

## Abbreviated Prescribing Information

### Ciclesonide ADVANZ PHARMA 80 mcg and 160 mcg per metered dose pressurised inhalation, solution

**Consult the Summary of Product Characteristics (SmPC) before prescribing.**  
**Additional information is available on request.**

**Presentations:** 1 actuation (delivered dose from the mouthpiece) contains 80 micrograms or 160 micrograms of ciclesonide. **Indication:** In treatment to control persistent asthma in adults and adolescents (12 years and older). **Dose:** The recommended dose of Ciclesonide Advanz Pharma is 160 micrograms once daily, which leads to asthma control in the majority of patients. In patients with severe asthma and while reducing or discontinuing oral corticosteroids a higher dose of up to 640 mcg/day may be used. Patients should be given a dose of inhaled ciclesonide which is appropriate to the severity of their disease. Once control is achieved, the dose of Ciclesonide Advanz Pharma should be individualised and titrated to the minimum dose needed to maintain good asthma control. Dose reduction to 80 micrograms once daily may be an effective maintenance dose for some patients. 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 this situation, patients should be reassessed and consideration given to the need for increased anti-inflammatory treatment therapy (e.g. a higher dose of Ciclesonide Advanz Pharma for a short period). To address specific patient needs, such as finding it difficult to press the inhaler and breathe in at the same time, Ciclesonide Advanz Pharma can be used with the AeroChamber Plus Flow-Vu spacer device.

**Special populations:** *Elderly and patients with renal or hepatic impairment.* There is no need to adjust the dose in elderly patients or those with hepatic or renal impairment. *Paediatric population:* The safety and efficacy of ciclesonide in children aged under 12 years have not yet been established. No sufficient data are available. **Administration:** Ciclesonide Advanz Pharma should preferably be administered in the evening although morning dosing of Ciclesonide Advanz Pharma has also been shown to be effective. The final decision on evening or morning dosing should be left to the discretion of the physician. *Precautions to be taken before handling or administering the medicinal product:* The patient needs to be instructed how to use the inhaler correctly. If the inhaler is new or has not been used for one week or more, three puffs should be released into the air. No shaking is necessary as this is a solution aerosol. During inhalation, the patient should preferably sit or stand, and the inhaler should be held upright with the thumb on the base, below the mouthpiece. Instruct the patient to remove the mouthpiece cover, place the inhaler into their mouth, close their lips around the mouthpiece, and breathe in slowly and deeply. While breathing in through the mouth, the top of the inhaler should be pressed down. Then, patients should remove the inhaler from their mouth, and hold their breath for about 10 seconds, or as long as is comfortable. The patient is not to breathe out into the inhaler. Finally, patients should breathe out slowly and replace the mouthpiece cover. The mouthpiece should be cleaned with a dry tissue or cloth weekly. The inhaler should not be washed or put in water. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Special warnings and precautions for use:** Ciclesonide Advanz Pharma should be administered with caution in patients with active or quiescent pulmonary tuberculosis, fungal, viral or bacterial infections, and only if these patients are adequately treated. Ciclesonide Advanz Pharma is not indicated in the treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required. Ciclesonide Advanz Pharma is not designed to relieve acute asthma symptoms for which an inhaled short-acting bronchodilator is required. Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids. 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. *Paediatric population:* It is recommended that the height of children and adolescents receiving prolonged treatment with inhaled corticosteroids is regularly monitored.

*Hepatic impairment:* There is no data available in patients with severe hepatic impairment. *Adrenal impairment:* The benefits of inhaled ciclesonide should minimise the need for oral steroids. However, patients transferred from oral steroids remain at risk of impaired adrenal reserve for a considerable time after transferring to inhaled ciclesonide. Patients transferred from oral steroids whose adrenocortical function is still impaired should carry a steroid warning card indicating that they need supplementary systemic steroid during periods of stress. Concomitant treatment with ketoconazole or other potent CYP3A4 inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. **Interactions:** In vitro data indicate that CYP3A4 is the major enzyme involved in the metabolism of the active metabolite of ciclesonide M1 in man. In a drug-drug interaction study at steady state with ciclesonide and ketoconazole as a potent CYP3A4 inhibitor, the exposure to the active metabolite M1 increased approximately 3.5-fold, whereas the exposure to ciclesonide was not affected. Therefore the concomitant administration of potent inhibitors of CYP 3A4 (e.g. ketoconazole, itraconazole cobicistat-containing products and ritonavir or nelfinavir) should be avoided unless the benefit outweighs the increased risk of systemic side effects of corticosteroids, in which case patients should be monitored for systemic corticosteroid side-effects. **Pregnancy and lactation:** There are no adequate and well-controlled studies in pregnant women. Infants born of mothers who received corticosteroids during pregnancy are to be observed carefully for hypoadrenalism. It is unknown whether inhaled ciclesonide is excreted in human breast milk. **Effects on ability to drive and use machines:** no or negligible influence on the ability to drive and use machines. **Undesirable effects:** For a full list of side effects, consult SmPC. 'Uncommon' and 'Rare' side effects are included in this prescribing information. *Uncommon side effects (>1/1 000, <1/100):* Nausea, vomiting, bad taste, application site reactions, application site dryness, oral fungal infections, headache, blurred vision, dysphonia, cough after inhalation, paradoxical bronchospasm, eczema and rash. *Rare side effects (1/10 000 – 1/ 1 000):* Palpitations, abdominal pain, dyspepsia, angioedema, hypersensitivity, hypertension.

**Legal Category:** Prescription Only Medicine [POM]

**Pack quantities and costs:** £26.24 per metered dose inhaler of 120 doses of 80 micrograms, £30.88 per metered dose inhaler of 120 doses of 160 micrograms

**Marketing authorisation holder:** Advanz Pharma Limited, Unit 17 Northwood House, Northwood Crescent, Dublin 9, D09 V504, Ireland

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