NOVARTIS

ULTIBRO® BREEZHALER®

(Indacaterol maleate and glycopyrronium bromide fixed dose combination)

110/50 microgram Inhalation powder, hard capsules

Basic Succinct Statement (BSS) (FLAME Indication)

Code: BSS ULTIBRO RD 15 APR 2019; APPR 01 NOV 2020

This material is only meant for Healthcare Professionals

ULTIBRO® BREEZHALER®

Important note: Before prescribing, consult full prescribing information.

Indications:

ULTIBRO® BREEZHALER® is indicated as a once-daily maintenance bronchodilator treatment to relieve symptoms and reduce exacerbations in patients with chronic obstructive pulmonary disease (COPD).

Dosage and administration:

Adults: recommended dosage is the once-daily inhalation of the content of one 110/50 mcg capsule using the ULTIBRO BREEZHALER inhaler.

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

Special populations:

Renal impairment: can be used at recommended dose in patients with mild to moderate renal impairment. Should be used only if expected benefit outweighs the potential risk in patients with severe renal impairment or end-stage renal disease requiring dialysis.

Hepatic impairment: Can be used at the recommended dose in patients with mild and moderate hepatic impairment. No data are available for subjects with severe hepatic impairment.

Geriatric patients: can be used at recommended dose in patients 75 years of age and older.

Method of administration: ULTIBRO BREEZHALER capsules must be administered by the oral inhalation route and only using the ULTIBRO BREEZHALER inhaler. Capsules must not be swallowed. ULTIBRO BREEZHALER should be administered at the same time of the day each day. If a dose is missed, it should be taken as soon as possible. Patients should be instructed not to take more than one dose in a day. Capsules must always be stored in the blister to protect from moisture, 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 glycopyrronium, which are components of ULTIBRO BREEZHALER, or to any of the excipients.

Warnings and precautions:

♦ULTIBRO BREEZHALER should not be administered concomitantly with other long-acting beta-agonists or long-acting muscarinic-antagonists. ♦**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 treatment of asthma. ♦**not for acute use:** should not be used as rescue therapy. ♦**hypersensitivity:** If hypersensitivity reaction occurs, ULTIBRO BREEZHALER should be discontinued immediately and alternative

therapy instituted. **♦paradoxical bronchospasm:** as with other inhalation therapy, administration may result in paradoxical bronchospasm that may be life-threatening. If paradoxical bronchospasm occurs, ULTIBRO BREEZHALER should be discontinued immediately and alternative therapy instituted. **♦anticholinergic effects related to glycopyrronium:** use with caution in patients with narrow-angle glaucoma and urinary retention. **♦systemic effects of beta-agonists:** 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. **♦patients with severe renal impairment:** to be used only if expected benefit outweighs potential risk in patients with severe renal impairment including end-stage renal disease requiring dialysis. **♦cardiovascular effects of beta-agonists:** 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 with beta-agonists:** 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 with beta agonists:** During long-term clinical studies ([ENLIGHTEN] and [RADIATE]), more patients on ULTIBRO BREEZHALER experienced clinically notable changes in blood glucose (4.9%) than on placebo (2.7%). ULTIBRO BREEZHALER has not been investigated in patients for whom diabetes mellitus is not well controlled.

Adverse drug reactions:

♦Common (≥1% to <10%) and potentially serious: Hyperglycemia and diabetes mellitus, hypersensitivity **♦Uncommon (≥0.1% to <1%) and potentially serious:** Glaucoma, ischemic heart disease, atrial fibrillation, paradoxical bronchospasm **♦Very common (≥10%):** Upper respiratory tract infection **♦Common (≥1% to <10%):** Nasopharyngitis, urinary tract infection, sinusitis, rhinitis, dizziness, headache, cough, oropharyngeal pain including throat irritation, dyspepsia, dental caries, pyrexia, chest pain, bladder obstruction including urinary retention **♦Uncommon (≥0.1% to <1%):** Musculoskeletal pain, insomnia, tachycardia, palpitations, epistaxis, dry mouth, pruritus/rash, muscle spasm, myalgia, peripheral edema, fatigue, gastroenteritis, pain in extremity. **♦Rare (≥0.01% to <0.1%):** Paresthesia **Not known:** Angioedema, dysphonia.