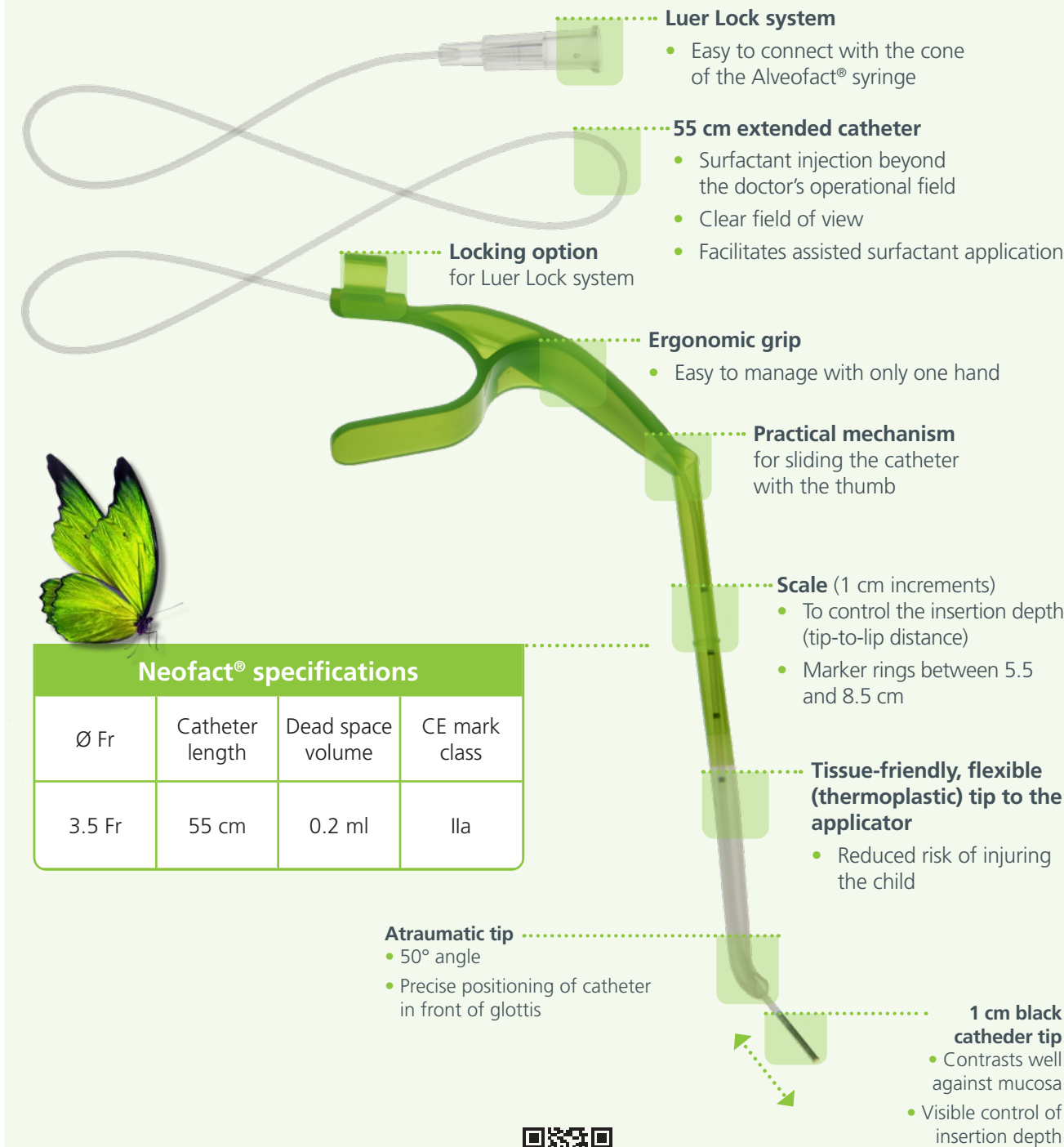


NEOFACT®

The innovative applicator for
instillation of surfactant

Approved⁴ and successfully clinically proven that less invasive
surfactant administration (LISA) is possible/feasible via Neofact⁶.

- Simple and practical handling
- Application of surfactant without Magill forceps
- Precise positioning in front of the glottis



Neofact® specifications			
Ø Fr	Catheter length	Dead space volume	CE mark class
3.5 Fr	55 cm	0.2 ml	Ila



Watch a video on the
use of Neofact® here
www.lyomark.com/neofact/

CE 0124

Alveofact®

Natural surfactant

- **High efficacy**
- **Good tolerability**
- **Convenient therapeutic management**

Effective · Tolerable · Convenient

How to reach us:

For ordering Alveofact® and Neofact®:

Phone: +49 89 / 45 08 08 78-44
Fax: +49 89 / 45 08 08 78-50
Email: sales@lyomark.com



¹ Seeger W, Grube C, Günther A, Schmidt R. (1993). Surfactant inhibition by plasma proteins: differential sensivity of various surfactant preparations. EUR Respir J 6:971-977, In-vitro-Untersuchung
² Gortner L, Bernsau U, Hellwege HH, Hieronimi G, Jorch G, Reiter HL. (1990). A Multicenter Randomized Controlled Clinical Trial of Bovine Surfactant for Prevention of Respiratory Distress Syndrome. In: An International Journal on Lungs, Airways, and Breathing, Springer International 408 Lung ISSN 0341-2040 LUNG 168(Suppl) 1-1224
³ Gortner L, Pohlandt F, Bartmann P, Disse B. (1990). "Treatment of respiratory distress syndrome (RDS) in very low birth weight infants with bovine surfactant. Monthly Journal of Paediatrics. 138:8-12"
⁴ Alveofact® SmPC (as of September 2020)
⁵ Alveofact® marketing authorisation: 19/12/1989; marketing authorisation number: 19273.00.00
⁶ Maiwald CA et al. Clinical evaluation of an application aid for less-invasive surfactant administration (LISA). Arch Dis Child Fetal Neonatal Ed, 2021; 106(2):211-214.

Alveofact® 45 mg/ml powder and solution for suspension
Active substance: Bovine lung phospholipid fraction (surfactant). **Composition:** 1 vial contains 50.76 to 60.0 mg (101.52 to 120.00 mg) bovine lung phospholipid fraction (dry powder), equivalent to a content of 66 µmol (54 mg) or 132 µmol (108 mg) total phospholipids as lyophilised powder. Other ingredients: sodium chloride, sodium hydrogen carbonate, water for injections. **Indications:** As prophylactic treatment in preterm neonates with a high risk of developing respiratory distress syndrome (RDS); as early treatment or interventional treatment in the presence of clinical and/or radiological signs of RDS. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. No substance-specific contraindications are known to date. **Note:** The benefits and risks of Alveofact® treatment for congenital infections in preterm neonates have not yet been fully explained. The efficacy of surfactant may be reduced in the presence of congenital pneumonia. Pulmonary function may also deteriorate in the event of concurrent pulmonary hypoplasia (long-term oligohydramnia from amniorrhexis or congenital renal dysfunction). **Undesirable effects:** No substance-specific adverse effects are known. Due to the fluid volume, short-term tracheal or bronchial obstruction may develop immediately after Alveofact® application. This can be resolved by increasing the inspiratory pressure for 30 to 60 seconds. **Note:** There have been isolated reports of tracheal obstruction from viscous material. No evidence has been found of a causal relationship with the use of Alveofact®. There have been reports of cerebral and pulmonary haemorrhaging, the incidence of which is roughly consistent with reports in the literature for this patient population. Sensitisation (hypersensitivity) to bovine lung protein is unlikely to already exist in preterm neonates, but could in principle lead to anaphylactoid reactions and necessitate the usual emergency therapy.
Marketing authorisation holder: Lyomark Pharma GmbH · Keltenring 17 · 82041 Oberhaching – Germany
Phone: +49 89 / 45 08 08 78 - 0 · info@lyomark.com · www.lyomark.com · **Medicinal product subject to medical prescription** · **Date of last revision of the text:** September 2020



Stand: 11/2021

Naturally unfurling the lungs



Alveofact®

Natural surfactant

Effective · Tolerable · Convenient



Alveofact® – effective

Highly effective

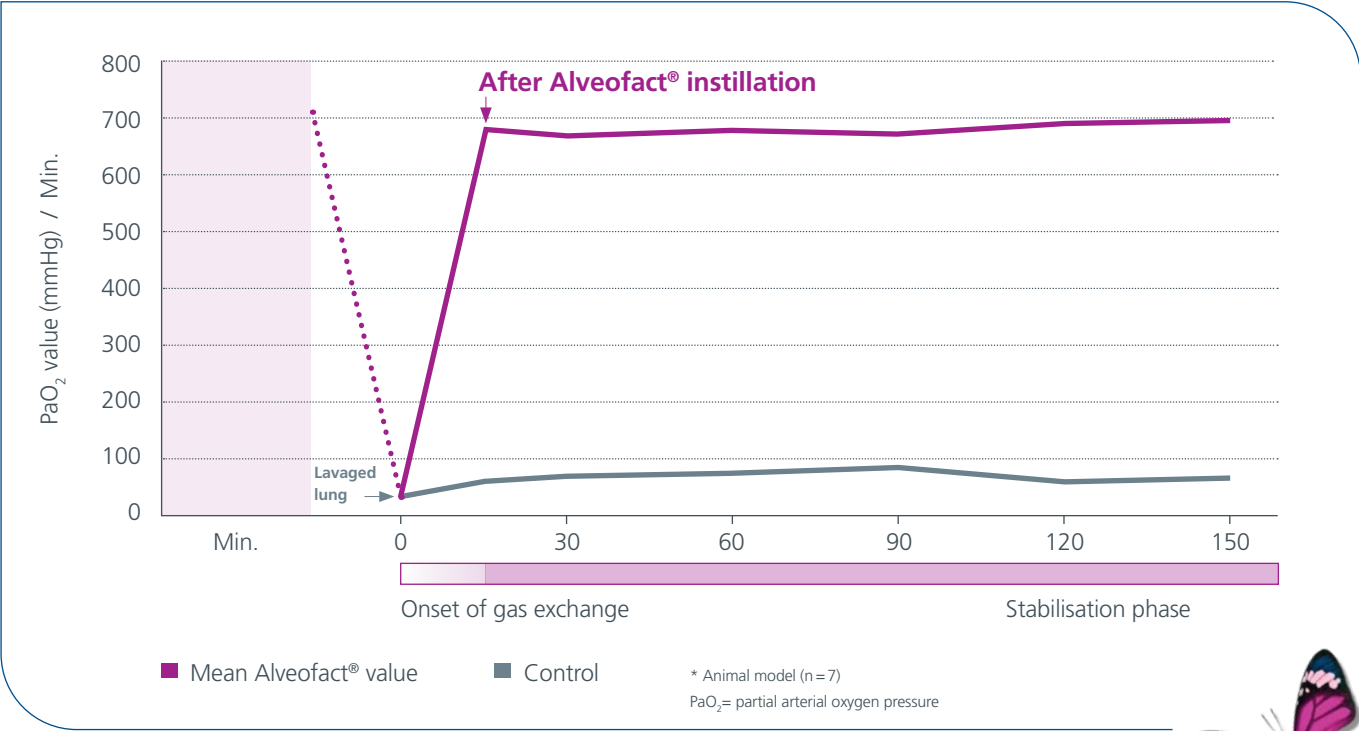
- High film stability given by the low sensitivity to surfactant inhibitors¹
- Rapid improvement in oxygenation^{2,3}

Produced in Germany to the highest quality standards

- Raw material extracted from the lung lavage of German cattle in the Allgäu region
- Wholly transparent production chain – from lung lavage to medicinal product
- Testing of each batch for biological activity at Charité University Hospital Berlin



Example: Testing of Alveofact® batches for biological activity*



Alveofact® – effective surfactant produced and tested in Germany

Alveofact® – convenient

User-friendly storage and stability:⁴

- Stable for three years without refrigeration (up to 30°C)
- No cold chain required
- No heating necessary to achieve a ready-to-use suspension
- Preparation with either a vial adapter or cannula
- Ready-to-use suspension remains stable for 24 hours (at 2°C - 8°C)



Approved for prophylaxis and therapy:⁴

- Initial dose of 100 mg/kg birth weight
- Flexible dosage: two pack sizes of 54 mg and 108 mg
- Dosage (and subsequent dosage) based on weight and requirements
- Less waste and therefore economical



Eco-friendly packaging:
Playing our part in reducing plastic waste at hospitals

Alveofact® – convenient therapeutic management with two pack sizes for dose efficiency

Alveofact® – good tolerability

Extract from Alveofact® SmPC:⁴

4.5 Interaction with other medicinal products and other forms of interaction:

No substance-specific interactions known so far.

4.8 Undesirable effects:

No substance-specific adverse effects known so far.



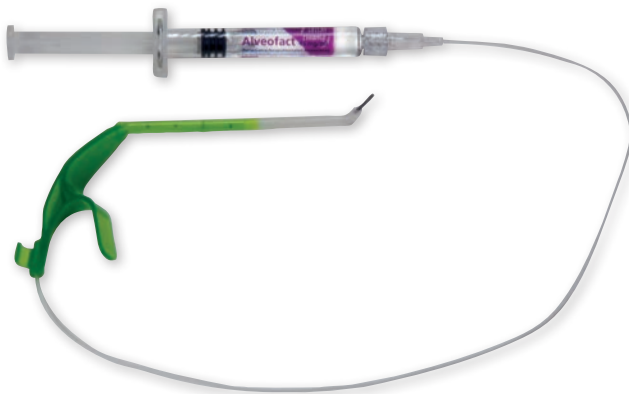
Alveofact® – no known substance-specific adverse effects⁴

Alveofact® since 1989⁵

User-friendly handling

Luer Lock system now for:

- Syringe
- Tip-cap
- Vial-adapter



Advantages of Luer Lock system:

- Firm connection improves handling during reconstitution.
- Luer Lock system establishes a firm connection between syringe and vial-adapter or cannula.
- New syringe also provides an ideal connection to the Neofact surfactant applicator.

Watch a video on the use of Alveofact® here
www.lyomark.com/alveofact/



Alveofact® and Neofact® – dependable partners in surfactant therapy