

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Salbutamol 2mg/ml nebuliser solution – temporary supply of unlicensed imported product

Dear Healthcare Professional,

Summary: Cipla EU Ltd would like to inform you of measures taken to ensure continuity of Salbutamol 2mg/ml nebuliser solution (PLGB 36390/0332) supply in Great Britain.

To ensure continuity in supply, Cipla (EU) Ltd. has obtained agreement from the Medicines and Healthcare products Regulatory Agency (MHRA) to supply, as an unlicensed medicine, its product which was manufactured for Australian market. This is due to some unforeseen issues at the manufacturing site of Salbutamol 2mg/ml nebuliser solution (PLGB 36390/0332). The Australian product is manufactured at a different manufacturing site and therefore this supply is not affected. Please note that the Australian product is manufactured by Cipla Ltd. using the same formulation and a similar manufacturing process as for the approved GB product. We expect normal supply to be resumed during March 2024.

A summary of the number of batches and corresponding packs imported into GB is presented into the table below.


Batch no.	Quantity (packs x 30's)	Exp. Date
IA30106	5,000	31/01/2026

As the medicinal products are identical to the approved GB product, these UK unlicensed batches will be supplied as a temporary measure and can be dispensed to patients until we resume supply of GB licensed stock with the currently approved PIL.

Please ensure the UK Summary of Product Characteristics (SPC) and Patient Information Leaflet (PIL) for Salbutamol 2mg/ml nebuliser solution (PLGB 36390/0332), are followed. For additional copies of the leaflet, please refer to Product/ Patient Information Leaflet (PIL) - (emc) <https://www.medicines.org.uk/emc/product/10257/smpc> (medicines.org.uk) or contact the company contact point (see below).

Whereas the Australian product is similar with the GB product there are some differences in presentation and the approved indications, posology, warnings and precautions, adverse reactions. These differences are summarised in the table below.

	GB Approved product	Australian product
Indications	Salbutamol nebuliser solutions are indicated for use in the routine management of chronic bronchospasm unresponsive to conventional therapy, and in the treatment of acute severe asthma.	For the relief of bronchospasm in patients with asthma or chronic obstructive pulmonary disease, and for acute prophylaxis against exercise-induced asthma or in other situations known to induce bronchospasm.
Posology	<p>Adults (including the elderly): 2.5 mg to 5 mg salbutamol up to four times a day. Up to 40 mg per day can be given under strict medical supervision in hospital.</p> <p>Paediatric Population Children aged 12 years and over: Dose as per adult population. Children aged 4-11 years: 2.5 mg to 5 mg up to four times a day.</p>	<p>Use in Adults and Children Children: 4-12 years. 2.5mg Adults: 5mg This dosage may be repeated as necessary every 4-6 hours. <i>The posology for children aged 12 years and over is missing.</i> <i>You should consider the same posology in this population as for the adult population.</i></p>
Special warnings and precautions		<p>The warning about risk of acute angle-closure glaucoma in patients treated with a combination of nebulised salbutamol and ipratropium bromide is missing in the Australian Product Information. <i>You should instruct your patients to use the product correctly and not let the solution or mist enter the eye, especially when given together with ipratropium bromide solution for nebulisation. This can be prevented by using a mouthpiece instead of a face mask or goggles.</i></p>
Undesirable effects		<p>The following undesirable effects are missing in the Australian product Information:</p> <ul style="list-style-type: none"> - Immune system disorders: bronchospasm, hypotension and collapse. - Metabolism and nutrition disorders: hypokalaemia, lactic acidosis. - Cardiac disorders: Myocardial ischaemia. - Respiratory, thoracic and mediastinal disorders: Paradoxical bronchospasm. <p>You should inform your patients about the possible occurrence of these undesirable effects.</p>

<p>Presentation</p>	<p>Product name: Salbutamol 2mg/ml nebuliser solution</p> <p>Pack size: Available in boxes containing 20 ampoules.</p> <p>Labelling: As approved by MHRA. Artworks attached.</p> <p>Shelf-life: 2 years unopened. 3 months after opening the foil over-wrap.</p> <p>Patient Leaflet: Included in the pack. Available also online on eMC website.</p>	<p>Product name: Salbutamol Cipla 5mg/2.5ml</p> <p>Pack size: Cartons of 30 x 2.5 mL ampoules.</p> <p>Labelling: As Approved by TGA. Artworks attached.</p> <p>Shelf-life: 3 years unopened. 3 months after opening the foil over-wrap.</p> <p>Patient Leaflet: Not included in the pack. Hard copies of the Australian patient leaflet will be provided by the company on request.</p> <p>An electronic copy can be access by your patients by scanning the QR code below with a smartphone.</p> 
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Please ensure all relevant staff are made aware of the content of this email and that the information is communicated to the patients.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card scheme electronically. Report via the website <https://yellowcard.mhra.gov.uk/> or search for the MHRA Yellow Card app in the [Google Play](#) or [Apple app Store](#), and some clinical IT systems (EMIS, SystemOne, Vision, MiDatabank) for healthcare professionals. Suspected side effects can also be reported by calling 0800 731 6789.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, treatment dates, and product brand name.

Company contact point

If you have any questions about this letter or require more information, please contact Cipla Medical Information team on 0800 0472144.

Dr Sahid Hocine QPPV
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Landline: +44 207 399 4891
Mobile: + 44 7876 572244

SH 17. nov. 2023

Pouch Label

Respule Label

Salbutamol
2mg/ml
nebuliser
solution
5mg / 2.5ml
For
inhalation
use
only
213661
Code No.:
GO/DRUGS/536

**Salbutamol 2mg/ml
nebuliser solution**
5mg/2.5ml

5 ampoules

Keep out of sight and reach of children.
PLGB 36390/0332

POM

Cipla

Cipla (EU) Limited,
Dixcart House, Addlestone Road,
Bourne Business Park, Addlestone,
Surrey, KT15 2LE, United Kingdom.

Each nebule contains 5mg / 2.5ml salbutamol (as sulphate)
FOR INHALATION USE ONLY.
Store in the original package. The ampoules should be protected from light after removal from the foil over-wrap.
Use within 3 months after opening the foil over-wrap.

Fill in use by date here. Use before: / / Code No.:
Use as directed by your doctor.
Read information leaflet before use.
Also contains sodium chloride, sulphuric acid for pH adjustment and water.

94/022

Carton

20 ampoules

**Salbutamol 2mg/ml
nebuliser solution**
5 mg / 2.5 ml ampoule

For inhalation use only

Cipla

Salbutamol 2mg/ml nebuliser solution
5 mg / 2.5 ml ampoule

Keep out of sight and reach of children.
Store in the original package.
The ampoules should be protected from light after removal from the foil over-wrap.
Use within 3 months after opening the foil over-wrap.

21092219

Unvarnished Area

Micro serration with lower depth

Salbutamol 2mg/ml nebuliser solution
5 mg / 2.5 ml ampoule

Each nebule contains 5mg / 2.5ml salbutamol (as sulphate).
Also includes sodium chloride, sulphuric acid for pH adjustment and water.

Inhale the solution using a nebuliser as directed by your doctor.

Please read the enclosed leaflet carefully before use.
FOR INHALATION USE ONLY.

Affix dispensing label here

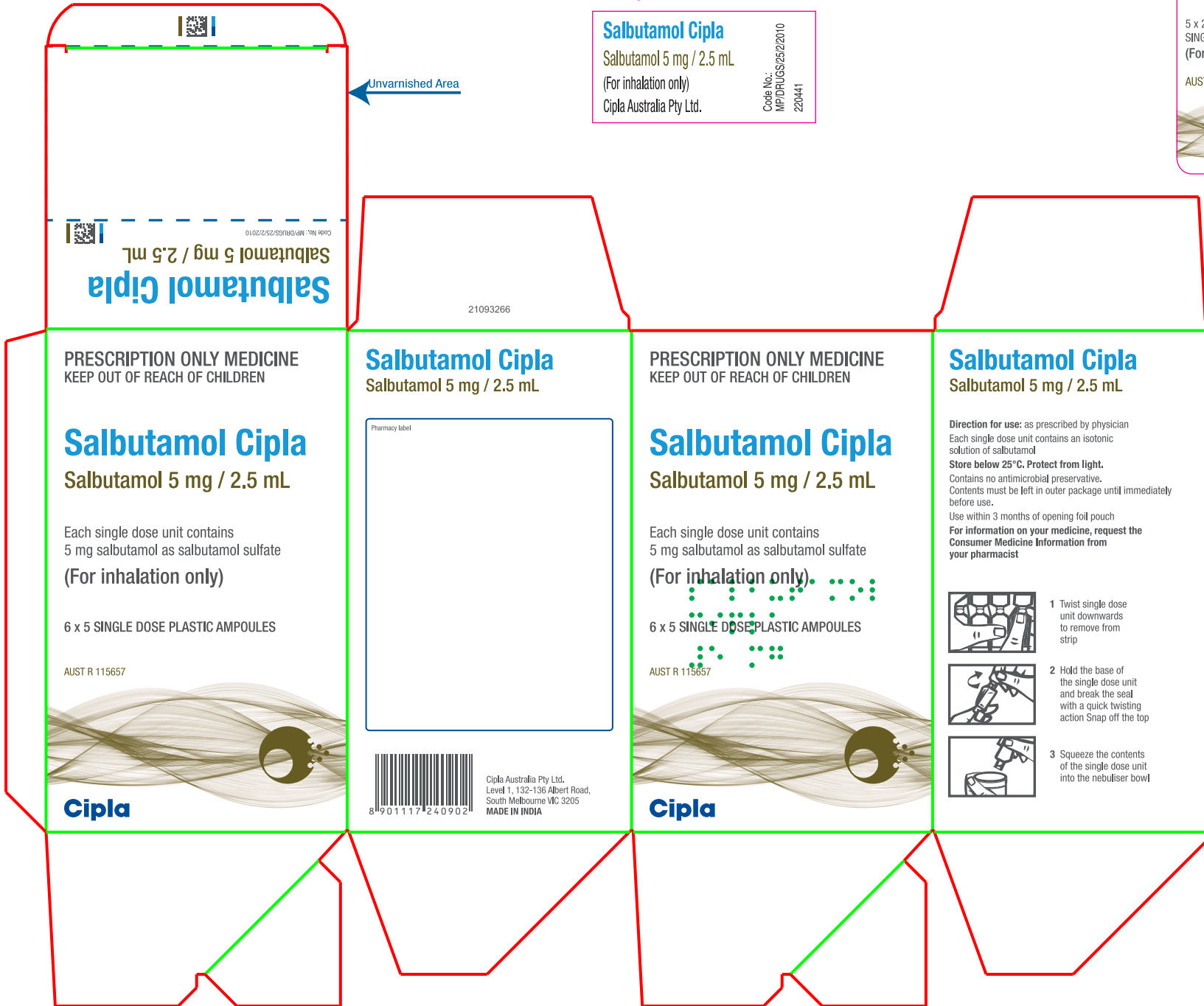
Unvarnished Area

Code No.: GO/DRUGS/536
MA Holder:
Cipla (EU) Limited,
Dixcart House, Addlestone Road,
Bourne Business Park, Addlestone,
Surrey, KT15 2LE, United Kingdom.
PLGB 36390/0332

POM

8 901117 003033

Carton



Respule Label

Salbutamol Cipla
 Salbutamol 5 mg / 2.5 mL
 (For inhalation only)
 Cipla Australia Pty Ltd.

Code No.:
 MP/DRUGS/25/2/2010
 220441

Pouch Label

PRESCRIPTION ONLY MEDICINE
 KEEP OUT OF REACH OF CHILDREN

Salbutamol Cipla
 Salbutamol 5 mg / 2.5 mL

5 x 2.5 mL PLASTIC AMPOULES
 SINGLE DOSE UNITS
 (For inhalation only)

AUST R 115657

Store below 25°C. Protect from light.
 Record date when foil first opened.
 Use within 3 months

Cipla
 Cipla Australia Pty Ltd.
 Level 1, 132-136 Albert Road,
 South Melbourne VIC 3205
 MADE IN INDIA
 Code No.: MP/DRUGS/25/2/2010

220442

PRESCRIPTION ONLY MEDICINE
 KEEP OUT OF REACH OF CHILDREN

Salbutamol Cipla
 Salbutamol 5 mg / 2.5 mL

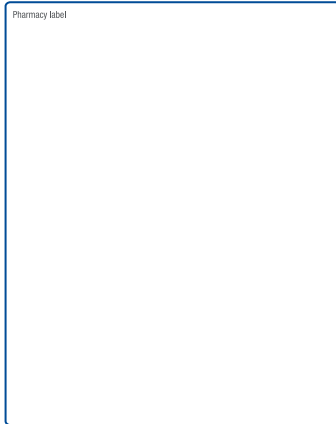
Each single dose unit contains
 5 mg salbutamol as salbutamol sulfate
 (For inhalation only)

6 x 5 SINGLE DOSE PLASTIC AMPOULES

AUST R 115657

Cipla

Salbutamol Cipla
 Salbutamol 5 mg / 2.5 mL



Cipla Australia Pty Ltd.
 Level 1, 132-136 Albert Road,
 South Melbourne VIC 3205
 MADE IN INDIA

PRESCRIPTION ONLY MEDICINE
 KEEP OUT OF REACH OF CHILDREN

Salbutamol Cipla
 Salbutamol 5 mg / 2.5 mL

Each single dose unit contains
 5 mg salbutamol as salbutamol sulfate
 (For inhalation only)

6 x 5 SINGLE DOSE PLASTIC AMPOULES

AUST R 115657

Cipla

Salbutamol Cipla
 Salbutamol 5 mg / 2.5 mL

Direction for use: as prescribed by physician
 Each single dose unit contains an isotonic
 solution of salbutamol
Store below 25°C. Protect from light.
 Contains no antimicrobial preservative.
 Contents must be left in outer package until immediately
 before use.
 Use within 3 months of opening foil pouch
**For information on your medicine, request the
 Consumer Medicine Information from
 your pharmacist**



1 Twist single dose
 unit downwards
 to remove from
 strip



2 Hold the base of
 the single dose unit
 and break the seal
 with a quick twisting
 action Snap off the top



3 Squeeze the contents
 of the single dose unit
 into the nebuliser bowl