Formulary Decision Guide: Asthma

Beclu 100&200 beclometasone dipropionate

KEY POINTS

- Beclu is an inhaled corticosteroid (beclometasone dipropionate) delivered via a pressurised metered dose inhaler (pMDI).[1,2]
- Beclu 100 and 200 are branded generic alternatives to Clenil® Modulite® 100 and 200 providing low and medium dose treatment options.[1-5]
- Beclu 100 is indicated for the prophylactic management of mild, moderate, or severe asthma in adults or children. Beclu 200 is indicated in adult asthma only.[1,2]
- Beclu offers potential NHS cost savings of up to £13 million per annum versus Clenil 100 & 200 pMDI list price.[6,7]
- Beclu 100 and 200 are certified carbon neutral products, achieved through carbon offsetting.[8]
- Inhaled medications should be prescribed by brand name.[9]

DRUG NAME

Beclu (beclometasone dipropionate) 100 micrograms per actuation pMDI.

Beclu (beclometasone dipropionate) 200 micrograms per actuation pMDI.

INDICATION

Beclu 100 is indicated for the prophylactic management of mild, moderate, or severe asthma in adults or children.[1]

Beclu 200 is indicated for the prophylactic management of mild, moderate, or severe asthma in adults.[2]

DOSAGE

Adults: Usual starting dose is 200 mcg twice daily. In severe cases this may be increased up to 600-800 mcg daily. Dose may be reduced when the patient's asthma has stabilised. Total daily dose should be administered as 2-4 divided doses.[1,2]

Children: Usual starting dose is 100 mcg twice daily. Depending on asthma severity, this may be increased up to 400 mcg administered in 2-4 divided doses. Beclu 200 mcg is not recommended for children.[2]

INHALER

Beclu inhalers include a dose indicator on the front of the actuator, which shows how many metered doses remain in the inhaler.[2]

The Volumatic™ spacer device may be used by patients who have difficulty synchronising aerosol actuation with inhalation and MUST always be used for:

- Patients aged 15 years and under taking any dose of Beclu.
- Patients aged 16 years and older taking total daily doses of 1000 mcg or more.[1,2]

BUDGETARY IMPLICATIONS

Compared with Clenil 100 and 200, both Beclu 100 and 200 offer an NHS list price saving of 30%.[6]

Cost savings with Beclu

The NHS spends **£44 million** on Clenil 100 and 200 annually.[6,7]

Pack strength & size	Clenil NHS List Price[6]	Beclu NHS list price	NHS Saving when Beclu prescribed
100 mcg x 200 doses	£7.42	£5.19	**£2.23**
200 mcg x 200 doses	£16.17	£11.31	**£4.86**

THERAPEUTIC EQUIVALENCE

Beclu 100 and 200 pMDIs have been shown to be therapeutically equivalent to Clenil 100 and 200 pMDIs based on following in-vitro tests:[5]

1. Delivered Dose Uniformity (DDU)
2. Aerodynamic Particle Size Distribution (APSD)
3. Spray Pattern
4. Plume Geometry
5. Force to Actuate

The APSD test was also completed using the Volumatic™ spacer device.

Prescribing information can be found overleaf

SAFETY

Refer to sections 4.4 and 4.8 of the SPC for all 'Special warnings and precautions for use' and 'Undesirable effects'. Adverse reactions typically seen with beclometasone are: oral fungal infections (oral candidiasis), dysphonia, throat irritation.

PRESCRIBING INFORMATION & REFERENCES

Prescribing Information: Beclu 100 and 200 pressurised metered dose inhaler (pMDI). Consult the full Summary of Product Characteristics (SmPC) before prescribing. Presentation: Each Beclu 100 pMDI contains 100 micrograms (mcg) beclometasone dipropionate (BDP). Each Beclu 200 pMDI contains 200 mcg BDP. **Indications:** Prophylactic management of mild, moderate or severe asthma in adults or children. **Dosage and administration:** For inhalation use only. A Volumatic™ spacer device may be used by patients who have difficulty synchronising actuation with inspiration and must always be used when Beclu is administered to adults and adolescents 16 years of age and older taking total daily doses of 1000 mcg or greater and for all doses when administered to children and adolescents 15 years of age and under. Starting dose of inhaled BDP should be adjusted to severity of disease. Dose may then be adjusted until control is achieved and then should be titrated to lowest dose at which effective control of asthma is maintained. Total daily dosage should be administered as two to four divided doses. ***Adults:*** Usual starting dose is 200 mcg twice daily. In severe cases this may be increased to 600 to 800 mcg daily. ***Children:*** Beclu 100 pMDI only: Usual starting dose 100 mcg twice daily. Depending on severity of asthma, daily dose may be increased up to 400 mcg. Beclu 200 pMDI is not recommended for children. **Contraindications:** Hypersensitivity to active substances or to any excipient (HFA-134a, ethanol, glycerol). **Warnings and precautions:** Patients should have relief medication available for acute asthma symptoms. Severe asthma requires regular medical assessment, as there is risk of severe attacks and even death. Patients must seek medical attention and have their condition assessed, should they find they are using their relief medication more often than normal or if it appears less effective. Do not stop Beclu treatment abruptly. Systemic effects may occur particularly with high doses taken for prolonged periods. These include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density and more rarely psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). Prolonged treatment with high doses of inhaled corticosteroids may result in clinically significant adrenal suppression. Monitor growth of children on prolonged treatment and if necessary reduce dose. Care is needed in transferring patients to Beclu from long-term or high-dose systemic steroids. Monitor adrenocortical function regularly as dose of systemic steroid is gradually reduced. Some patients may experience symptoms during withdrawal from systemic steroids; these patients should be encouraged to continue with the gradual withdrawal and change to inhaled BDP unless there are objective signs of adrenal insufficiency. Patients withdrawn from systemic steroids whose adrenocortical function is impaired should carry a steroid warning card. Replacement of systemic steroid treatment with inhaled therapy sometimes unmasks allergies. Titrate dose of Beclu to the lowest dose at which effective asthma control is maintained. Patients reporting blurred vision or visual disturbances should be considered for referral to an ophthalmologist, as causes may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy. Additional systemic steroid cover may be necessary during periods of stress or elective surgery. Care is necessary in patients with active or quiescent pulmonary tuberculosis. **Interactions:** Beclu contains a small amount of ethanol with theoretical potential for interaction in sensitive patients taking disulfiram or metronidazole. Possibility of systemic effects with concomitant use of strong CYP3A inhibitors (e.g. ritonavir, cobicistat) cannot be excluded and therefore caution and appropriate monitoring is advised. **Fertility, pregnancy and lactation:** Not to be used in pregnancy or lactation unless expected benefits outweigh the potential risks. **Side effects:** ***Very common:*** oral candidiasis. ***Common:*** hoarseness and throat irritation. ***Uncommon:*** rash, urticaria, pruritus, erythema. ***Very Rare:*** oedema of eyes, face, lips and throat, adrenal suppression, growth retardation (children and adolescents), decreased bone density, cataract, glaucoma, paradoxical bronchospasm, wheezing, dyspnoea, cough. ***Unknown:*** psychomotor hyperactivity, sleep disorders, anxiety, depression, aggression, behavioural disorders (predominantly in children), headache, nausea, blurred vision. Refer to SmPC for full list of side effects. **Legal category:** POM. **Price and pack:** Each presentation provides 200 actuations. Beclu 100 pMDI £5.19, Beclu 200 pMDI £11.31. **Marketing authorisation (MA) no(s):** PL 35507/0206, PL 35507/0207. **MA Holder:** Lupin Healthcare UK Ltd, The Urban Building, Second Floor, 3-9 Albert Street, Slough, Berkshire, SL1 2BE, United Kingdom. **PI last revised:** Jan 2023. Volumatic™ is a registered trademark of the GlaxoSmithKline Group of Companies.

References:

1. Beclu 100. Summary of Product Characteristics (SPC). Lupin Healthcare UK Limited.
2. Beclu 200. Summary of Product Characteristics (SPC). Lupin Healthcare UK Limited.
3. Clenil 100. Summary of Product Characteristics (SPC). Chiesi Ltd. https://www.medicines.org.uk/emc/product/6975/smpc Accessed: March 2023.
4. Clenil 200. Summary of Product Characteristics (SPC). Chiesi Ltd. https://www.medicines.org.uk/emc/product/6976/smpc Accessed: March 2023.
5. Lupin Healthcare Limited. Data on File. UK-BEC-2212-00001
6. NHS BSA. Drug Tariff. https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff Accessed: March 2023.
7. General Practice Prescribing Data Nov 2021 - October 2022. This public sector information is licensed under the Open Government Licence v3.0 (http://www.nationalarchives.gov.uk/doc/open-government-licence/version/3 Accessed: March 2023
8. Certifications of carbon neutrality for Beclu 100 & 200 pMDI.
9. British Thoracic Society/Scottish Intercollegiate Guidelines. British Guideline on the Management of Asthma. July 2019.

Carbon footprint standard™ Carbon Neutral Product

CARBON NEUTRALITY ACHIEVED THROUGH CARBON OFFSETTING[8]

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk or search for MHRA Yellow Card in the Google Play or Apple App store. Adverse events should also be reported to Lupin Healthcare UK Limited on +44 (0)1565 751 378 or EU-PV@lupin.com

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UK-BEC-2301-00005 March 2023