Medicines & Healthcare products Regulatory Agency

DRUG SAFETY UPDATE (DSU)

Short-acting beta 2 agonists (SABA) (salbutamol and terbutaline): reminder of the risks from overuse in asthma and to be aware of changes in the SABA prescribing guidelines

Specialisms: *General practice, Pharmacy, Respiratory disease and allergy*

Summary

Healthcare professionals and patients are reminded of the risk of severe asthma attacks and increased mortality associated with overuse of SABA with or without anti-inflammatory maintenance therapy in patients with asthma. Healthcare professionals should be aware of the change in guidance that no longer recommends prescribing SABA without an inhaled corticosteroid.

Advice for Healthcare Professionals:

- excessive use of SABA to relieve acute asthma symptoms may mask progression of the underlying disease and contribute to an increased risk of severe and potentially life-threatening asthma exacerbations
- do not prescribe SABA to people of any age with asthma without a concomitant prescription of an inhaled corticosteroid[1] (see Asthma: diagnosis, monitoring and chronic asthma management (BTS, NICE, SIGN) NICE guideline [NG245], 2024)
- ensure all patients with asthma receive optimal anti-inflammatory maintenance therapy even when their asthma is well controlled and that treatment is individualised to the patient
- review and adjust asthma treatment in patients who take more than twice weekly “as needed” SABA
- urgently review patients where there has either been an increase in the number of prescriptions requested for SABA reliever inhalers or a failure to collect prescribed anti-inflammatory maintenance treatment
- anti-inflammatory reliever (AIR) therapy and maintenance and reliever therapy (MART) are recommended alternatives for people over 12 years of age with poorly controlled asthma[1].
- report suspected adverse drug reactions to the Yellow Card scheme

Advice for Healthcare Professionals to Provide to Patients:

- seek urgent medical assistance if worsening asthma symptoms (for example, chest tightness, wheezing, coughing, or difficulty breathing) are not relieved by using the asthma reliever medicines prescribed by a healthcare professional to be used during an asthma attack
- if a blue inhaler is prescribed as the asthma reliever medication to be used during an asthma attack, a separate asthma preventer therapy will always be prescribed for regular daily use as well
- use the asthma anti-inflammatory maintenance medication as prescribed by a healthcare professional even when asthma is well-controlled and the blue inhaler is rarely or never needed
- if the blue inhaler does not have a dose counter, manually track the doses used and ensure you always have access to a spare inhaler before your current inhaler runs out or expires.
- follow your agreed asthma plan if you have one or ask your healthcare professional for an asthma review if the prescribed asthma blue reliever inhaler is needed more than twice a week.
- your healthcare professional can provide advice on recommended alternative treatments (to the blue inhaler) for people over 12 years of age with poorly controlled asthma.
- report suspected adverse drug reactions to the Yellow Card scheme

Background

The asthma reliever medications salbutamol and terbutaline are prescription-only SABA medications used to treat breathing problems in people with asthma and similar conditions.

Prior to December 2024, inhaled SABA was recommended to be used as required as reliever therapy for people with symptomatic asthma. In a small minority of people with asthma with infrequent, short-lived wheeze, and normal lung function, occasional use of inhaled SABA reliever therapy was considered as potentially the only treatment needed to manage their symptoms.

Updates to SABA product information

A review of the risk of SABA overuse was initiated in the UK by the MHRA and in the EU by the Pharmacovigilance Risk Assessment Committee (PRAC) in 2022. The evidence reviewed included published observational data from 187,675 UK primary care electronic health care records from patients with asthma aged 12 years and over as well as similar data from other participating countries[3]. An association was identified in the UK across all asthma severities between having 3 or more SABA prescriptions over the 1-year study

period and experiencing severe asthma exacerbations. This association was independent of the use of anti-inflammatory maintenance asthma therapy.

Based on the findings of the review[4,5], regulatory action was taken in 2023 to strengthen the warnings in the approved UK product information for SABA medications on the risk of masking asthma deterioration by overuse of SABA relievers.[6,7]

Advice was also included

- on the importance of regular use of preventer medication even when asthma is well controlled and when a reliever inhaler is rarely needed
- recommending that patients seek medical attention as soon as possible if their use of a SABA reliever inhaler increases. This is to ensure timely re-evaluation of asthma treatment.

Updates to the UK asthma guidelines 2024[1,2]

The UK asthma guidelines[1] were updated in November 2024 following a review of the evidence from multiple sources including national reviews of asthma deaths in both adults and children. The evidence highlighted that clinical outcomes with asthma were poorest in all age groups when using SABA alone. SABA overuse was associated with an increased risk of severe asthma exacerbations, hospitalisations and mortality irrespective of asthma severity or co-administration of anti-inflammatory therapy. As a result, in accordance with the updated UK asthma guidelines, the prescribing of inhaled SABA monotherapy for people of any age with asthma without prescribing a concomitant approved asthma preventer anti-inflammatory medication is no longer recommended. The guidance now recommends that the majority of people with asthma should be controlled on either AIR or MART treatment without the need for SABA. The personalised asthma action plan should be reviewed at every asthma review to ensure pharmacological treatment is optimised if asthma control is suboptimal.

National Child Mortality Database report[8]

A report was published in December 2024 by the UK National Child Mortality Database Programme on child deaths which occurred between April 2019 and March 2023 due to asthma or anaphylaxis. The findings confirmed previous evidence on the risks associated with overuse of SABA. Of the 54 child deaths due to asthma which were identified, 87% (47) had an excessive number of reliever inhalers (three or more) dispensed in the year before their death, with 27 children (50%) having 12 or more reliever inhalers dispensed. Furthermore, for 35 (65%) children, there was insufficient dispensing of preventer inhalers with fewer than 9 dispensed in the year preceding their death, and 23 (43%) children receiving 4 or fewer preventer inhalers.

Reporting advice

Healthcare professionals, patients, and caregivers are asked to submit reports using the Yellow Card scheme electronically using:

- the Yellow Card website.
- the Yellow Card app; download from the Apple App Store or Google Play Store
- some clinical IT systems for healthcare professionals (EMIS, SystmOne, Vision, MiDatabank, and Ulysses)

When reporting suspected adverse drug reactions, please provide as much information as possible, including information about medical history, any concomitant medication, onset timing, and treatment dates.

Additional information

You can sign up to receive email notifications for Drug Safety Updates.

You can sign up to receive our monthly round-up of safety communications.

References

1. NICE Guideline [NG245]. 'Recommendations | Asthma: diagnosis, monitoring and chronic asthma management (BTS, NICE, SIGN) | Guidance | NICE' 27 November 2024
2. Primary Care Respiratory Society (PCRS) Guide. 'New asthma guidelines infographic - FINAL' 2024
3. Quint JK and others. 'Short-Acting Beta-2-Agonist Exposure and Severe Asthma Exacerbations: SABINA Findings From Europe and North America'. J Allergy Clin Immunology Pract. 2022: Volume 10(9), pages 2297-2309.
4. Scientific Conclusions of the Review of Terbutaline. 'Terbutaline: CMDh scientific conclusions and grounds for the variation, amendments to the product information and timetable for the implementation - PSUSA/00002897/202112'.13-14 September 2022.
5. Scientific Conclusions of the Review of Salbutamol. 'Levosalbutamol, Salbutamol: CMDh scientific conclusions and grounds for the variation, amendments to the product information and timetable for the implementation – PSUSA/00010330/202301'. 10-11 October 2023.
6. Salbutamol product information
7. Terbutaline product information
8. National Child Mortality Database Programme Thematic Report. 'Asthma-and-anaphylaxis.pdf' December 2024

Stakeholder engagement:

- Royal College of General Practitioners
- Asthma + Lung UK

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