NOVARTIS

Regulatory Affairs

# **TREZILENT®** (alpelisib)
50mg, 150 mg and 200 mg Film-coated tablets

## Basic Succinct Statement (BSS)

**Code: BSS RD 13 Jan 20 APPR 7 Jan 21**

. **This material is only meant for Healthcare Professionals**

## TREZILENT®

**Important note:** Before prescribing, consult full prescribing information.

**Presentation:** Film-coated tablets (FCT) containing 50 mg, 150mg and 200mg of alpelisib.

**Indications:** Trezilent® is indicated in combination with fulvestrant for the treatment of postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer following progression on or after an endocrine-based regimen.

### Dosage and administration:

**Adults:** The recommended dose of Trezilent is 300 mg taken orally, once daily on a continuous basis. Trezilent should be taken immediately following food, at approximately same time each day. If a dose of Trezilent is missed, it can be taken up to 9 hours after the time it is normally administered. After more than 9 hours, the dose should be skipped for that day. On the next day, Trezilent should be taken at its usual time. If patient vomits after taking the Trezilent dose, the patient should not take an additional dose on that day, and should resume the usual dosing schedule the next day, at the usual time.

**Special populations:** ♦*Renal impairment:* Mild or moderate: No dose adjustment is necessary. ♦ *Severe:* Caution is recommended. ♦*Hepatic impairment:* Mild, moderate or severe: No dose adjustment is necessary. ♦*Geriatrics (≥65 years):* No dose adjustment is required. ♦*Pediatrics (≤18 years):* Safety and efficacy have not been established.

**Contraindications:** ♦Patients with severe hypersensitivity to the active substance or to any of the excipients.

### Warnings and precautions:

♦**Hypersensitivity (including anaphylactic reaction):** Serious hypersensitivity reactions (including anaphylactic reaction and anaphylactic shock), manifested by symptoms including, but not limited to, dyspnea, flushing, rash, fever or tachycardia were reported in patients treated with Trezilent in clinical studies. Trezilent should be permanently discontinued in patients with serious hypersensitivity reactions. Appropriate treatment should be promptly initiated. ♦**Severe cutaneous reactions:** Cases of severe cutaneous reactions, including Stevens-Johnson syndrome (SJS), erythema multiforme (EM), toxic epidermal necrolysis (TEN), and drug reaction with eosinophilia and systemic symptoms (DRESS) were reported in patients treated with Trezilent . Patients should be advised of the signs and symptoms of severe cutaneous reactions. If symptoms or signs of severe cutaneous reactions are present, Trezilent should be interrupted until the etiology of the reaction has been determined. A consultation with dermatologist is recommended. If a severe cutaneous reactions is confirmed, Trezilent should be permanently discontinued. Trezilent should not be reintroduced in patients who have experienced previous severe cutaneous reactions during Trezilent treatment. ♦ **Hyperglycaemia:** Hyperglycaemia was reported in of patients treated with Trezilent in the phase III clinical study. Patients should be advised of the signs and symptoms of hyperglycaemia. Based on the severity of the hyperglycaemia, Trezilent may require treatment

interruption, dose reduction, or treatment discontinuation. ♦ **Pneumonitis**: Pneumonitis including serious cases of pneumonitis/acute interstitial lung disease have been reported in Trezilent treated patients in clinical studies. Patients should be advised to promptly report any new or worsening respiratory symptoms. In patients who have new or worsening respiratory symptoms or are suspected to have developed pneumonitis, Trezilent treatment should be interrupted immediately and the patient should be evaluated for pneumonitis. A diagnosis of non-infectious pneumonitis should be considered. Trezilent should be permanently discontinued in all patients with confirmed pneumonitis.

## Adverse drug reactions:

♦**Very common (≥10%):** Diarrhoea, nausea, vomiting, stomatitis, abdominal pain, dyspepsia, fatigue, mucosal inflammation, oedema peripheral, pyrexia, mucosal dryness, urinary tract infection, weight decreased, blood creatinine increased, decreased appetite, headache, dysgeusia, rash, alopecia, pruritus, dry skin, activated partial thromboplastin time increased, hemoglobin decreased, lymphocyte count decreased, platelet count decreased, alanine aminotransferase increased, albumin decreased, calcium corrected decreased, gamma-glutamyl transferase increased, glucose plasma increased, glucose plasma decreased, lipase increased, potassium decreased, magnesium decreased. ♦**Uncommon** (**(≥0.1 to <1%**): Ketoacidosis, Stevens-Johnson syndrome (SJS).

♦**Adverse drug reactions from post-marketing experience (frequency not known):** Drug reaction with eosinophilia and systemic symptoms (DRESS).

**Description of select ADRs and treatment recommendations, where applicable: ♦ Rash:** Topical corticosteroid treatment should be initiated at the first signs of rash and oral corticosteroids should be considered for more moderate to severe rashes. Additionally, antihistamines are recommended to manage symptoms of rash. Oral antihistamines may be initiated prophylactically, at the time of initiation of treatment with Trezilent. ♦ Gastrointestinal **(GI) toxicity (nausea, diarrhoea, vomiting):** Severe diarrhoea and clinical consequences, such as dehydration and acute kidney injury have been reported during treatment with Trezilent and resolved with appropriate intervention. Patients should be managed according to local standard of care medical management, including electrolyte monitoring, administration of anti-emetics and antidiarrhoeal medications and/or fluid replacement and electrolyte supplements, as clinically indicated.