

Clenil® Modulite® 100mcg (beclometasone): release of batches of different appearance and without dose indicator; actions needed from dispensers

Dear Healthcare Professional,

Due to an increased demand, additional batches of Clenil® Modulite® (beclometasone) 100mcg are to be released into the UK supply chain following authorisation by the Medicines and Healthcare products Regulatory Agency (MHRA). These batches are likely to come into circulation from 11th May 2020 and full details of concerned batch numbers can be found at the following website link:

<https://www.chiesi.uk.com/supply-of-chiesi-products>

Summary of key information related to batch variation:

- These inhalers contain the same medication as before, beclometasone, and therefore require no change to either the way prescriptions are written, or the way patients manage their asthma.
- Medicine is provided in the same inhaler device (pressurised metered dose inhaler; pMDI).
- The only differences in the batch variation are related to the appearance:
 - The colours of the plastic actuator and protective cap are beige and yellow respectively (instead of brown and beige respectively; see images below);
 - The beige actuator is not embossed;
 - There is no dose indicator, however patients who received Clenil 100mcg prior to September 2019 (when this feature was added to the inhaler) may not notice that a dose indicator is not included.
 - The differences have no effect on the safety profile (adverse effects) of the medicine, however, patients should have increased vigilance for when they may need a new inhaler and should confirm the dosage on the labelling of the outer package and canister.



Clenil 100mcg inhaler
subject to the batch-specific variation



Clenil 100mcg inhaler from a regular batch

If dispensing this product, healthcare professionals should:

- Check carefully the dosage of the Clenil 100mcg inhaler written on the labelling on the packaging, prior to dispensing as the Clenil 100mcg; this medicine is a very similar colour to Clenil 50mcg. Patients/caregivers should also be advised to check the dosage on the labelling on the package and the canister.
- As usual, recommend that patients keep track of when they start to use their inhaler – each Clenil 100mcg inhaler (irrespective of batch) contains 200 doses of medication so if a patient is taking two puffs of their inhaler twice a day, this means the inhaler will last for over a month.
- Clarify to patients and caregivers that, as with all strengths of Clenil, the inhaler can be used with a volumetric spacer.
- Remind your patients to clean their inhaler once a week as usual, referring to the package leaflet for cleaning instructions.

Additional information

We expect continued stock deliveries over the coming weeks and months, and we have good stock levels of all our products. We can also confirm that production of all our respiratory products continues uninterrupted at all of our manufacturing sites.

We repeat our appeal to all healthcare professionals involved in prescribing and dispensing our range of products to help us maintain supply by continuing to write monthly repeat prescriptions rather than prescriptions for multiple months' supply of inhalers until such time as the short-term pressures begin to ease. This will help us immensely in being able to continue to supply all our products to all our patients during this time by bringing demand in line with supply.

Adverse Event Reporting

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. Report on the Yellow Card Scheme website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Chiesi Limited on 0800 009 2329, or at pv.uk@chiesi.com.

Further Information

Please do not hesitate to contact Medical Information (medinfo.UK@chiesi.com) should you have any further questions or require additional information.

Many thanks,