 anesthetic concentration during inspiration, replace the absorber immediately;

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

ATRASORB recommends replacing the CO_2 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 hydroxides (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.

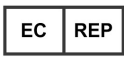
a) Empty the canister with the used CO_2 absorbing element in an appropriate location;
b) Fill the canister only with a new CO_2 absorber element;
c) Make sure that when closing the filled canister, there is no dust or CO_2 absorber element particles preventing the system from sealing.

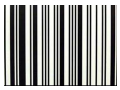
2 - In the event of a serious incident occurring with the medical device, it must be immediately reported to the manufacturer and the competent authority of the member state in which the users and/or patients are established.

Personal protective measures

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

5 – Symbol table

	Manufacturer
	Authorized Representative/Mandatory Representative in the European Community/European Union
	Date of manufacture
	Expiration date
	Non-sterile
	Batch
	Do 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
	Barcode
	Medical device
	CE Marking

6 – Manufacturer's data

Atrasorb Hospital Products Industry Ltda.
Address: Av. Piracicaba, 351 – Vila Nova São Roque

City: São Roque-SP

CNPJ: 05.691.570/0004-31

Contact: +55 11 5521-2076

E-mail: atrasorb@atrasorb.com.br

7 – Details of the authorized representative/representative in the European Community/European Union

EC REP

CINTERQUAL International Trade Solutions Ltd.

Taxpayer/VAT number 507288041

Address: Av. 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 SDS (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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