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Product Information Update (PIU): Important information for healthcare professionals

Brief summary:

Salbutamol pressurised metered dose inhaler - reinforcing information regarding number of prescribed doses available.

Dear Healthcare Professional,

This letter is to reinforce information about salbutamol pressurised metered dose inhaler (pMDIs) without dose counters in relation to the number of prescribed doses available as per the label.

The inhaler contains enough salbutamol for 200 actuations (puffs) only. After 200 actuations (puffs), the inhaler can continue to spray but without the prescribed dose of salbutamol.

Action required by Healthcare Professionals

Please ensure that all relevant staff are made aware of the content of this letter and that the information below is communicated to patients:

“Your inhaler contains enough medicine for 200 puffs only (whether inhaled and/or released into the air for testing) and it contains a propellant gas to deliver the medicine. However, after 200 puffs, your inhaler can continue to spray the gas but without the right dose of salbutamol, so you cannot be sure you will receive any medicine after using 200 puffs. The inhaler does not have a dose counter. Methods of telling that the inhaler is empty like shaking it, weighing it, floating it in water, are not reliable and are not recommended. Cases of severe worsening of asthma symptoms following accidental use of empty inhalers have been reported. It is recommended that you record the number of puffs used and that you have a spare inhaler available. If you are using more than one inhaler, it is recommended to keep track of the number of puffs for each inhaler separately”.

The communication of this information has been agreed with the Health Products Regulatory Authority (HPRA).

Reporting of suspected adverse reactions

Adverse events should be reported directly to the Health Products Regulatory Authority (HPRA) on their website: www.hpra.ie. Adverse events should also be reported to GlaxoSmithKline on 1800 244 255 or via online form <https://gsk.public.reportum.com>.

If you have any questions, please contact GSK Medical Information on 1800 244 255.

Yours faithfully

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Country Medical Director

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