


ATRASORB INDÚSTRIA DE PRODUTOS HOSPITALARES LTDA. 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 : atrasorb@atrasorb.com.br			 Atrasorb PHARMA FREE	
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1 – Product

Carbon dioxide absorber in pellets **Atrasorb PHARMA FREE**

Indications

CO₂ (carbon dioxide) absorbent - Atrasorb PHARMA FREE in pellets for medical use, in closed or semi-closed anaesthetic inhalation circuits, with the use of halogenated anaesthetics.

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

2 – Composition / Specification

2.1 Chemical composition and purpose:

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

6834-92-0 – Sodium silicate - Chemical formula: Na₂SiO₃

2390-59-2 – Ethyl Violet - Chemical formula: C₃₁H₄₂N₃Cl

2.2 Technical specifications:

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

3 – Product Description

Atrasorb PHARMA FREE, CO₂ absorbent, is a chemical compound used as filter for closed breathing circuits in Medicine, Diving, Submarines, Coal Mines and where CO₂ absorption is needed.

Its pyramidal or half-spherical shape provides better compaction in the tank and, consequently, greater CO₂ 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 (CO₂) through a chemical filtration process.

Atrasorb PHARMA FREE has a limited lifespan, at the end of which it should be replaced so there may not be re-inhalation of CO₂ by the patient / user. For this it has a progress indicator.

The usage progress indicator of Atrasorb PHARMA FREE is Ethyl Violet, which transforms the color of the lime from white to violet as the CO₂ absorption capacity is depleted.

Atrasorb PHARMA FREE has a humidity composition between 12 and 19% H₂O (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 FREE 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, 15.0, 16.0, and 18.0 Kg), with identification label of the delineated product and caps distinguished by their yellow color (PHARMA FREE).

4 – Instructions for use

4.1 – When in systems with closed CO₂ 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 - In case of continuous lime use, the replacement must be done when the violet color reaches 3/4 (three-fourths) of the canister. If there is indication of CO₂ (carbon dioxide) content in the air flow, the replacement occurs when the index reaches the level of 1% CO₂.

4.3 - In case of intermittent use, the average time of use is from 7 (seven) to 8 (eight) hours or 180 liters of CO₂ per kilogram of the product (test conducted with air flow of 10 liters/minute with 4% CO₂ by volume), bearing in mind that, between the periods of use, the lime returns to white, depending on the time between periods. Control must be done by recording the time of use or through the maximum index of 1% CO₂ 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 (CO₂ 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 FREE must be replaced in the breathing system at least once every seven days or when the CO₂ concentration in the inhalation gas

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reaches 1% (7.6 mmHg).

c) As already specified, the absorbent element has a lifespan (CO₂ absorption capacity) of approximately 7 (seven) to 8 (eight) hours per kilogram of the product. After this, it stops absorbing CO₂ and if it is at rest for a long period of time, the absorbent 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. In case you are using a Gas analyser, it will indicate CO₂ retention by the patient. Therefore, the CO₂ 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 CO₂ retention by the patient.

b) Washing of system with Nitrogen (N₂)

During induction and after anesthesia, the gases that remain in the breathing system (and in the patient's lungs) contain about 79% Nitrogen (N₂). If the anaesthetic procedure to be used has minimum or low flow, press the direct O₂ flow button to eliminate this Nitrogen (N₂).

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 CO₂ and the CO₂ absorbent.

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

- More residual CO₂ 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 CO₂ retention by the patient even with a new Atrasorb PHARMA FREE.

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 CO₂ Absorbent Element (Atrasorb PHARMA FREE) from the Valve Filter. The Canister has a transparent wall to allow the display of the CO₂ absorbent element's colour in its interior. The replacement and/or fueling is performed by emptying and/or filling the canister with the CO₂ absorbing Element up to the Canister's cap level.

The canister must not remain filled with the CO₂ 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).

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.

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e) Replacement of the CO₂ Absorbent Element (Atrasorb PHARMA FREE)

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 CO₂ Absorbent Element (Atrasorb PHARMA FREE) is used.

The CO₂ 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 CO₂ absorbent element implies in the formation of water inside the canister, and also in its heating.

The CO₂ Absorbent Element has a limited lifespan, 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 rest. However, its efficiency is reduced by more than 90%. Therefore, replace the saturated Atrasorb PHARMA FREE as previously mentioned.

2 – The lifespan of the Absorbent is measured in liters of absorbed CO₂, which is approximately from 7 to 8 hours or 180 liters per kilogram of the product. The Absorbent used and kept at rest, returns to its original color after some time. If the canister in use is refilled, it **NO LONGER ABSORBS CO₂, CHANGES COLOR RAPIDLY** (lifespan indicator) and **CAUSES RE-INHALATION OF CO₂**. Therefore, never use absorbent packages to store used Atrasorb PHARMA FREE, 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 CO₂ 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 CO₂ 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 CO₂ Absorbent and Halogenated being used, such as:
 - reduction in the CO₂ absorption capacity;
 - re-inhalation of CO₂ by the patient;
 - absorption or decomposition of the anaesthetic agent;
 - increase of heat generation in the CO₂ 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 CO₂ 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 CO₂ Absorbent Element contains calcium hydroxide (lime) and can cause irritation in the eyes, skin and respiratory system. When replacing the CO₂ Absorbent Element, be careful not to spill it.





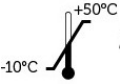



- 1) - Empty the canister with the used CO₂ Absorbent Element, in an appropriate place;
- 2) - Refill the Canister only with new CO₂ Absorbent Element;
- 3) - Make sure that when closing the refilled canister, there is no dust or CO₂ Absorbent Element particles preventing the sealing of the system.

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

7. Dados do representante europeu



CINTERQUAL Soluções de Comércio Internacional Ltda.

Legal entity No. 507288041 – Enrolled with Commercial Registry Office of Lisbon under No. 14302/050609

Address: Rua Fran Pacheco, 220, 2nd floor- 2900-374 – Setúbal - Portugal

8. Labelling



Important Informations

- Absence of sodium and potassium hydroxide
- Less intrusive space
- Greater absorption of CO₂
- When used, shows a nitids change of color
- Sealed packing
- After open check the instruction for disposal

Quality Management System
Certificate ISO 9001 - TUV Rheinland from Brazil

Health Product Management System
Certificate ISO 13485 - TUV Rheinland from Brazil

Nomenclatures: HD Code: 382480, NCM: 38249071 | Expiration: 3 years from fabrication

CE 2797 FDA

Technical Specifications

Portugués Hidróxido de cálcio, Silicato de sódio, Etil violeta, Água	Español Hidróxido de calcio, Silicato de sodio, Violeta de etila, Agua	English Calcium hydroxide, Sodium silicate, Ethyl violet, water
Deutsch Calciumhydroxid, Natriumsilikat, Ethylviolet, Wasser	Nederlands Kalk, Natriumsilicaat, Ethyl violet Water	Français L'hydroxyde de calcium, Le silicate de sodium, Ethyl violette, eau

TECHNICAL DATA
Product: **Atrasorb PHARMA FREE**
LOT: **AB09J17**
10/2017 10/2022
Moisture: 12 - 19 %
Net weight: 4.500 Kg - Gross weight: 4.700 Kg

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Irritating
Irritating to the respiratory tract. Risk of serious damage to eyes. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. Wear protective equipment for eyes and face.

Av. Piracicaba, 351, Vila Nova São Roque, São Roque - SP - Brazil - CEP 18131-230
 Head office: CNPJ: 05.691.570/0001-99 - Inscr. Estadual: 116.612.970.114
 Branch: CNPJ: 05.691.570/0004-31 - Inscr. Estadual: 653.066.864.115
 PABX: +55 11 5521-2076 | E-mail: atrasorb@atrasorb.com.br

European representative:
CINTERQUAL - Soluções de Comércio Internacional Ltda., Pessoa coletiva nº: 507288041
 Inscricao na Conservatoria do Registro Comercial de Lisboa sob o nº 14302/050609
 Rua Fran Pacheco, nº 220, 2º andar, 2900-374 - Setúbal - Portugal

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.

