NOVARTIS

ONBREZ® BREEZHALER®

(indacaterol maleate)

150 microgram and 300 microgram inhalation powder hard capsules

Basic Succinct Statement

CODE: BSS RD 30 SEPT 2013; APPR 6 AUG 2014
This material is only meant for Healthcare Professionals

ONBREZ® BREEZHALER®

Important note: Before prescribing, consult full prescribing information.

Presentation: Inhalation powder hard capsules containing indacaterol maleate equivalent to 150 microgram (mcg) indacaterol; inhalation powder hard capsules containing indacaterol maleate equivalent to 300 mcg indacaterol.

Indications: ONBREZ® BREEZHALER® is a long-acting beta$_2$-agonist indicated for maintenance bronchodilator treatment of airflow obstruction in adult patients with chronic obstructive pulmonary disease (COPD).

Dosage:

Adults: recommended dosage is the once-daily inhalation of the content of one 150 mcg capsule using the ONBREZ BREEZHALER inhaler. The dosage should only be increased on medical advice. Once-daily inhalation of the content of one 300 mcg capsule using the ONBREZ BREEZHALER inhaler, has been shown to provide additional clinical benefit to some patients, e.g. with regard to breathlessness, particularly for patients with severe COPD. The maximum dose is 300 mcg once-daily.

Children (<18 years): should not be used in patients under 18 years of age.

Special patients population: no dosage adjustment is required for geriatric patients, patients with mild and moderate hepatic impairment, or renally impaired patients; no data is available for subjects with severe hepatic impairment.

Method of administration

ONBREZ BREEZHALER capsules must be administered only by the oral inhalation route and only using the ONBREZ BREEZHALER inhaler. Capsules must not be swallowed. ONBREZ BREEZHALER should be administered at the same time of the day each day. If a dose is missed, the next dose should be taken at the usual time the next day. Capsules must always be stored in the blister, and only removed immediately before use. Patients should be instructed on how to administer the product correctly. Patients who do not experience improvement in breathing should be asked if they are swallowing the medicine rather than inhaling it.

Contraindications: ♦Known hypersensitivity to indacaterol or to any of the excipients.

Warnings/Precautions: **♦asthma:** should not be used in asthma Long-acting beta$_2$-adrenergic agonists may increase the risk of asthma-related serious adverse events, including asthma-related deaths, when used for the treatment of asthma **♦paradoxical bronchospasm:** as with other inhalation therapy, administration may result in paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs, ONBREZ BREEZHALER should be discontinued immediately and alternative therapy instituted **♦hypersensitivity:** If hypersensitivity reaction occurs, ONBREZ BREEZHALER should be discontinued immediately and alternative therapy instituted **♦deterioration of disease:** in case of deterioration of COPD whilst on treatment, a re-evaluation of the patient and COPD treatment regimen should be undertaken **♦systemic effects:** as with other beta$_2$-adrenergic agonists, should be used with caution in patients with cardiovascular disorders (coronary artery disease, acute myocardial infarction, cardiac arrhythmias, hypertension); in patients with convulsive disorders or thyrotoxicosis; in patients who are unusually responsive to beta$_2$-adrenergic agonists **♦cardiovascular effects**: like other beta$_2$-adrenergic agonists, may produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse

rate, blood pressure, and/or symptoms, ECG changes ♦**hypokalemia:** beta$_2$-adrenergic agonists may produce significant hypokalemia in some patients, which has the potential to produce adverse cardiovascular effects. In patients with severe COPD, hypokalemia may be potentiated by hypoxia and concomitant treatment which may increase the susceptibility to cardiac arrhythmias ♦**hyperglycemia:** clinically notable changes in blood glucose were generally more frequent by 1 to 2% during clinical studies at the recommended doses than on placebo ♦should not be used in conjunction with other long-acting beta$_2$-adrenergic agonists or medications containing long-acting beta$_2$-adrenergic agonists.

Pregnancy: should be used during pregnancy only if the expected benefit justifies the potential risk to the foetus.

Breast-feeding: should only be considered if the expected benefit to the woman is greater than any possible risk to the infant.

Fertility: reproduction studies or other data in animals did not reveal a problem or potential problem concerning fertility in either males or females.

Interactions: ♦should be administered with caution to patients being treated with monoamine oxidase inhibitors, tricyclic antidepressants, or drugs known to prolong the QT-interval ♦concomitant administration of other sympathomimetic agents may potentiate the undesirable effects ♦concomitant treatment with methylxanthine derivatives, steroids, or non-potassium sparing diuretics may potentiate the possible hypokalemic effect of beta$_2$-adrenergic agonists ♦should not be given together with beta-adrenergic blockers (including eye drops) unless there are compelling reasons for their use ♦inhibition of the key contributors of indacaterol clearance, CYP3A4 and P-gp, has no impact on safety of therapeutic doses.

Adverse reactions:

♦**Uncommon (0.1 to 1%) and potentially serious**: hypersensitivity, paradoxical bronchospasm. ♦**Very common (>10%):** nasopharyngitis, upper respiratory tract infection. ♦**Common (1 to 10%)**: headache, dizziness, cough, muscle spasm, oropharyngeal pain incl. throat irritation, sinusitis, peripheral edema, ischemic heart disease, palpitations, diabetes and hyperglycemia, rhinorrhea, musculoskeletal pain, chest pain, pruritus/rash. ♦**Uncommon (0.1 to 1%)**: atrial fibrillation, tachycardia, paresthesia, myalgia.