

1 - Product

Carbon dioxide absorber pills - Atrasorb PHARMA

Indications

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

Produced with a low concentration of sodium hydroxide and absence of potassium hydroxide, which significantly reduces the interaction with halogenated anesthetics, such as sevoflurane, desflurane, halothane, enflurane and isoflurane, it can be used with these agents, always observing the ideal maintenance of humidity of the product, avoiding, for example, unnecessary gas flows and keeping the system closed (valves, fans, etc.) outside the procedures (See item 4.8 Precautions / warnings).

2 – Composition / Specification

2.1 Chemical Composition

Calcium hydroxide (absorbent);

Sodium hydroxide (alkalinizing and absorbing);

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 %);

1310-73-2 – Sodium Hydroxide - Chemical formula: NaOH (≥ 2.5% - ≤ 3.0%);

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 Physical-chemical characteristics

- 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, absorber of CO₂ 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 of CO₂, 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 has a limited shelf life, at the end of which it must be replaced so that there is no rebreathing of CO₂ by the patient / user. For this, it has an indicator of evolution.

The evolution indicator of the use of Atrasorb PHARMA is ethyl violet, which transforms the color of white lime into violet as the absorption capacity of CO₂.

Atrasorb PHARMA has a moisture composition between 12 to 19% H₂O (according to the specification of the United States Pharmacopoeia - USP). Its degree of hardness allows for safe transport, avoiding the formation of dust.

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Atrasorb PHARMA packaging 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 blue color (PHARMA), Barrels of 50 kg 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 of CO₂ that contains a reservoir or canister suitable for depositing the product (eg: 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 appears on the batch identification label on the packaging and 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 the CO₂ (carbon dioxide) in the air flow, the exchange takes place when the index reaches the level of 1% of CO₂.

4.3 - In the case of intermittent use, the average time of use is 7 (seven) to 8 (eight) hours or 190 liters CO₂ per kilogram of product (test performed with an air flow of 10 liters/minute with 4% CO₂ 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 CO₂ 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).


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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 (CO₂ 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.

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Each environment or mode of operation interferes differently with the product (eg, use of high or low flow, temperature conditions in the operating room, leaks in the circuit, etc.), therefore, Atrasorb PHARMA must be replaced in the breathing system by the 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 approximately 7 (seven) to 8 (eight) hours or 190 liters 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 - Notes:

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 (N₂)

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 flow 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 exhaust 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.

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 for placing the CO₂ absorber element (Atrasorb PHARMA) 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).

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

e) Replacement of the CO₂ absorber element (Atrasorb PHARMA)

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) 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 implies the formation of water inside the canister, and also 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).

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1 -Saturated Atrasorb PHARMA (purple or violet) 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 as mentioned earlier.

2 -Absorber life is measured in liters of absorbed CO₂, 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, 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:

- 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


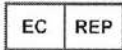





The absorbing element CO₂ contains calcium (lime) and sodium (caustic soda) hydroxides and may cause irritation to eyes, skin and respiratory system. When replacing the heat absorbing element CO₂, be careful not to spill it.




- 1) Empty canister with absorber element CO₂ used, in an appropriate place;
- 2) Only fill the canister with a heat absorbing element CO₂ new;
- 3) Make sure that when closing the filled canister, there are no dust or particles from the heat absorber element CO₂ preventing 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: PFF2 filter.

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.

Address: Avenida Piracicaba, 351 – Vila Nova São Roque

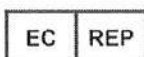
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7 - Data of the European representative



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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 in www.atrasorb.com.br.