GIMA

PROFESSIONAL MEDICAL PRODUCTS

DISTANZIATORE PER AEROSOL
SPACER FOR AEROSOL
SÉPARATEUR POUR AÉROSOL
SEPARADOR DE AEROSOL
CÂMARA EXPANSORA PARA AEROSSOL
SPACER FÜR AEROSOL
SPACER FÖR AEROSOL
AFSTANDHOUDER VOOR AEROSOL
ROZPĚRKA PRO AEROSOL
TÁVTARTÓ AEROSZOLHOZ
PRZEKŁADKA DO AEROZOLU
STARPLIKAS AEROSOLAM
DISTANȚIERE PENTRU AEROSOL
ODSTOJNIK ZA AEROSOL
ΑΕΡΟΘΑΛΑΜΟΣ ΓΙΑ ΑΕΡΟΛΥΜΑ

È necessario segnalare qualsiasi incidente grave verificatosi in relazione al dispositivo medico da noi fornito al fabbricante e all'autorità competente dello Stato membro in cui si ha sede.

All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.

Il est nécessaire de signaler tout accident grave survenu et lié au dispositif médical que nous avons livré au fabricant et à l'autorité compétente de l'état membre où on a le siège social.

Es necesario informar al fabricante y a la autoridad competente del Estado miembro en el que se encuentra la sede sobre cualquier incidente grave que haya ocurrido en relación con el producto sanitario que le hemos suministrado.

É necessário notificar ao fabricante e às autoridades competentes do Estado-membro onde ele está sediado qualquer acidente grave verificado em relação ao dispositivo médico fornecido por nós.

Jeder schwere Unfall im Zusammenhang mit dem von uns gelieferten medizinischen Gerät muss unbedingt dem Hersteller und der zuständigen Behörde des Mitgliedsstaats, in dem das Gerät verwendet wird, gemeldet werden.

Det är nödvändigt att meddela tillverkaren och de behöriga myndigheterna i den berörda medlemsstaten, om alla allvarliga olyckor som inträffat i samband med den medicintekniska utrustning som levererats av oss.

Alle ernstige ongelukken die zich in verband met het door ons geleverde medische hulpmiddel voordoen, moeten gemeld worden aan de fabrikant en aan de bevoegde instantie van de lidstaat waar u gevestigd bent

Je třeba nahlásit jakoukoli vážnou nehodu, ke které došlo v souvislosti s námi dodávaným zdravotnickým prostředkem, výrobci a příslušnému orgánu členského státu, ve kterém máte sídl

A gyártónak, illetve a székhely szerinti tagállam illetékes hatóságának jelezni kell bármilyen olyan súlyos balesetet, amely az általunk szállított orvostechnikai eszközzel kapcsolatban történt

Należy poinformować producenta i kompetentne władze danego Kraju członkowskiego o każdym poważnym wypadku związanym z wyrobem medycznym naszej produkcji

Par nopietnu negadījumu, kas notiek saistībā ar mūsu piegādāto medicīnisko ierīci, jāziņo ražotājam un tās dalībvalsts kompetentā iestādei, kurā negadījums ir radies

Orice accident grav produs, privitor la dispozitivul medical fabricat de firma noastră, trebuie semnalat producătorului și autorității competente în statul membru pe teritoriul căruia își are sediul utilizatorul

Potrebno je prijaviti svaku ozbiljnu nezgodu koja se dogodila u vezi s isporučenim medicinskim proizvođaču i nadležnom tijelu države članice u kojoj se nalazi

Σε περίπτωση που διαπιστώσετε οποιοδήποτε σοβαρό περιστατικό σε σχέση με την ιατρική συσκευή που σας παρέχουμε θα πρέπει να το αναφέρετε στον κατασκευαστή και στην αρμόδια αρχή του κράτους μέλους στο οποίο βρίσκεστε.

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ENGLISH

1 IMPORTANT INFORMATION

1.1 General

Please read these instructions for use carefully and completely. Do not discard, so you can consult them at a later date. If you fail to comply with the instructions for use, injury or damage to the device cannot be ruled out.

If symptoms persist or if your condition worsens, discontinue the application and contact your doctor immediately.

1.2 Information about the instructions for use

These instructions for use are intended for the user at home.

1.3 Structure of safety instructions

Safety-critical warnings are categorised according to hazard levels in these instructions for use:

- The signal word WARNING is used to indicate hazards which, without precautionary measures, can result in serious injury or even death.
- The signal word CAUTION is used to indicate hazards which, without precautionary measures, can result in minor to moderate injury or impair treatment.
- The signal word NOTICE is used to indicate general precautionary measures which are to be observed to avoid damaging the product during use.

1.4 Treatment of babies, children and anyone who requires assistance

Anyone who requires assistance must be supervised constantly by an adult during inhalation therapy.

This is the only way to ensure safe and effective treatment. Individuals in this group often underestimate the hazards involved, thus result in a risk of injury.

The product contains small parts. Small parts can block the airways and lead to a choking hazard. Therefore, make sure that you always keep all components of the product out of the reach of babies and infants.

This product is only designed for patients who are able to breathe by themselves and are conscious. This is the only way to ensure effective treatment and avoid a choking hazard.

1.5 Hygiene

Only use the spacer and accessories that have been cleaned and dried as described in chapter 4 for inhalation therapy. Contamination and residual moisture encourage the growth of bacteria, so increase the risk of infection.

Therefore, please observe the following hygiene instructions:

- - Each spacer must only be used at home by a single patient for hygiene reasons.
- Make absolutely sure you also carry out cleaning and drying before using the device for the first time.
- For cleaning, always use fresh tap water of drinking water quality.
- Make sure all components are dried properly whenever you have performed cleaning.
- Do not keep the SPACER and accessories in a damp environment or together with damp objects.

2 PRODUCT DESCRIPTION

2.1 Components

Check that all components of your DALU product are contained in your package. If anything is missing, please notify the dealer from whom you purchased the DALU product immediately.

No.	Components	Specification/Size		
		L (Large)	C (Child)	I (Infant)
1.	Masks	√	x	x
		x	√	x
		x	x	√
2.	Dust cap (optional)	√	√	√
3.	Mouthpiece	√	√	√
4.	Storage body	√	√	√
5.	Back piece	√	√	√
6.	Valves	√	√	√
7.	Whistle (optional)	√	√	√
Note: "√" stands for having this components while "×" for none				

2.2 Intended purpose

The SPACER is a holding chamber, and is used in conjunction with medication sprays or "metered dose inhalers" in the treat- ment of diseases of the airways.

2.3 Intended use

Spacer for aerosol is intended for use by treating chronic obstructive pulmonary disease and asthma with medicine-assisted inhalation device. The spacer is a holding chamber, and it is used in conjuction with medication sprays or "metered dose inhalers" in the treatment of disease of the airways.

2.4 Combination of medical devices

The Spacer for aerosol should be used in conjuction with "metered dose inhalers" in the treatment of disease of the airways. The metered dose inhalers are approximate rectangular, 23±2mm long x 16.5±2 mm wide.

There are no contraindications known.

2.5 Product combinations

The SPACER has these spefications: with small mask, with medium mask or with large mask. Patients can choose the appropriate specifications based on the size of the face.

2.6 Description of function

The SPACER helps to: minimise coordination mistakes when using metered dose inhalers avoid deposition of large quantities of medication in the oropharyngeal area, and the undesirable side effects associated therewith With a flexible connecting adaptor it can be used with all standard metered dose inhalers.

2.7 Material information

PETG/PP/ABS	Inhalation chamber, Mouthpiece
Silicone	Valve in the chamber, mask

Thermoplastic rubber	Connecting adaptor for metered dose inhaler.

2.8 Shelf life

All materials are latex-free. The shelf life ot the Spacer for Aerosol is 3 years. The product is recommended to be replaced after 12 months or be replaced after using 1460 times.

3 INHALATION

3.1 Function check

Clear pathway through the valve

After receiving the SPACER, check that the path through the valve in the mouthpiece is unobstructed.
If the valve is obstructed, the SPACER must not be used.

Position of the valve

Before every use, check that the valve is in the correct position inside the SPACER mouthpiece:

- Check that the valve is in the position shown inside the mouthpiece. If necessary, use a stream of water to correct its position.
- Dry the SPACER completely before using it again.

3.2 Preparation for inhalation

WARNING

Since the inhalation chamber of the SPACER is not completely closed, small particles can get in, and might be breathed in during an inhalation session (choking hazard). Therefore, it is imperative to make sure there are no foreign bodies inside the SPACER before every use.

CAUTION

Check all product components and the accessories before each use. Replace any broken, misshapen or seriously discoloured parts. Please also follow the instructions for assembly given below.
Damaged components and an in- correctly assembled holding chamber may impair the function of the holding chamber and thus the treatment as well.

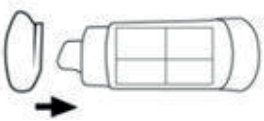
CAUTION

If the mask is being used, make sure that the expiratory valve shim is pressed out. If the valve shim is deflected inward, the dosage delivered may be insufficient when inhaling.

3.3 Performing the inhalation

- 1) Carefully examine the product for damage, missing parts or foreign objects. Remove any foreing objects prior to use.

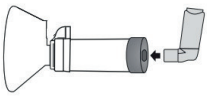
- 2) Remove CAP from the MDI, shake MDI immediately before use and insert MDI into the backpiece of the chamber.



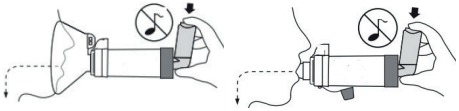
CAUTION

Before the patient starts inhaling, ensure that all parts are firmly connected to each other. Otherwise, insufficient dosage may be delivered.

- Remove CAP from the MDI, shake MDI immediately before use and insert MDI into the backpiece of the chamber.



- Try to exhale, and hold mask against the face, press MDI and inhale slowly. If there is not a mask,place lips around mouthpiece,press MDI and inhale slowly. Hold mask in place and breathe in and out through the chamber for 5-6 breaths. Slow down inhalation if a tone is heard. Hold breath for 5-10 seconds



CAUTION

If you use a mask, make sure that the mask completely covers both corners of the mouth and the nose. Otherwise, the
treatment can be less effective due to escaping aerosol, because of underdosage, for example. For possible side effects of escaping aerosol, please read the instructions for use of the medication in question.

CAUTION

Children younger than 18 months should inhale four to six times; children older than 18 months should inhale deeply two to four times. Otherwise, insufficient dosage may be delivered.
For adults, one breath is enough to inhale the medication from the SPACER

- If the doctor asks you to take medicine for more than one spray, please take a rest for one minute, and then repeat step 4 and step 5.

4 CLEANING

Regularly clean all product components and the accessories used, if they are visibly dirty immediately after use.

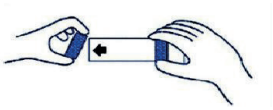
4.1 Preparation

The chamber is usually cleaned once a week.

- Take the metered dose inhaler out of the connecting ring on the inhalation chamber and close it with the protective cap provided for this purpose.
- If applicable, detach the mask from the mouthpiece.
- Disconnect the mouthpiece from the inhalation chamber (if applicable).

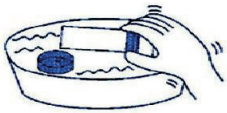
4.2 Cleaning

- Remove the back piece and disassemble the other parts of the spacer.



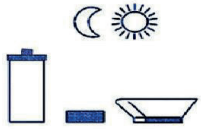
- Rinse in clean water.

- Let air dry in vertical position.

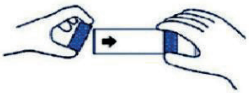


- Soak both parts for 15 minutes in lukewarm water with liquid detergent. Agitate gently.

- Shake out excess water. Do not rub dry.



- Replace back piece when unit is completely dry and ready for use.



4.3 Visual inspection

Inspect all product components after each cleaning. Replace any broken, misshapen or seriously discolored parts.

4.4 Drying and storage

- Dry all individual parts completely.

Because of the antistatic properties of the inhalation chamber,don't rub dry or heat dry.

- Place the protective cap over the mouthpiece (if applicable).

Info: The protective cap protects the mouthpiece from damage during transport and storage.

- Attach the mouthpiece to the inhalation chamber (if applicable).
- Store the SPACER and its accessories in a dry, dust-free place (safely out of continuous direct sunlight).

5 MISCELLANEOUS

5.1 Disposal

All product components can be disposed with domestic waste unless this is prohibited by the disposal regulations prevailing in the respective member countries.

5.2 Explanation of symbols

REF	Product code		Keep away from sunlight
LOT	Lot number		Keep in a cool, dry place
	Manufacturer	CE	Medical Device compliant with Regulation (EU) 2017/745
MD	Medical Device		Caution: read instructions (warnings) carefully
	Consult instructions for use	EC REP	Authorized representative in the European community
	Date of manufacture	UDI	Unique identifier

GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.