PHARCO
PHARMACEUTICALS

Direct Healthcare Professional Communication

January 2, 2023

Subject: Confirming the proper dosage and method of administration of FARCOLIN® respirator solution to prevent the potential error in clinical practice resulting from the incorrect use of the product due to the packaging type.

Pharco in agreement with Saudi Food and Drug Authority would like to inform you the correct use of Farcolin to avoid potential wrong route of administration.

Summary

Pharco corporation would like to inform you of important safety information regarding the usage of **FARCOLIN** Respirator Solution 0.5% w/v (5mg/ml) of salbutamol.

The rout of administration of this product must only be through inhalation by a suitable nebulizer and **NOT** as drops. This product should NOT be swallowed or Injected

Further clarification

- **Name of the medicinal product:** Farcolin respirator solution 0.5% w/v (5mg/ml) of salbutamol (as Salbutamol Sulfate BP)
- **Pharmaceutical form:** Solution for nebulisation.
- **Method of administration:**
  Farcolin Respirator Solution is intended for **inhalation use only**, to be breathed-in through the mouth, under the direction of a physician, using a **suitable nebulizer**. **The solution should not be injected or swallowed.**
  Farcolin Respirator Solution may be administered intermittently or continuously. Salbutamol has a duration of action of 4 to 6 hours in most patients.

Intermittent administration

Adults:

- Farcolin Respirator solution 0.5ml (2.5mg of salbutamol) should be diluted to a final volume of 2ml with sterile normal saline. This may be increased to 1ml (5mg of salbutamol) diluted to a final volume of 2.5ml. The resulting solution is inhaled from a suitably driven nebuliser until aerosol generation ceases. Using a correctly matched nebuliser and driving source this should take about ten minutes.

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الإدارة والمصانع: العامرية الكيلو ٣١ طريق الإسكندرية.القاهرة الصحراوي تليفون ٤٤٠/١٤٠/١٣٠ ٤٤٨٠ - ٠٣ - ٢+
محمول: ١٠/١٠٠٠٣٩٣١٠٠٠ - ٢+ فاكس: ٤٤٨٠٧٣٠/٤٤٨٦٥٦٠ - ٠٣ - ٢+ المراسلات: ص.ب١٢سيدي جابر- الإسكندرية
مكتب الإسكندرية: ٤٩٦طريق الحرية - بولكلي تليفون: ٥٨٢٣٧٤٥/٥٨٣٩٦٧٠ /٥٨٤٢٥٥٠ -٠٣-٥٨٤٢٥٥٠ +٢
محمول: ٢٦/١٦٨٢٠٢٥-٠١٠٠-٢+ فاكس: ٥٨٣٠٩٥٨-٠٣-٢+
مكتب القاهرة: ٢شارع محمد رشدي متفرع من شارع الجمهورية-ميدان الأوبرا تليفون: ٣٦٥/٥٢٩/٣٩٢٠٨٤٥-٠٢-٢+
محمول: ٢٨/١٦٨٢٠٢٧-٠١٠٠-٢+ فاكس: ٣٩٢١٥٣٥-٠٢-٢+

- Farcolin Respirator Solution may be used undiluted for intermittent administration. For this, 2ml of Farcolin Respirator Solution (10mg of salbutamol) is placed in the nebuliser and the patient allowed to inhale the nebulised solution until bronchodilation is achieved. This usually takes 3 - 5 minutes.
- Some adult patients may require higher doses of salbutamol up to 10mg, in which case nebulisation of the undiluted solution may continue until aerosol generation ceases. Intermittent treatment may be repeated up to four times daily.

Paediatric Population

- The same mode of administration for intermittent administration is also applicable to children. The minimum starting dosage for children under the age of 12 years is 0.5ml (2.5mg of salbutamol) diluted to 2 to 2.5ml with sterile normal saline.
- Some children (over the age of 18 months) may, however, require higher doses of salbutamol up to 5mg. Intermittent treatment may be repeated up to four times daily.
- Children aged 12 years and over: Dose as per adult population.

Continuous administration

- Farcolin Respirator Solution is diluted with sterile normal saline to contain 50-100 micrograms of salbutamol per ml, (1-2ml solution made up to 100ml with diluent). The diluted solution is administered as an aerosol by a suitably driven nebuliser. The usual rate of administration is 1-2mg per hour

The information in this letter has been approved by the Saudi Food and Drug Authority (SFDA).

Please refer to the health care provider guide at the following link
https://www.sfda.gov.sa/sites/default/files/2021-02/Farcolin%C2%AE%20HCP%20ppt%20.pdf

Call for reporting

We also encourage you to report any adverse events experienced by your patients. Please report suspected adverse drug reactions associated with **FARCOLIN®** by contacting:

Local representative/ Pharco Corporation

Aziziyah District - Zimmo Building

Tel: + 966 12 283 0181 - Mob:+966 558183111

Email: pharmacovigilance@pharco-sa.com - afnan.almahmudi@pharco-sa.com

The National Pharmacovigilance Centre (NPC) Saudi Food and Drug Authority (SFDA)

SFDA Call Center: 19999

E-mail: npc.drug@sfda.gov.sa, Website: https://ade.sfda.gov.sa

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