NEW ZEALAND DATA SHEET

1. PRODUCT NAME

BECLAZONE 50 micrograms CFC-Free Inhaler
BECLAZONE 100 micrograms CFC-Free Inhaler
BECLAZONE 250 micrograms CFC-Free Inhaler
(beclometasone dipropionate inhaler, CFC-Free, 50 mcg, 100 mcg and 250 mcg)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose delivers 50 mcg, 100 mcg or 250 mcg beclometasone dipropionate.

Excipient with known effect: ethanol (anhydrous)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pressurised inhalation, suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Beclometasone dipropionate provides effective anti-inflammatory action in the lungs and offers preventive background treatment of asthma.

Severe asthma requires regular medical assessment as death may occur. Patients with severe asthma have constant symptoms and frequent exacerbations, with limited physical capacity, and PEF values below 60% predicted at baseline with greater than 30% variability, usually not returning entirely to normal after a bronchodilator. These patients will require high dose inhaled (see section 4.2 Dose and method of administration) or oral corticosteroid therapy. Sudden worsening of symptoms may require increased corticosteroid dosage which should be administered under urgent medical supervision.

Adults
Prophylactic management in:

Mild asthma (PEF values greater than 80% predicted at baseline with less than 20% variability): Patients requiring intermittent symptomatic bronchodilator asthma medication on more than an occasional basis.

Moderate asthma (PEF values 60-80% predicted at baseline with 20-30% variability): Patients requiring regular asthma medication and patients with unstable or worsening asthma on other prophylactic therapy or bronchodilator alone.

Severe asthma (PEF values less than 60% predicted at baseline with greater than 30% variability): Patients with severe chronic asthma. On transfer to high dose inhaled beclometasone dipropionate, many patients who are dependent on systemic corticosteroids for adequate control of symptoms may be able to reduce significantly or eliminate their requirement for oral corticosteroids.

Paediatric population (7-12 years)
Any child who requires prophylactic asthma medication (see section 4.2 Dose and method of administration).

4.2 Dose and method of administration

Patients should be made aware of the prophylactic nature of therapy with inhaled beclometasone dipropionate and that it should be taken regularly even when they are asymptomatic. The dosage of beclometasone dipropionate should be adjusted according to the individual response. If patients find that short-acting relief bronchodilator treatment becomes less effective or they need more inhalations than usual, medical attention must be sought. In patients who find co-ordination of a pressurised metered dose inhaler difficult a spacer device may be used with BECLAZONE CFC-Free Inhaler.

The therapeutic effect occurs after a few days' treatment and reaches its maximum after 2-3 weeks.

Dose

Adults and children over 12 years of age

Patients should be given a starting dose of inhaled beclometasone dipropionate (BECLAZONE 50 micrograms CFC-Free Inhaler or BECLAZONE 100 micrograms CFC-Free Inhaler or BECLAZONE 250 micrograms CFC-Free Inhaler) which is appropriate for the severity of their disease based on the following guidance:

Mild asthma: 200 to 600mcg per day in divided doses.

Moderate asthma: 600 to 1000mcg per day in divided doses.

Severe asthma: Up to 1000mcg per day in divided doses.

The dose may then be adjusted until control is achieved or reduced to the minimum effective dose according to the individual response.

Paediatric population (7–12 years)

Up to 200mcg per day in divided doses.

Children should be given a starting dose of inhaled beclometasone dipropionate which is appropriate for the severity of their disease. The dose may then be adjusted until control is achieved or reduced to the minimum effective dose according to the individual response. There are no data on the use of Beclazone CFC-Free Inhaler in children aged under seven years.

Method of administration

For inhalation use.

Special populations

There is no need to adjust the dose in elderly patients or in those with hepatic or renal impairment.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Asthma Management

The management of asthma should follow a stepwise programme, and patient response should be monitored clinically and by lung function tests. Increasing use of short-acting inhaled ß2 agonists to control symptoms indicates deterioration of asthma control. Under these conditions, the patient's therapy plan should be reassessed. Sudden and progressive deterioration in asthma control is potentially life-threatening and consideration should be given to increasing corticosteroid dosage. In patients considered at risk, daily flow monitoring may be instituted. BECLAZONE CFC-Free Inhaler is not for use in acute attacks but for routine long-term management. Patients will require a fast- and short-acting inhaled bronchodilator to relieve acute asthmatic symptoms.

Patients' inhaler technique should be checked to make sure that aerosol actuation is synchronised with inspiration of breath for optimum delivery of the medicine to the lungs.

Lack of response or severe exacerbations of asthma should be treated by increasing the dose of inhaled beclometasone dipropionate and, if necessary, by giving a systemic steroid and/or an antibiotic if there is an infection.

Systemic Effects
Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods; these effects are much less likely to occur than with oral corticosteroids. Possible systemic effects include Cushing's Syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract, glaucoma, blurred vision and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). It is important, therefore, that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control is maintained (see section 4.8 Undesirable Effects).

Possible systemic effects also include growth retardation in children and adolescents.

It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroid is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of inhaled corticosteroid if possible, to the lowest dose at which effective control of asthma is maintained. In addition, consideration should be given to referring the patient to a paediatric respiratory specialist.

Certain individuals can show greater susceptibility to the effects of inhaled corticosteroid than do most patients.

Visual disturbance
Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

Transfer from Systemic Steroids
Because of the possibility of impaired adrenal response, patients transferring from oral steroid therapy to inhaled beclometasone dipropionate therapy should be treated with special care, and adrenocortical function regularly monitored.

The patient should be in a reasonably stable state before being given beclometasone dipropionate inhaler in addition to his usual maintenance dose of systemic steroid. After about a week, gradual withdrawal of the systemic steroid is started by reducing the daily dose by 1 mg prednisolone, or its equivalent of other corticosteroids, at not less than weekly intervals. Patients treated with systemic steroids for long periods of time or who have received high doses may have adrenocortical suppression. With these patients adrenocortical function should be monitored regularly and their dose of systemic steroid reduced cautiously. Some patients feel unwell (i.e. headache, nausea, articular or muscular discomfort) during the withdrawal phase despite maintenance or even improvement of respiratory function. They should be encouraged to persevere with the inhaler and withdrawal of systemic steroid continued unless there are objective signs of adrenal insufficiency. Spirometric and clinical assessments should be provided while reducing oral corticotherapy.

Most patients can be successfully transferred to beclometasone dipropionate inhaler with maintenance of good respiratory function, but special care is necessary for the first months after the transfer until

the pituitary-adrenal system has sufficiently recovered to enable the patient to cope with emergencies such as trauma, surgery or infections.

Following introduction of inhaled beclometasone dipropionate, withdrawal of systemic therapy should be gradual and patients encouraged to carry a steroid warning card indicating the possible need for additional therapy in times of stress or elective surgery.

They should also be given a supply of oral steroid to use in emergency, for example when the asthma worsens as a result of a chest infection. The dose of beclometasone dipropionate inhaler should be increased at this time and then reduced to the maintenance level after the systemic steroid has been discontinued.

In rare cases inhaled therapy may unmask underlying eosinophilic conditions (e.g. Churg Strauss syndrome). These cases have usually been associated with reduction or withdrawal of oral corticosteroid therapy. A direct causal relationship has not been established.

Similarly replacement of systemic steroid treatment with inhaled therapy sometimes unmasks allergies such as allergic rhinitis or eczema previously controlled by the systemic medicine. These allergies should be symptomatically treated with antihistamine and/or topical preparations, including topical steroids.

Particular care should be taken to minimise the use of topical corticosteroids in patients with immunosuppression.

Treatment with BECLAZONE CFC-Free Inhaler should not be stopped abruptly.

As with all inhaled corticosteroids, special care is necessary in patients with active or quiescent pulmonary tuberculosis.

4.5 Interaction with other medicines and other forms of interaction

Concurrent administration of barbiturates, phenytoin or rifampicin may enhance the metabolism and reduce the effects of oral corticosteroids. Response to anticoagulants may be reduced and, on some occasions enhanced, by oral corticosteroids. Concurrent administration of oral corticosteroids or the potassium depleting diuretics such as thiazides or frusemide may cause excessive potassium loss. Beclomethasone is less dependent on CYP3A metabolism than some other corticosteroids, and in general interactions are unlikely; however, the 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 with the use of such agents. No known interactions have been reported for inhaled beclometasone dipropionate.

4.6 Fertility, pregnancy and lactation

Pregnancy

No specific studies have been performed examining the safety in human pregnancy and lactation for beclometasone dipropionate. Beclometasone dipropionate inhalation may be associated with intrauterine growth retardation in humans. Studies in animals have shown reproductive toxicity. The use of beclometasone dipropionate in pregnancy requires that the possible benefits be weighed against the possible hazards.

Breastfeeding

The transfer of beclometasone dipropionate into milk has not been examined. It is reasonable to assume that beclometasone dipropionate is excreted in milk but at the doses used for inhalation there is low potential for significant levels in breast milk.

Fertility
No specific studies have been performed with beclometasone dipropionate with regard to the safety in human fertility. Although results of animal studies have shown some impaired fertility, this occurs at high doses levels.

4.7 Effects on ability to drive and use machines
Beclometasone dipropionate is unlikely to produce an effect.

4.8 Undesirable effects
Frequency estimate: very common = 10%, common = 1% to <10%, uncommon = 0.1% to <1%, rare = 0.01% to <0.1%, very rare <0.01%, not known (cannot be estimated from the available data).

Adults

Infections and infestations *Common (>1/100 and <1/10)*	Candidiasis in mouth and throat
Immune system disorders *Rare (>1/10,000 and <1/1000)*	Allergic reactions: angioedema in eyes, throat, lips and face
Endocrine disorders *Very rare (<1/10,000, including isolated reports)*	Adrenal suppression (systemic effect)
Eye disorders *Uncommon* *Very rare (<1/10,000, including isolated reports)* *Not known*	Blurred vision Cataract, glaucoma (systemic effect) Central serous retinopathy
Respiratory, thoracic and mediastinal disorders *Common (>1/100 and <1/10)* *Rare (>1/10,000 and <1/1000)*	Hoarseness and throat irritation Paradoxical bronchospasm
Skin and subcutaneous tissue disorders *Very rare (<1/10,000, including isolated reports)*	Urticaria, rash, pruritus, erythaema
Musculoskeletal and connective tissue disorders *Very rare (<1/10,000, including isolated reports)*	Decreased bone mineral density (systemic effect)
Psychiatric disorders *Not known*	Psychomotor hyperactivity, sleep disorders, anxiety, depression, aggression, behavioural changes.

Paediatric population

Endocrine disorders *Very rare (<1/10,000, including isolated reports)*	Growth retardation in children and adolescents
Psychiatric disorders *Not known*	Behavioural changes.

Candidiasis of the mouth and throat (thrush) occurs in some patients, the incidence of which is increased with doses greater than 400mcg beclometasone dipropionate per day. Patients with high blood levels of Candida precipitins, indicating a previous infection, are most likely to develop this complication. Patients may find it helpful to rinse out their mouth with water after using the inhaler. Symptomatic candidiasis can be treated with topical anti-fungal therapy whilst still continuing with the BECLAZONE CFC-Free Inhaler.

In some patients inhaled beclometasone dipropionate may cause hoarseness or throat irritation. It may be helpful to rinse out the mouth with water immediately after inhalation. The use of a large volume 'spacer' device may be considered.

As with other inhalation therapy, paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with a fast-acting inhaled bronchodilator. BECLAZONE CFC-Free Inhaler should be discontinued immediately, the patient assessed, and if necessary alternative therapy instituted.

Hypersensitivity reactions including rashes, urticaria, pruritus, erythema and oedema of the eyes, face, lips and throat have been reported.

Possible systemic effects include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma and more rarely, a range of psychological or behavioural effects eg. anxiety, sleeping disorders or behavioural changes including hyperactivity, aggression and irritability (predominantly in children) (see section 4.4 Special warnings and precautions for use).

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://pophealth.my.site.com/carmreportnz/s/

4.9 Overdose
Acute inhalation of beclometasone dipropionate doses in excess of those recommended may lead to temporary suppression of adrenal function. This does not need emergency action as adrenal function is recovered in a few days, as verified by plasma cortisol measurements. However if higher than recommended dosage is continued over prolonged periods, some degree of adrenal suppression may result. Monitoring of adrenal reserve may be necessary. In cases of beclometasone dipropionate overdose, therapy may still be continued at a suitable dosage for symptom control.

The acute toxicity of beclometasone dipropionate is low. The only harmful effect that follows inhalation of large amounts of the drug over a short period is suppression of hypothalamic-pituitary-adrenal (HPA) function. No special emergency action need be taken. Treatment with beclometasone dipropionate inhaler should be continued at the recommended dose to control the asthma; HPA function recovers in a day or two.

In the unlikely event of grossly excessive intake of beclometasone dipropionate for weeks or months on end, a degree of adrenocortical atrophy could occur in addition to suppression of HPA function. The patient should be treated as steroid-dependent and transferred to a suitable maintenance dose of a systemic steroid such as prednisolone. Once the patient's condition has stabilised he should be transferred to beclometasone dipropionate by the method described above (see section 4.4 Special warnings and precautions for use).

For risk assessment and advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Glucocorticoid, ATC code: R03B A01

Beclometasone dipropionate (BDP) is a pro-drug with weak glucocorticoid receptor binding affinity. It is hydrolysed via esterase enzymes to the active metabolite beclometasone-17-monopropionate (B-17-MP), which has high topical anti-inflammatory activity.

5.2 Pharmacokinetic properties

Absorption

When administered via inhalation (via metered dose inhaler), systemic absorption of unchanged BDP occurs through the lungs with negligible oral absorption of the swallowed dose. There is extensive conversion of BDP to its active metabolite B-17-MP within the lung prior to absorption. The systemic absorption of B-17-MP arises from both lung deposition (36%) and oral absorption of the swallowed dose (26%). The absolute bioavailability following inhalation is approximately 2% and 62% of the nominal dose for unchanged BDP and B-17-MP respectively. BDP is absorbed rapidly with peak plasma concentrations first being observed (t_{max}) at 0.3 hours. B-17-MP appears more slowly with a t_{max} of 1 hour. There is an approximately linear increase in systemic exposure with increasing inhaled dose.

When administered orally the bioavailability of BDP is negligible but pre-systemic conversion to B-17-MP results in 41% of the dose being absorbed as B-17-MP.

Metabolism

BDP is cleared very rapidly from the systemic circulation, by metabolism mediated via esterase enzymes that are found in most tissues. The main product of metabolism is the active metabolite (B-17-MP). Minor inactive metabolites, beclometasone-21-monopropionate (B-21-MP) and beclometasone (BOH), are also formed but these contribute little to the systemic exposure.

Distribution

The tissue distribution at steady-state for BDP is moderate (20L) but more extensive for B-17- MP (424L). Plasma protein binding is moderately high (87%).

Elimination

The elimination of BDP and B-17-MP are characterised by high plasma clearance (150 and 120L/hour) with corresponding terminal elimination half-lives of 0.5 hours and 2.7 hours. Following oral administration of tritiated BDP, approximately 60% of the dose was excreted in the faeces within 96 hours mainly as free and conjugated polar metabolites. Approximately 12% of the dose was excreted as free and conjugated polar metabolites in the urine. The renal clearance of BDP and its metabolites is negligible.

5.3 Preclinical safety data

Preclinical safety studies indicate that beclometasone dipropionate shows negligible systemic toxicity when administered by the inhaled route. Inhaled beclometasone dipropionate has been used clinically, as a formulation containing chlorofluorocarbon (CFC) propellants, for over twenty years. Preclinical studies in rats and dogs with beclometasone dipropionate in the hydrofluoroalkane propellant, norflurane (1,1,1,2-tetrafluoroethane) or HFA-134a, have shown a comparative safety profile to the current CFC-containing products.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol (Anhydrous) 99.5%
Hydrofluoroalkane 134a (HFA-134a)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 25°C. Do not refrigerate or freeze. Do not expose to temperatures higher than 50°C. As with most inhaled medicines in aerosol canisters, the therapeutic effect of this medicine may decrease when the canister is cold.

Using the inhaler

Test spray the inhaler before you use it for the first time and also if you have not used it for a while.

1. Take the cap of the inhaler. Make sure the mouthpiece clean and free of fluff and dirt.
2. Hold the inhaler upright with your thumb on the base and your first finger on top of the can. Shake the inhaler vigorously up and down.
3. Breathe out normally as far as is comfortably can. Then hold the mouthpiece between your lips. Breathe in slowly and deeply. As you start to breathe in, press the aerosol can with your first finger to spray the aerosol and release the medicine. Continue to breathe in slowly and deeply.
4. Take the inhaler out of your mouth and hold your breath for 10 seconds, or as long as you comfortably can.
5. If you need more than one puff, wait for about one minute and then start again from step 2. Put the cap back on the inhaler.

Note:-Do not rush step 3. It is important that you start to breathe in as slowly as possible just before using your inhaler. Practice in front of a mirror for the first few times. If you see 'mist' coming from the top of the inhaler or from the sides of your mouth you should start again from step 2.

Cleaning your inhaler

You must keep your inhaler clean, especially the mouthpiece. This will prevent deposits from the aerosol building up. Clean your inhaler at least once a week.

Take the metal can from the plastic body and rinse the plastic body and cap in warm water. Do not use very hot water to clean your inhaler. Dry thoroughly (leave to dry overnight if possible) but do not use direct heat. Put the metal can back in the plastic mouthpiece and replace the cap. Do not put the metal can into water. Failure to allow the mouthpiece to dry will result in an increase in blockage problems.

6.5 Nature and contents of container

BECLAZONE CFC-Free Inhaler is a metered dose aerosol inhaler consisting of a pressurised aluminium canister fitted with a metered dispensing valve, and fitted into a plastic actuator/mouthpiece with a cap, as follows:

BECLAZONE 50 micrograms CFC-Free Inhaler, cream colour actuator/mouthpiece and brown colour cap.

BECLAZONE 100 micrograms CFC-Free Inhaler, brown colour actuator/mouthpiece and white colour cap.

BECLAZONE 250 micrograms CFC-Free Inhaler, wine colour actuator/mouthpiece and pink colour cap.

Each canister contains 200 metered doses. The Inhaler contains the CFC-free propellant HFA 134a.

6.6 Special precautions for disposal

The canister is pressurised: it must not be burnt, punctured or broken even when apparently empty. Any unused medicine or waste material should be disposed of in accordance with local requirements.

7. MEDICINE SCHEDULE

Prescription Medicine

8. SPONSOR

Teva Pharma (New Zealand) Limited
PO Box 128244
Remuera
Auckland 1541
Telephone: 0800 800 097

9. DATE OF FIRST APPROVAL

28 August 2008

10. DATE OF REVISION OF THE TEXT

7 January 2026

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
4.5	Added drug interaction for corticosteroids and CYP3A4 inhibitors
4.8, 4.9, 6.6	Updated and added text as required by Data Sheet Explanatory Guide January 2025 v1.3.