120x280mm

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Minvair™

(Indacaterol + Mometasone Furoate)

Highnoon

COMPOSITION

Minvair 150mcg/80mcg Rotacaps:
Each capsule contains:
Indacaterol (as Acetate) 150mcg
Mometasone Furoate 80mcg

Each delivered dose contains:
Indacaterol (as Acetate) 125mcg
Mometasone Furoate 62.5mcg

Minvair 150mcg/160mcg Rotacaps:
Each capsule contains:
Indacaterol (as Acetate) 150mcg
Mometasone Furoate 160mcg

Each delivered dose contains:
Indacaterol (as Acetate) 125mcg
Mometasone Furoate 127.5mcg

Minvair 150mcg/320mcg Rotacaps:
Each capsule contains:
Indacaterol (as Acetate) 150mcg
Mometasone Furoate 320mcg

Each delivered dose contains:
Indacaterol (as Acetate) 125mcg
Mometasone Furoate 260mcg

DESCRIPTION

Indacaterol belongs to group of medicine called bronchodilators. They relax the muscles of small airways in the lungs. This helps to open the airways and makes it easier for air to get in and out of the lungs. When they are taken regularly, it helps the small airways to remain open.
Mometasone furoate belongs to a group of medicines called corticosteroids, often simply called steroids. Corticosteroids reduce inflammation. They reduce the swelling and irritation in the small airways in the lungs and so gradually ease breathing problems. Corticosteroids also help to prevent attacks of asthma.

MECHANISM OF ACTION

Indacaterol is a Long-Acting Beta-Agonist (LABA). When inhaled, indacaterol acts locally in the lung as a bronchodilator. The pharmacological effects of beta 2 -adrenoceptor agonist drugs, including indacaterol, are at least in part attributable to stimulation of intracellular adenyl cyclase, the enzyme that catalyses the conversion of adenosine triphosphate (ATP) to cyclic-3', 5'-adenosine monophosphate (cyclic AMP). Increased cyclic AMP levels cause relaxation of bronchial smooth muscle and inhibition of release of mediators of immediate hypersensitivity from cells, especially from mast cells.
Mometasone furoate is a synthetic corticosteroid with high affinity for glucocorticoid receptors and local anti-inflammatory properties. It is known to inhibit the release of leukotrienes from leukocytes of allergic patients. In cell culture, mometasone furoate demonstrated high potency in inhibition of synthesis and release of IL-1, IL-5, IL-6 and TNF-alpha. It is also a potent inhibitor of leukotriene production and of the production of the cytokines IL-4 and IL-5 from human CD4+ T-cells.

PHARMACOKINETICS

Peak concentration of indacaterol occurs about 15 minutes after inhalation, and absolute bioavailability was on average 43 to 45%. Indacaterol is metabolized by cytochrome P450 isoenzymes, particularly CYP3A4. Uridine diphosphate glucuronosyltransferase 1A1 (UGT 1A1) also contributes to metabolism and indacaterol is a low affinity substrate for P-glycoprotein. When indacaterol was given orally, at least 77% was excreted in the faeces; renal clearance plays a minor role in the excretion via the urine. The average terminal half-life was 45.5 to 126 hours, but a half-life of 40 to 56 hours was calculated after repeated dosing.
Mometasone furoate is poorly absorbed after inhalation, intranasal use and tropical application. It undergoes hepatic metabolism mainly by cytochrome p450 isoenzymes CYP3A4. The terminal elimination half-life is about 5 hours; metabolites are excreted mainly in the faeces and to lesser extent in the urine.
Concomitant administration of orally inhaled indacaterol, and mometasone furoate under steady-state conditions did not affect the pharmacokinetics of any of the active substances.

INDICATIONS

It is indicated as a once-daily maintenance treatment of asthma in adults and adolescents 12 years of age and older where use of a combination of long-acting beta2-agonist and inhaled corticosteroid is appropriate.

DOSAGE AND ADMINISTRATION

This product is for inhalation use only.
Inhalation of the content of one capsule of Minvair 150/80 micrograms once daily is recommended in patients who require a combination of a long-acting beta$_2$-agonist and a low dose of inhaled corticosteroid. Inhalation of the content of one capsule of Minvair 150/160 micrograms or 150/320 micrograms once-daily is recommended in patients who require a combination of a long-acting beta$_2$-agonist and a medium or high dose of inhaled corticosteroid.
The maximum recommended dose is Minvair 150/320 micrograms once daily.
It may be used in pediatric patients (12 years of age and older) at the same posology as in adults. The safety and efficacy of in pediatric patients below 12 years of age have not been established.

CONTRAINDICATIONS

- Hypersensitivity to the active substances or to any of the ingredients.

ADVERSE EFFECTS

The reported adverse events are; oral candidiasis, oropharyngeal candidiasis, hypersensitivity, drug eruption, drug hypersensitivity, rash erythematous, rash pruritic, urticaria, angioedema, allergic oedema, periorbital swelling, swelling of eyelid, hyperglycemia, headache, tension headache, tachycardia, sinus tachycardia, supraventricular tachycardia, oropharyngeal pain, oral pain, oral discomfort, throat irritation, odynophagia, pruritus, anal pruritus, eye pruritus, nasal pruritus, pruritus, pruritus genital, musculoskeletal pain, back pain, myalgia, neck pain, musculoskeletal chest pain, muscle spasm, cough, increase risk of infection, rhinorrhea, paranesthesia, skin reactions, difficult swallowing, wheezing, drop in blood pressure, hoarseness and changes to your voice, increase thrust, frequent urination, dry skin, blurred vision, fatigue, dizziness, swelling of lip and face.

DRUG INTERACTION

Information on the potential for interactions is based on the potential for each of the monotherapy components:

- There is a potential for an additive interaction with concomitantly used anticholinergic medications. Therefore, avoid its coadministration with other anticholinergic-containing drugs as this may lead to an increase in anticholinergic effects.
- Beta-adrenergic blockers may weaken or antagonise the effect of beta2 -adrenergic agonists. Therefore, this medicinal product should not be given together with beta-adrenergic blockers unless there are compelling reasons for their use. Where required, cardio selective beta-adrenergic blockers should be preferred, although they should be administered with caution.
- If additional adrenergic drugs are to be administered by any route, they should be used with caution because of the sympathetic effects of indacaterol.
- Concomitant hypokalaemia treatment with methylxanthine derivatives, steroids, or non-potassium-sparing diuretics may potentiate the possible hypokalaemia effect of beta2 -adrenergic agonists.
- Electrocardiographic (ECG) changes and/or hypokalaemia that may result from the administration of non-potassium sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, such as indacaterol.
- Like other medicinal products containing a beta2-adrenergic agonist, this medicinal product should be administered with caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or medicinal products known to prolong the QT interval, as any effect of these on the QT interval may be potentiated. Medicinal products known to prolong the QT interval may increase the risk of ventricular arrhythmia.
- Inhibition of CYP3A4 and P-glycoprotein (P-gp) has no impact on the safety of therapeutic doses of this product. Inhibition of the key contributors of indacaterol clearance (CYP3A4 and P-gp) or mometasone furoate clearance (CYP3A4) raises the systemic exposure of indacaterol or mometasone furoate up to two-fold. Due to the very low plasma concentration achieved after inhaled dosing, clinically significant interactions with mometasone furoate are unlikely. However, there may be a potential for increased systemic exposure to mometasone when strong CYP3A4 inhibitors (e.g. ketoconazole, itraconazole, nelfinavir, ritonavir, cobicistat) are coadministered.
- The co-administration of this medicinal product with other medicinal products containing long-acting muscarinic antagonists or long-acting beta2 -adrenergic agonists has not been studied and is not recommended as it may potentiate adverse reactions.

WARNINGS AND PRECAUTIONS

- This medicinal product (Indacaterol and Mometasone) should not be used to treat acute asthma symptoms, including acute episodes of bronchospasm, for which a short-acting bronchodilator is required. Increasing use of short-acting bronchodilators to relieve symptoms indicates deterioration of control and patients should be reviewed by a physician. Patients should not stop treatment without physician supervision since symptoms may recur after discontinuation. It is recommended that treatment with this medicinal product (Indacaterol and Mometasone) should not be stopped abruptly. If patients find the treatment ineffective, they should continue treatment but must seek medical attention. Increasing use of reliever bronchodilators indicates a worsening of the underlying condition and warrants a reassessment of the therapy. Sudden and progressive deterioration in the symptoms of asthma is potentially life-threatening and the patient should undergo urgent medical assessment.
- Immediate hypersensitivity including anaphylaxis reactions have been reported. If signs suggesting allergic reactions occur, in particular angioedema (including difficulties in breathing or swallowing, swelling of the tongue, lips, and face), urticaria or skin rash, this combination (Indacaterol and Mometasone) should be discontinued immediately, and alternative therapy instituted.
- As with other inhalation therapy, administration of this medicinal product may result in paradoxical bronchospasm, which can be life-threatening. If this occurs, treatment should be discontinued immediately, and alternative therapy instituted.
- This combination (Indacaterol and Mometasone) should be used with caution in patients with narrow-angle glaucoma. Prescribers and patients should be alert for signs and symptoms of acute narrow-angle glaucoma (e.g., eye pain or discomfort, blurred vision, visual halos or coloured images in association with red eyes from conjunctival congestion and corneal oedema). Instruct patients to contact their doctor immediately should any of these signs or symptoms develop.
- As with other inhaled drugs containing beta2 -adrenergic, it should not be used more often than recommended, at higher doses than recommended, or in conjunction with other medications containing LABAs, as an overdose may result. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs.
- Patients using this combination (Indacaterol and Mometasone) should not use another medicine containing a LABA for any reason.
- Like other medicinal products containing beta2-adrenergic agonists, this combination (Indacaterol and Mometasone) can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, or symptoms. If such effects occur, this combination (Indacaterol and Mometasone) may need to be discontinued.
- In addition, beta- adrenergic agonists have been reported to produce ECG changes, such as flattening of the T-wave, prolongation of the QTc interval, and ST segment depression, although the clinical significance of these findings is unknown.
- This medicinal product (Indacaterol and Mometasone) should be used with caution in patients with coexisting conditions like cardiovascular disorders (coronary artery disease, acute myocardial infarction, cardiac arrhythmias, hypertension), convulsive disorders or thyrotoxicosis, and in patients who are unusually responsive to beta2 -adrenergic agonists.
- Beta2 -adrenergic agonists may produce significant hypokalaemia in some patients, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation.
- In patients with severe COPD, hypokalaemia may be potentiated by hypoxia and concomitant treatment which may increase the susceptibility for cardiac arrhythmias.
- Inhalation of high doses of beta 2 -adrenergic agonists may produce increases in plasma glucose. Upon initiation of treatment, plasma glucose should be monitored more closely in diabetic patients.
- If oropharyngeal candidiasis develops, it should be treated with appropriate local or systemic (i.e., oral) antifungal therapy while remaining on treatment with Mometasone or its combination therapy, but at times therapy with it may need to be interrupted. After administration, advise patients to rinse the mouth with water and spit out contents without swallowing.
- Systemic effects may occur with inhaled corticosteroids, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Possible systemic effects may include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataracts, glaucoma, and, more rarely, a range of psychological or behavioral effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). It is therefore important that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control of asthma is maintained.
- Visual disturbance may be reported with systemic and topical (including intranasal, inhaled and intraocular) corticosteroid use. Patients presenting with symptoms such as blurred vision or other visual disturbances should be considered for referral to an ophthalmologist for evaluation of possible causes of visual disturbances, 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.
- During withdrawal from oral corticosteroids, some patients may experience symptoms of systemically active corticosteroid withdrawal, e.g., joint and/or muscular pain, lassitude, and depression, despite maintenance or even improvement of respiratory function.
- Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids, including mometasone. The clinical significance of small changes in BMD with regard to long-term outcomes is unknown. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants and corticosteroids) should be monitored and treated with established standards of care.
- Orally inhaled corticosteroids, including Mometasone or its combination may cause a reduction in growth velocity when administered to paediatric patients. Monitor the growth of paediatric patients receiving it routinely (e.g., via stadiometry).
- It should be administered with caution in patients with pulmonary tuberculosis or in patients with chronic or untreated infections.

USE IN SPECIAL POPULATION

Pregnancy.
There are no adequate and well-controlled studies with this combination (Indacaterol and Mometasone) in pregnant women. Women should be advised to contact their healthcare provider if they become pregnant while taking this combination (Indacaterol and Mometasone). Indacaterol may inhibit labour due to a relaxant effect on uterine smooth muscle. Therefore, it should only be used during pregnancy if the expected benefit to the patient justifies the potential risk to the foetus.

Lactation
It is not known whether this combination (Indacaterol and Mometasone) and their metabolites are excreted in human milk, have effects on a breast-fed infant, or its effects on milk production. Excretion of indacaterol and their metabolites in the milk of lactating rats is known. Other inhaled corticosteroids similar to mometasone furoate are transferred into human milk. The use of this combination (Indacaterol and Mometasone) by breast-feeding women should only be considered if the expected benefit to the woman is greater than any possible risk to the infant.

Fertility
Reproduction studies and other data in animals do not indicate a concern regarding fertility in either males or females.

Elderly population
No adjustment of this combination (Indacaterol and Mometasone) dosage in geriatric patients is warranted. It can be used at the recommended dosage in elderly patients 65 years of age and older.

Renal impairment
No dose adjustment is required in patients with renal impairment.

Hepatic impairment
This combination (Indacaterol and Mometasone) can be used at the recommended dose in patients with mild and moderate hepatic impairment. Studies in subjects with severe hepatic impairment have not been performed.

Paediatric population
The safety and effectiveness of this combination (Indacaterol and Mometasone) in paediatric patients (below 12 years of age) have not been established. This combination is not indicated for use in paediatric patients.

OVERDOSAGE

General supportive measures and symptomatic treatment should be initiated in cases of suspected overdose.
An overdose will likely produce signs, symptoms or adverse effects associated with the pharmacological actions of the individual components (e.g. tachycardia, tremor, palpitations, headache, nausea, vomiting, drowsiness, ventricular arrhythmias, metabolic acidosis, hypokalemia, hyperglycemia, suppression of hypothalamic pituitary adrenal axis function). The use of cardio selective beta blockers may be considered for treating beta$_2$-adrenergic effects, but only under the supervision of a physician and with extreme caution since the use of beta-adrenergic blockers may provoke bronchospasm. In serious cases, patients should be hospitalized.

Method of Administration

For inhalation use only. The capsules must not be swallowed.
Patients should be instructed on how to administer the medicinal product correctly. Patients who do not experience improvement in breathing should be asked if they are swallowing the capsule rather than inhaling it.
The capsules must be administered only using the revolizer. The inhaler provided with each new prescription should be used.
It should be administered at the same time of the day each day. It can be administered irrespective of the time of the day. The capsules must always be stored in the blister to protect from moisture and light, and only removed immediately before use. After inhalation, patients should rinse their mouth with water without swallowing. If a dose is missed, it should be taken as soon as possible. Patients should be instructed not to take more than one dose a day.

DOSAGE AND INSTRUCTIONS

To be sold and used on the prescription of a registered medical practitioner only. Keep out of reach of children. Do not store above 30°C. Keep in a dry place. Protect from light.

ROTACAP IS INTENDED FOR USE THROUGH ROTAFLO OR REVOLIZER ONLY AND IS NOT TO BE SWALLOWED.

PRESENTATION

Minvair 150mcg/80mcg Rotacaps:
Alu. Alu. Blister Pack of 3 x 10's.

Minvair 150mcg/160mcg Rotacaps:
Alu. Alu. Blister Pack of 3 x 10's.

Minvair 150mcg/320mcg Rotacaps:
Alu. Alu. Blister Pack of 3 x 10's.

من وائیر™

(انڈاکیٹیرال + مومیٹاسون فیوروئیٹ)

خوراک و ہدایات:

صرف مستند ڈاکٹر کے نسخہ کے مطابق ہی دوا فروخت اور استعمال کی جائے۔
بچوں کی پہنچ سے دور رکھیں۔ 30°C سے زیادہ درجہ حرارت پر نہ رکھیں۔
خشک جگہ پر رکھیں۔ روشنی سے بچائیں۔

روٹاکیپسول کھانے کے لئے نہیں ہے۔
صرف روٹافلو یا ریوولائزر کے ذریعے استعمال کریں۔

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