

June 2021

Clenil® Modulite® (beclometasone): release of additional batches for all strengths using the standard colours of the inhaler actuators with no dose indicator

Dear Healthcare Professional,

As Chiesi continues to experience increased demand for inhalers, in order for all strengths of Clenil (beclometasone; 50/100/200/250mcg) to be available to patients in actuators using the standard colours, new additional batches of all strengths (with no dose indicator) will be released into the UK supply chain following authorisation by the Medicines and Healthcare products Regulatory Agency (MHRA). These inhalers are likely to come into circulation from July 2021 for several months and will provide patients reassurance as the colour of their inhalers will be familiar.

For further information of concerned batch numbers please visit the Chiesi UK website:
<https://www.chiesi.uk.com/supply-of-chiesi-products>

Summary of key information related to additional batches with no dose indicator:

- 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.
- The medicine is provided in the same inhaler device (pressurised metered dose inhaler; pMDI).
- The only difference in the new additional batches is **the lack of dose indicator** on any strength of Clenil (50/100/200/250mcg)
 - Please note that the previous Clenil 100mcg inhalers with no dose indicator (supplied since May 2020), where the colour of the plastic actuator and protective cap were beige and yellow respectively; these may still be in the supply chain (Figure 1). From July 2021, all strengths will be replaced by new batches where the actuator and cap will revert back to the standard colours but **without a dose indicator** (Figure 2).
- These differences have no effect on the safety profile (adverse effects) of the medicines, 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 packaging and canister.



Figure 1
Clenil 100mcg inhaler subject to the batches supplied since May 2020 (to be discontinued)

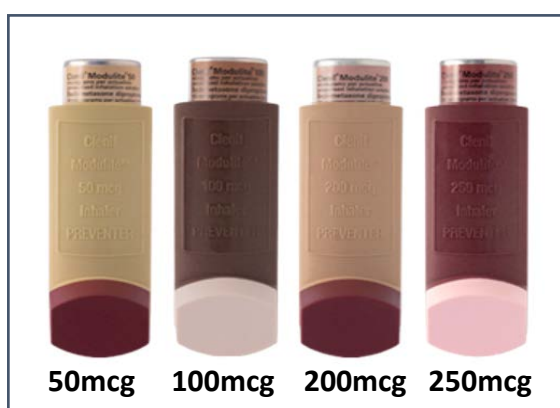


Figure 2
Clenil 50/100/200/250mcg inhalers subject to the **new** batches available from July 2021 with no dose indicators

- The batches will be released with previously authorised packaging i.e. the carton, label, and leaflet without the dose indicator information.

If dispensing this product, healthcare professionals should:

- Advise patients/caregivers that this inhaler does not contain a dose indicator but that the medicine and the inhaler are the same.
- Advise patients/caregivers 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 inhaler (irrespective of batch or strength) 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 all strengths of Clenil 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.

Adverse Event Reporting

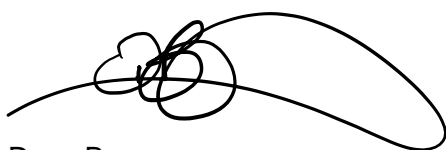
Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme. Report on the Yellow Card Scheme website www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

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,



Dave Barnes

Technical Director