For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

Ciclesonide inhaler

Ciclohale - C inhaler

INN: Ciclesonide
Dosage form: Inhalers
COMPOSITION
Ciclohale - C 80 Inhaler
Each actuation delivers
Ciclesonide ..... 80 mcg
In propellant HFA 134a ..... q.s.
Absolute alcohol content ..... 8.8 % v/v
Ciclohale - C 160 Inhaler
Each actuation delivers
Ciclesonide ..... 160 mcg
In propellant HFA 134a ..... q.s.
Absolute alcohol content ..... 8.8 % v/v
Therapeutic Class: Inhaled Corticosteroid.
DESCRIPTION
Ciclohale - C 80 / 160 Inhaler is a solution filled in aluminium container in CFC free propellant gas. The aluminium container is fitted with a metering value. On visual examination there should be no sign of physical damage or Leakage.

Pharmacology
Pharmacodynamic properties
Ciclesonide exhibits low binding affinity to the glucocorticoid-receptor. Once orally inhaled, ciclesonide is enzymatically converted in the lungs to the principal metabolite (desisobutyryl ciclesonide) which has a pronounced anti-inflammatory activity and is thus considered as the active metabolite.
Pharmacokinetic properties
Absorption:
The oral bioavailability of both ciclesonide and the active metabolite is negligible (<0.5% for ciclesonide, <1% for the metabolite). The systemic bioavailability for the active metabolite is >50 % by using ciclesonide metered dose inhaler. As the oral bioavailability for the active metabolite is <1%, the swallowed portion of the inhaled ciclesonide does not contribute to systemic absorption.
Distribution:
Following intravenous administration to healthy subjects, the initial distribution phase for ciclesonide was rapid and consistent with its high lipophilicity. The volume of distribution averaged 2.9 l/kg. The total serum clearance of ciclesonide is high (average 2.0 l/h/kg) indicating a high hepatic extraction. The percentage of ciclesonide bound to human plasma proteins averaged 99%, and that of the active metabolite 98-99%, indicating an almost complete binding of circulating ciclesonide/active metabolite to plasma proteins. Only the free fraction of a drug in the systemic circulation is available for a further pharmacodynamic effect, which explains the low potential for suppression of the hypothalamic-pituitary-adrenal axis.
Quantitative tissue distribution studies in rats showed a pronounced affinity of the radiolabelled ciclesonide to the lung. Most of this radioactivity can be attributed to the biologically active metabolite and to its lipophilic fatty acid ester conjugates.
Metabolism:
Ciclesonide is primarily hydrolysed to its biologically active metabolite by esterase enzymes in the lung. Investigation of the enzymology of further metabolism by human liver microsomes showed that this compound is mainly metabolised to hydroxylated inactive metabolites by CYP3A4 catalysis. Furthermore, reversible lipophilic fatty acid ester conjugates of the active metabolite were detected in the lung; this process is reversible leading to an increase in the retention time of the active metabolite in the target organ.
Excretion:
Ciclesonide is predominantly excreted via the faeces (67%), after oral and intravenous administration, indicating that excretion via the bile is the major route of elimination.
INDICATIONS
Ciclohale-C is indicated for treatment of mild to moderate persistent asthma in adults (18 years and older)
DOSAGE AND ADMINISTRATION
Adults (18 years and older)
The recommended starting dose of Ciclohale-C pMDI is 160 µg (200 µg ex valve) once daily. The maximum recommended dose for Ciclohale-C is 640 µg. (800 µg ex valve)
Once control is achieved the dose of Ciclohale-C should be individualised and titrated to the minimum dose needed to maintain good asthma control. Ciclohale-C should preferably be administered in the evening although morning dosing of Ciclesonide has also been shown to be effective. There is no need to adjust the dose in elderly patients or those with hepatic or renal impairment.
CONTRAINDICATIONS
Ciclohale-C is contraindicated in patients with history of hypersensitivity to ciclesonide or any of its components.
WARNINGS AND PRECAUTIONS
Ciclohale-C 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 for the above mentioned conditions.
Ciclohale-C is not indicated in the treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.
Ciclohale-C is not designed to relieve acute asthma symptoms for which an inhaled short-acting bronchodilator is required. Patients should be advised to have such rescue medication available.
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. Possible systemic effects include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma. It is therefore important that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control of asthma is maintained.
For the transfer of patients being treated with oral corticosteroids:
The transfer of oral steroid-dependent patients to inhaled ciclesonide, and their subsequent management, needs special care as recovery from impaired adrenocortical function, caused by prolonged systemic steroid therapy, may take a considerable time.
Patients who have been treated with systemic steroids for long periods of time, or at a high dose, may have adrenocortical suppression. With these patients adrenocortical function should be monitored regularly and their dose of systemic steroid reduced cautiously.
After approximately a week, gradual withdrawal of the systemic steroid is started by reducing the dose by 1 mg prednisolone per week, or its equivalent. For maintenance doses of prednisolone in excess of 10 mg daily, it may be appropriate to cautiously use larger reductions in dose at weekly intervals.
Some patients feel unwell in a non-specific way during the withdrawal phase despite maintenance or even improvement of respiratory function. They should be encouraged to persevere with inhaled ciclesonide and to continue withdrawal of systemic steroid, unless there are objective signs of adrenal insufficiency.
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, e.g. worsening asthma attacks, chest infections, major intercurrent illness, surgery, trauma, etc.
Replacement of systemic steroid treatment with inhaled therapy sometimes unmasks allergies such as allergic rhinitis or eczema previously controlled by systemic drug.
Paradoxical bronchospasm with an immediate increase of wheezing or other symptoms of bronchoconstriction after dosing should be treated with an inhaled short-acting bronchodilator, which usually results in quick relief. The patient should be assessed and therapy with Ciclesonide should only be continued if, after careful consideration the expected benefit is greater than the possible risk.
Correlation between severity of asthma and general susceptibility for acute bronchial reactions should be kept in mind.
Patients' inhaler technique should be checked regularly to make sure that inhaler actuation is synchronised with inhaling to ensure optimum delivery to the lungs.
DRUG INTERACTIONS
The serum levels of ciclesonide and its metabolite desisobutyryl ciclesonide are low. Clinically relevant interactions are not to be expected. However, co-administration with a potent inhibitor of the cytochrome P 450 3A4 system (e.g. ketoconazole and protease inhibitors, such as ritonavir) should be considered with caution because there might be an increase in ciclesonide / desisobutyryl ciclesonide serum levels. A drug-druginteraction study with ciclesonide and a CYP3A4 probe substrate (erythromycin) has shown no mutual interaction.
Pregnancy and lactation
There are no adequate and well-controlled studies in pregnant women. However, serum concentrations of ciclesonide are generally very low following inhaled administration; thus, fetal exposure is expected to be negligible and the potential for reproductive toxicity low. As with other inhaled corticosteroid preparations, ciclesonide should not be used during pregnancy or lactation unless the potential benefit to the mother justifies the potential risk to the mother, fetus or infant.
Infants born of mothers who received corticosteroids during pregnancy are to be observed carefully for hypoadrenalism.
Patients with Renal and Hepatic Impairment
In view of the pharmacokinetics characteristics obtained in elderly and in patients with hepatic insufficiency, dose adjustment is not necessary in these populations.
Due to the lack of renal excretion of the active metabolite, studies on renal impaired patients have not been performed
UNDESIRABLE EFFECTS
A. Approximately 4% of patients experienced adverse reactions in clinical trials with Ciclesonide given in the dose range 100 to 1600 micrograms per day. In the majority of cases, these were mild and did not require discontinuation of treatment with Ciclesonide.
B. Common (1-10%):
Paradoxical bronchospasm (1.0%)
Uncommon (0.1-1%):
Hoarseness (0.9%)
Application site reactions such as burning, inflammation, and irritation (0.6%)
Bad taste (0.4%)
Application site dryness (0.3%)
Rash and eczema (0.3%)
Cough after inhalation (0.3%)
C. Paradoxical bronchospasm may occur immediately after dosing and is an unspecific acute reaction to all inhaled medications, which may be related to the drug, the excipient, or evaporation cooling in the case of metered dose inhalers. In the majority of cases, this reaction is mild and does not require the withdrawal of Ciclesonide. It may even subside with Ciclesonide.
D. Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods
OVERDOSE
Acute:
Inhalation by healthy volunteers of a single dose of 3600 micrograms of ciclesonide was well tolerated.
The potential for acute toxic effects following overdose of inhaled ciclesonide is low. After acute overdosage no specific treatment is necessary.
Chronic:
After prolonged administration of 1600 micrograms of ciclesonide, no clinical signs of adrenal suppression were observed. However, if higher than recommended dosage is continued over prolonged periods, some degree of adrenal suppression cannot be excluded. Monitoring of adrenal reserve may be necessary.
PACKING/PACK Size
Ciclohale - C 80 Inhaler
Packing: Each Carton containing aerosol of 120 metered dose.
Pack size: 120 metered dose
Ciclohale - C 160 Inhaler
Packing: Each Carton containing aerosol of 120 metered dose.
Pack size: 120 metered dose
Storage Conditions, user instructions pharmaceutical precautions
Storage Condition :
Store Below 30°C, Do not freeze.
Presentation
Ciclohale - C 80 Inhaler: 120 metered doses
Ciclohale - C 160 Inhaler: 120 metered doses

Cipla