

24-Aug-26

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Asthalin 100 micrograms Inhaler (Salbutamol Sulphate), PLGB 36390/0330 – Clarification of paediatric dosing information on the outer carton

Dear Healthcare Professional,

Summary

Cipla (EU) Limited in agreement with the MHRA would like to inform healthcare professionals of an inconsistency between the age-related information currently printed on the outer carton of Asthalin 100 micrograms Inhaler and the approved UK Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL).

The outer carton of certain batches currently in the UK market states:

“For adults and children over 12 years of age.”

This statement is outdated and does not reflect the currently approved product information.

The current approved SmPC and PIL include dosing recommendations for **children aged 4–11 years**, as well as for **adults and children aged 12 years and over**.

Healthcare professionals should therefore refer to and follow the currently approved SmPC and PIL when prescribing, dispensing or advising patients on the use of Asthalin 100 micrograms Inhaler.

Further information

The discrepancy relates solely to the age-related statement on the outer carton. There is no change to the formulation, quality, efficacy or performance of Asthalin 100 micrograms Inhaler.

The relevant information is summarised below:

	Outer carton of affected batches	Current approved UK SmPC/PIL
Age-related information	“For adults and children over 12 years of age.”	Asthalin is indicated for use in adults, adolescents and children aged 4–11 years. Dosing recommendations are provided for children aged 4–11 years and for adults and children aged 12 years and over.
Action for healthcare professionals	Disregard the age statement on the affected outer carton to determine patient eligibility or dosing.	Follow the current approved SmPC and PIL for prescribing, dispensing and dosing information.

The discrepancy arose because the outer carton wording was not updated following an earlier regulatory variation that introduced dosing recommendations for children aged 4–11 years into the approved product information.

Cipla (EU) Limited has revised the carton artwork to align it with the currently approved SmPC and PIL. Future batches will be supplied using the corrected carton artwork.

Advice to healthcare professionals

Please:

- continue to prescribe and dispense Asthalin 100 micrograms Inhaler in accordance with the current approved SmPC;

- be aware that the statement “For adults and children over 12 years of age” on the outer carton of affected batches does not reflect the current approved paediatric use of the product;
- reassure patients, parents and caregivers, where necessary, that affected inhalers may continue to be used in accordance with the prescribing instructions and the current PIL; and
- ensure relevant healthcare professionals and pharmacy staff are made aware of this information.

The current approved UK SmPC and PIL for Asthalin 100 micrograms Inhaler (PLGB 36390/0330) are available on the electronic Medicines Compendium (eMC).

Call for reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the [Yellow Card website](#)
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

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

Company contact point

If you have any questions about this communication or require further information, please contact:

Cipla Medical Information

Tel: **0800 047 2144**

Yours sincerely,

Dr Sahid Hocine
UK QPPV
Cipla (EU) Limited