


<b>ATRASORB INDÚSTRIA DE PRODUTOS HOSPITALARES LTDA.</b> Avenida Piracicaba, 351, Vila Nova São Roque - 18131-230, São Roque-SP, Brazil Phones: + 55 11 5521-2076 CNPJ [Corporate Taxpayer Number]: 05.691.570/0004-31 – State Registration: 653.066.864.115 e-mail : <a href="mailto:atrasorb@atrasorb.com.br">atrasorb@atrasorb.com.br</a>			 Absorvedor de CO <sub>2</sub> <b>Atrasorb PHARMA FIX</b>	
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## 1 – Produto

Carbon dioxide absorber in pellets Atrasorb PHARMA FIX

### Indications

CO<sub>2</sub> (carbon dioxide) absorbent - Atrasorb PHARMA FIX in closed or semi-closed anaesthetic inhalation circuits, with the use of halogenated anaesthetics. Also in cases where the color change after saturation has to be permanent.

As it only contains calcium hydroxide as absorber, in addition to calcium chloride and calcium sulfate, which optimize the hydration of the product, its use in procedures with halogenated anaesthetics, such as Sevoflurane, Desflurane, Halothane, Enflurane and Isoflurane is more recommended, because the absorption reaction is less exothermic, significantly reducing the formation of toxic compounds (See item 4.8 Precautions / warnings).

## 2 – Composition / Specification

### 2.1 Chemical composition and purpose:

Calcium Hydroxide (absorber)  
Calcium Chloride (Humectant)  
Calcium Sulfate (Binder)  
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)<sub>2</sub>  
10035-04-8 – Calcium Chloride – Chemical formula: CaCl<sub>2</sub>.2H<sub>2</sub>O  
100101-41-4 – Calcium Sulfate – Chemical formula: CaSO<sub>4</sub>.2H<sub>2</sub>O  
1327-36-2 – Sodium silicate - Chemical formula: Na<sub>2</sub>SiO<sub>3</sub>  
2390-59-2 – Ethyl Violet - Chemical formula: C<sub>31</sub>H<sub>42</sub>N<sub>3</sub>Cl

### 2.2 Physicochemical characteristics:

- Grain size: (2.00 to 4.75 mm): 4.5 mm average
- Grain format: semispherical pellets
- Humidity: 12 to 19% (according to application)
- Colour: white to slightly blue
- Post-saturation indicator: color change from white to violet

## 3 – Product Description

Atrasorb PHARMA FIX, CO<sub>2</sub> absorber, is a chemical compound used as a filter for closed respiratory circuits in the Medical area.

Its pyramidal or half-spherical shape provides better compaction in the tank and, consequently, greater CO<sub>2</sub> absorption area, aside from preventing powder formation.


When used in filters, combined or not, allows the reutilization of exhaled gases with no re-inhalation of Carbon Dioxide (CO<sub>2</sub>) through a chemical filtration process.

Atrasorb PHARMA FIX has a limited lifespan, at the end of which it should be replaced so there may not be re-inhalation of CO<sub>2</sub> by the patient / user. For this it has a progress indicator.

The usage progress indicator of Atrasorb PHARMA FIX is Ethyl Violet, which transforms the color of the lime from white to violet as the CO<sub>2</sub> absorption capacity is depleted.

Atrasorb PHARMA FIX has a humidity composition between 12 and 19% H<sub>2</sub>O (according to specification from the United States Pharmacopeia – USP). Its degree of hardness permits a safe transportation preventing powder formation.

The packaging of Atrasorb PHARMA FIX is hermetically sealed, ensuring its humidity content, allowing the product to have a 5-year warranty.

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## Forms of presentation

The packages are composed of Plastic Containers (available for quantities of 1.0, 4.3, 4.5, 5.0 and 18.0 Kg), with identification label of the delineated product and caps distinguished by the light blue color.

## 4 – Instructions for use

4.1 – When in systems with closed CO<sub>2</sub> absorption circuit that contain a tank or canister appropriate for deposition of the product (Ex.: Anesthesia Machines / Systems with re-inhalation).

Handling, use, monitoring and control of the product must be done by a qualified professional of the medical field, as well as the assessment of the environmental conditions for the procedures.

Handling and storage:

- In its original packaging, in a protected environment without exposure to the weather.
- Avoid mechanical shocks or strong shakes.
- Temperature range between -20° C and +50° C.
- Relative humidity between 10 and 90 % (without condensation).

The product expiration date, located in the lot identification tag in the packaging label, must be observed, to avoid its use after its lifespan.

4.2 – The average time of use is from 7 (seven) to 8 (eight) hours or 190 liters of CO<sub>2</sub> per kilogram of the product (test conducted with air flow of 10 liters/minute with 4% CO<sub>2</sub> by volume, in an anaesthesia machine with artificial servo-controlled respiratory system). The replacement must be done when the violet color reaches 3/4 (three-fourths) of the canister. If there is indication of CO<sub>2</sub> (carbon dioxide) content in the air flow, the replacement occurs when the index reaches the level of 1% CO<sub>2</sub>.

4.3 - Control must be done by recording the time of use or through the maximum index of 1% CO<sub>2</sub> in the air flow, if measurement using a capnograph / gas analyser, which is the most efficient control mechanism, is available.

4.4 – Having reached the maximum filtration limit, the product must be removed from the canister and discarded (see MSDS – Material Safety Data Sheet).

### ATTENTION!!


The material to be discarded after use must be properly identified and separated, to avoid incorrect use.

4.5 - After the opening of the packaging, it is recommended for the product to be used within a maximum of 30 days and the container to remain protected from heat and light (preferably kept in its own box). After this period, it must be disposed of (see MSDS – Material Safety Data Sheet).

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

- a) the normal procedure is that of filling of the canister and its immediate use.
- b) when its immediate use does not take place, its duration (CO<sub>2</sub> absorption capacity) will depend on factors like:
  - room temperature;
  - incidence of light and sun light;
  - equipment sealing;
  - loss of humidity of the product, which interferes significantly in the absorption capacity; and
  - quality of the inhaled air.

ATTENTION: Each environment or operation mode interferes differently in the product (Ex.: Use of high or low flow, temperature conditions in the Operating Room, Leaks in the circuit, etc.) therefore, Atrasorb PHARMA FIX must be replaced in the breathing system at least once every seven days or when the CO<sub>2</sub> concentration in the inhalation gas reaches 1% (7.6 mmHg).

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c) As already specified, the absorbent element has a lifespan (CO<sub>2</sub> absorption capacity) of approximately 7 (seven) to 8 (eight) hours or 190 liters of CO<sub>2</sub> per kilogram of the product. After this, it stops absorbing CO<sub>2</sub>. In case you are using a Gas analyser, it will indicate CO<sub>2</sub> retention by the patient. Therefore, the CO<sub>2</sub> absorbent must be replaced by a new one.

#### 4.7 Observations:

##### a) Anaesthesia with Minimum or Low Flows

When Anesthesia is employed with Minimum or Low flows (between 0.5 and 1 liter/min.), for long periods of time, it is common to increase the humidity as well in the hoses of the breathing system. Disconnect the inspiratory and expiratory hoses and valves and clean them before and after long duration procedures.

The valves contain a space for this water accumulation, empty the hoses and valves in case this water accumulation exceeds the acceptable limits. This procedure clears the hoses and eliminates a possible CO<sub>2</sub> retention by the patient.

##### b) Washing of system with Nitrogen (N<sub>2</sub>)

During induction and after anesthesia, the gases that remain in the breathing system (and in the patient's lungs) contain about 79% Nitrogen (N<sub>2</sub>). If the anaesthetic procedure to be used has minimum or low flow, press the direct O<sub>2</sub> flow button to eliminate this Nitrogen (N<sub>2</sub>).

##### c) How to prevent water accumulation in the system

Water accumulation in the flow sensors or existence of water in the detection lines can cause false alarms. Water comes from two factors: from the exhaled gases which, when in contact with the environment due to temperature difference, condense in the tubes and from the chemical reaction between the exhaled CO<sub>2</sub> and the CO<sub>2</sub> absorbent.

Under least fresh gas flow conditions, greater water accumulation will occur due to less gas depletion and there will be:

- More residual CO<sub>2</sub> in the absorbent to react and to produce water;
- More humid exhaled gas in the patient's circuit and absorbent; and
- In case you are using a Gas Analyzer, it can indicate CO<sub>2</sub> retention by the patient even with a new Atrasorb PHARMA FIX.

#### Solution:

- When replacing the absorbent, empty the water tank of the container and the circuit tubes;
- Make sure that the condensed water in the breathing circuit tubes are maintained below the flow sensors and that there is no infiltration in the flow sensors;
- Water condensation could be reduced in the breathing circuit tubes through the use of HME type filter in the connection of the patient's airways.


##### d) Canister

The canister is a container for placing the CO<sub>2</sub> Absorbent Element (Atrasorb PHARMA FIX) from the Valve Filter.

The Canister has a transparent wall to allow the display of the CO<sub>2</sub> absorbent element's colour in its interior and also a coaxial shape which allows a better distribution of the gases in its interior, therefore a better utilization of the CO<sub>2</sub> Absorbent Element.

Refilling or replacement of the canister is done by removing the conical cap and emptying or filling the canister with the CO<sub>2</sub> Absorbent Element up to the Canister's cap level.

The canister must not remain filled with the CO<sub>2</sub> Absorbent Element without use for about 7 days or more (Observe internal procedures and the instructions from the manufacturer of the equipment for cleaning and maintenance of Equipment).

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We recommend that the canister be washed weekly with water and mild soap, to ensure its durability and perfect operation, in spite of being self-sterilizing.

#### a) Replacement of the CO<sub>2</sub> Absorbent Element (Atrasorb PHARMA FIX)

The Valve Filter allows the reutilization of the exhaled gases with no carbon dioxide re-inhalation by the patient (closed and semi-closed systems). For this, a CO<sub>2</sub> Absorbent Element (Atrasorb PHARMA FIX) is used.

The CO<sub>2</sub> absorbent element is a granulated consumption material, which is placed inside the canister to absorb the carbon dioxide from the exhaled gases, through a chemical filtration process.

The chemical reaction of carbon dioxide absorption by the CO<sub>2</sub> absorbent element implies in the formation of water inside the canister, and also in its heating.

The CO<sub>2</sub> Absorbent Element has a limited lifespan, at the end of which it must be replaced (see items 4.1 to 4.6)..

#### ATTENTION!!

Never use absorbent packages to store used Atrasorb PHARMA FIX or mix the new absorbent with an used absorbent.

#### 4.8 Precautions / warnings

- Do not use it in procedures in which Trichloroethylene and Chloroform are used, because the reaction can lead to the formation of toxic products.
- Do not wash the CO<sub>2</sub> Absorbent Element with dry gas or basal or continuous oxygen flow for a long period of time, when it is not being used, because this changes the humidity;
- When humidity of the CO<sub>2</sub> Absorbent Element is changed to levels lower than what is specified by the manufacturer, some undesirable reactions can be produced, regardless of the type of CO<sub>2</sub> Absorbent and Halogen being used, such as:
  - reduction in the CO<sub>2</sub> absorption capacity;
  - re-inhalation of CO<sub>2</sub> by the patient;
  - absorption or decomposition of the anaesthetic agent;
  - increase of heat generation in the CO<sub>2</sub> Absorbent Element which in turn causes a temperature increase of the gas breathed by the patient.

These reactions can cause several damages to the patient, among these we can point out Compound A, Carbon Monoxide, Formaldehyde and Methanol poisoning (they may be formed with the degradation of anaesthetics due to low humidity or heat from the reaction), superficiality of the anaesthetic plan and even burns in the respiratory airways.

- In cases of suspected low humidity in the product, unusual temperature increase during the washing procedure or a delay in the increase of the concentration of the anaesthetic in the inhalation, immediately substitute the absorbent.
- Never add water to the absorbent to try correcting the drop in the humidity level, because it may cause a reduction in the absorption capacity due to the excess of humidity. The product has its humidity controlled in the manufacturing process, meeting the United States Pharmacopeia requirements (USP), within the 12 to 19% range (more common between 16 and 18%).

ATRASORB recommends the replacement of the CO<sub>2</sub> Absorbent Element regardless of the color, if the Anaesthesia Device has not been used for a period of 7 days or more (see item 4.6 of this Instruction).

#### ATTENTION!!













The CO<sub>2</sub> Absorbent Element contains calcium hydroxide (lime) and can cause irritation in the eyes, skin and respiratory system. When replacing the CO<sub>2</sub> Absorbent Element, be careful not to spill it.




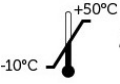



- 1) - Empty the canister with the used CO<sub>2</sub> Absorbent Element, in an appropriate place;
- 2) - Refill the canister only with new CO<sub>2</sub> Absorbent Element;
- 3) - Make sure that when closing the refilled canister, there is no dust or CO<sub>2</sub> Absorbent Element particles preventing the sealing of the system.

#### Personal protective measures

- Protection for skin/eyes: Tight-fitting safety goggles
- Hand protection: Glove material: Nitrile rubber – Glove thickness: 0.11 mm
- Breathing protection – Necessary in case there is powder formation: Type of filter recommended: P 2 Filter

### 5. Table of symbols

	Manufacturer
	Authorized representative in the European Community
	Manufacturing date
	Expiration date
	Lot
	Non sterile
	Do not reuse it
	Fragile, handle with care
	See instructions for use
	Respiratory tract irritant. Risk of serious eye injuries
	Corrosive. May cause serious skin burns and injuries to the eyes
	Caution

	Causes skin sensitization and skin and eye irritation
	Write direction for stacking
	Maximum stacking
	Storage temperature range
	Protect against humidity
	Protect against heat
	Bar Code

## 6. Manufacturer contact information



Atrasorb Indústria de Produtos Hospitalares Ltda.

**Address:** Avenida Piracicaba, 351 – Vila Nova São Roque

**City:** São Roque-SP

**CNPJ [Corporate Taxpayer Number]:** 05.691570/0004-31

**Phone:** 55 11 5521-2076



**E-mail:** [contato@atrasorb.com.br](mailto:contato@atrasorb.com.br)

## 7. European representative contact information



**CINTERQUAL. Address:** Lisbon under No. 14302/050609, headquartered at Fran Pacheco street, No. 220, 2<sup>nd</sup> floor, 2900-374 – Setúbal - Portugal, represented by its Mr. Carlos Joaquim de Carvalho Ganopa, Engineer.

**8. LABELLING**

 <p><b>Absorvedores de CO<sub>2</sub></b></p> <div style="border: 1px dashed black; padding: 5px; margin-bottom: 10px;"> <p><b>Sistema de Gestão da Qualidade</b>  Certificado ISO 9001 - TUV Rheinland do Brasil</p> <p><b>Sistema de Gestão de Produtos para Saúde</b>  Certificado ISO 13485 - TUV Rheinland do Brasil</p> </div> <p><b>Nomenclaturas:</b>  HS Code: 382499  NCH: 38249971</p> <p><b>Validade:</b>  5 anos da data de produção</p> <p><b>Certificados:</b></p>  <p>2797</p> <p><small>PRODUZIDO POR:  Atrasorb Indústria de Produtos Hospitalares Ltda  PABX: 55 11 5521-2076   E-mail: <a href="mailto:atrasorb@atrasorb.com.br">atrasorb@atrasorb.com.br</a></small></p> <p><small>Av. Piracicaba, 351, Vila Nova São Roque, São Roque - SP - Brasil - CEP 18131-230  Matriz: CNPJ: 05.691.570/0001-99 - Inscr. Estadual: 116.612.970.114  Filial: CNPJ: 05.691.570/0004-31 - Inscr. Estadual: 653.066.864.115</small></p>	<p><b>TECHNICAL DATA</b></p> <p><b>Product: ATRASORB PHARMA FIX</b></p> <p><b>LOT PX03A19-WV</b></p> <p><b>01/2019</b> <b>01/2024</b></p> <p>Moisture: 16 - 18 %</p> <p><b>Net weight: 4.500 Kg</b> <b>Gross weight: 4.700 Kg</b></p>  <p><b>7898592081193</b></p>
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**9. More information about the product (risks, protection and first aid measures, handling, storage, etc.) can also be found at the MSDS (Material Safety Data Sheet – FISPQ in Brazil) of the product and at [www.atrasorb.com.br](http://www.atrasorb.com.br).**

