08/02/2021

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Direct Healthcare Professional Communication

Soprobec (beclometasone dipropionate) 200 micrograms per actuation pressurised inhalation solution – change in the colour of plastic actuator and protective cap

Dear Healthcare Professional,

The Marketing Authorisation Holder of Soprobec (beclometasone dipropionate) 200 micrograms per actuation pressurised inhalation solution, in agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), would like to inform you about the imminent change in the colours of the plastic actuator and protective cap of this product, as described below:

Summary

- **Soprobec 200 micrograms inhaler, with a light brown actuator with cream dust cap, will soon be replaced by a pink actuator with red dust cap.**
- **The new coloured inhalers contain the same medication as before and patients can continue as normal with the new inhalers.**
- **The changes are to avoid confusion with a similar product with a lower strength of beclomethasone dipropionate.**
- **The new coloured inhaler has a message "New actuator colour" on the outer carton, including the pink colour of the side flash.**

Background to safety concern

Soprobec is indicated for the prophylactic management of mild, moderate, or severe asthma in adults or children:

- Mild asthma: Patients requiring intermittent symptomatic bronchodilator asthma medication on a regular basis.
- Moderate asthma: Patients with unstable or worsening asthma despite prophylactic therapy or bronchodilator alone.
- Severe asthma: Patients with severe chronic asthma and those who are dependent on systemic corticosteroids for adequate control of symptoms.

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The change in colours of the plastic actuator and protective cap of this product was proposed by the Marketing Authorisation Holder following the concerns expressed by MHRA with regards to a potential risk for confusion with a similar beclometasone product of lower strength and therefore being considered as having a potential patient safety implication.

The above change in colours of the plastic actuator and protective cap have been approved by MHRA and will be implemented in the manufacture of new batches shortly to be phased into the UK supply chain.

Since Soprobec 200 micrograms Inhaler with approved colours is already in UK market, there is possibility of both colours of the Soprobec 200 micrograms inhaler being available at the same time in the market, which may lead to possible confusion and potential patient safety implications.

To avoid issues associated with having two different coloured versions of the Soprobec 200 microgram inhalers available at the same time, Glenmark would like to clarify and inform about these changes to new Soprobec 200 micrograms Inhaler to all healthcare professionals:

- The new coloured inhalers contain the same active medication (beclometasone dipropionate) and ingredients as before, and therefore require no change to either the way prescriptions are written, or the way patients manage their asthma.
- The medicine is provided in the same inhaler device (pressurised metered dose inhaler; pMDI).
- The only differences are related to appearance: the colour of the actuator and protective dust cap changed to pink and red, respectively (instead of brown and cream, respectively; see images below).
- The differences in colours have no effect on the safety profile (adverse effects) of the product or in the way it should be administered by the patient.
- The change in colour was done just to avoid a potential risk for confusion of the product in old colours for actuator and cap with a similar product.
- To further assist in recognising the batches carrying the new coloured inhaler, the outer carton are marked with the message “New actuator colour” and include pink coloured side flashes (see images below).

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Soprobec 200 micrograms Inhaler with **NEW actuator/protective cap colour**	Soprobec 200 micrograms Inhaler with **OLD actuator/protective cap colour**
	

Further information on recommendations to healthcare professionals

If dispensing this product, healthcare professionals should:

- Check carefully the dosage of the product written on the labelling on the packaging and the product pack contains the inhaler with new colours for actuator and protective cap, i.e. the carton has the statement "New actuator colour" included on the colour of the side flash.
- If the patient has used before Soprobec 200 micrograms, clarify for the patient and/or caregiver that apart from the colour changes the product is the same as that previously used and requires no difference to the way the inhaler is used or how the product works.
- As usual, recommend that patients keep track of when they start to use their inhaler (each inhaler contains 200 doses of medication) to ensure they have an ongoing supply e.g. if a patient is taking two puffs of their inhaler twice a day, this means the inhaler will last for over a month.
- Remind your patients to clean their inhaler once a week as usual.
- Inform the patient and/or caregiver that more information about this change in colours, how to use, store and clean their Soprobec inhaler is available on the website: www.soprobec.co.uk/.

Call for reporting

Healthcare professionals are asked to report any suspected adverse reactions to the Yellow Card Scheme electronically.

Report via the website https://www.gov.uk/yellowcard, the free Yellow Card app available from the Apple App Store or Google Play Store, and some clinical IT systems (EMIS, SystmOne, Vision, MiDatabank) for healthcare professionals. People who do not have online access to report a suspected side effect to the Yellow Card scheme can call 0800 731 6789 for free.

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

Company contact point
Any suspected adverse reactions should also be reported to the company:

Glenmark Pharmaceuticals Europe Ltd
Building 2, Croxley Green Business Park, Watford WD18 8YA,
Tel: 0800 458 0383

If you have further questions or require additional information, please contact the Glenmark Medical Information department (Telephone: 0800 458 0383; Email: Medical_information@glenmarkpharma.com).

Yours sincerely,

Gauri Utturkar
UK QPPV