NOVARTIS

SEEBRI® BREEZHALER®

(glycopyrronium bromide)

50 microgram inhalation powder hard capsules

Basic Succinct Statement

Version 3.1

Code: BSS RD 11 FEB 20; APPR 07 OCT 20

This material is only meant for Healthcare Professionals

SEEBRI® BREEZHALER®

Important note: Before prescribing, consult full prescribing information.

Presentation: Inhalation powder hard capsules containing glycopyrronium bromide equivalent to 50 microgram glycopyrronium.

Indications: SEEBRI BREEZHALER is indicated as a once-daily maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

Dosage and administration:

Adults: recommended dosage is the once-daily inhalation of the content of one 50 microgram capsule using the SEEBRI BREEZHALER inhaler.

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

Special populations: no dosage adjustment is required for geriatric patients, patients with hepatic impairment or patients with mild and moderate renal impairment. Care should be taken in patients with severe renal impairment including end-stage renal disease requiring dialysis.

Method of administration: SEEBRI BREEZHALER capsules must be administered only by the oral inhalation route and only using the SEEBRI BREEZHALER inhaler. Capsules must not be swallowed. SEEBRI BREEZHALER should be administered at the same time of the day each day. If a dose is missed, the next dose 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, and only removed immediately before use. Patients should be instructed on correct use of the inhaler. 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 glycopyrronium, which is the active component of SEEBRI BREEZHALER, or to any of the excipients.

Warnings and precautions: **♦acute use:** should not be used as rescue therapy **♦hypersensitivity:** if hypersensitivity reaction occurs, SEEBRI 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, SEEBRI BREEZHALER should be discontinued immediately and alternative therapy instituted **♦anticholinergic effect:** use with caution in patients with narrow-angle glaucoma and urinary retention **♦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.

Adverse drug reactions:

♦Common (1 to 10%): dry mouth, insomnia, gastroenteritis, nasopharyngitis **♦Uncommon (0.1 to 1%)**: dyspepsia, dental caries, pain in extremity, musculoskeletal chest pain, rash, fatigue, asthenia, sinus congestion, productive cough, throat irritation, epistaxis, rhinitis, cystitis, hyperglycaemia, dysuria, urinary retention, atrial fibrillation, palpitations, hypoesthesia, **♦Not known**: angioedema, paradoxical bronchospasm, hypersensitivity, pruritus, dysphonia **♦Elderly patients only**: headache, urinary tract infection.