IMPORTANT NOTE: Before prescribing, consult the full product information. ▪ **PRESENTATION:** Hard capsules containing 200 mg sonidegib. ▪ **INDICATIONS:** Odomzo (Sonidegib) is indicated for the treatment of adult patients with locally advanced basal cell carcinoma (BCC) who are not amenable to curative surgery or radiation therapy. ▪ **DOSAGE AND ADMINISTRATION: Adults:** The recommended dose is 200 mg sonidegib taken orally once daily at least two hours after a meal and at least one hour before the following meal, at the same time each day. ▪ **Special populations: Patients with renal impairment:** Sonidegib has not been studied in patients with renal impairment. Based on the available data, sonidegib elimination via the kidney is negligible. A population pharmacokinetic analysis did not find a significant influence of renal function on the apparent clearance (CL/F) of sonidegib, suggesting that dose adjustment is not necessary in patients with renal impairment. ▪ **Patients with hepatic impairment:** No dose adjustment is required in patients with hepatic impairment. ▪ **Paediatric patients:** The safety and efficacy of Odomzo have not been established in paediatric patients with BCC. ▪ **CONTRAINDICATIONS**: Pregnancy and breast-feeding. ▪ **Warnings and precautions: Muscle related adverse events:** CK levels should be checked prior to starting treatment and as clinically indicated thereafter, e.g. if muscle-related symptoms are reported. If clinically notable elevation of CK is detected, renal function should be assessed. Dose modification or interruption guidelines should be followed. Patients should be closely monitored for muscle-related symptoms if Odomzo is used in combination with certain medicinal products that may increase the potential risk of developing muscle toxicity (e.g. CYP3A4 inhibitors, chloroquine, hydroxychloroquine, fibric acid derivatives, penicillamine, zidovudine, niacin and HMG-CoA reductase inhibitors). Closely monitor patients with neuromuscular disorders (e.g. inflammatory myopathies, muscular dystrophy amyotrophic lateral sclerosis, and spinal muscular atrophy) due to an increased risk of muscle toxicity. ▪ **Blood donation:** Patients should be instructed not to donate blood while taking Odomzo and for at least 20 months after ending treatment. ▪ **Women of childbearing potential:** Women of child-bearing potential must use two methods of recommended contraception, including one highly effective method and a barrier method, while taking Odomzo and for 20 months after ending treatment. Healthcare professionals must educate patients so they understand and acknowledge all the conditions of the Odomzo Pregnancy Prevention Programme**.** ▪ **Pregnancy:** Negative pregnancy status must be confirmed by a test performed by a healthcare provider within 7 days prior to initiation of Odomzo treatment. Odomzo must not be used during pregnancy. ▪ **Breast-feeding:** Women must not breast feed while taking Odomzo and for at least 20 months after ending treatment. ▪ **Sexually active males:** Men should not father a child or donate semen while taking Odomzo and for at least 6 months after ending treatment. Sexually active males must use a condom, regardless of vasectomy status, during intercourse and for 6 months after ending treatment to prevent exposure of female partners to the drug via seminal fluid. ▪ **Fertility:** Male and female fertility may be compromised with Odomzo. Fertility preservation strategies should be discussed with women of childbearing potential prior to starting treatment with Odomzo. ▪ **Undesirable effects:** Very common (≥1/10): amenorrhea, decreased appetite, dysgeusia, headache, nausea, diarrhoea, vomiting, abdominal pain, alopecia, pruritus, muscle spasms, myalgia, musculoskeletal pain, fatigue, pain, weight decreased. Common (≥1/100 to <1/10): constipation, dyspepsia, gastroesophageal reflux disorder, rash, abnormal hair growth, myopathy (muscular fatigue and muscular weakness), dehydration. **Laboratory abnormalities:** Very common (≥1/10): haemoglobin decreased, lymphocyte count decreased, amylase increased, blood glucose increased, lipase increase, serum creatinine phosphokinase increase, serum creatinine increased, alanine amino transaminase (ALT) increased, aspartate amino transaminase (AST) increased. ▪ **Interactions:** Avoid concomitant use of strong CYP3A inhibitors, including but not limited to ritonavir, saquinavir, telithromycin, ketoconazole, itraconazole, voriconazole, posaconazole and nefazodone. Avoid concomitant use of strong CYP3A inducers, including but not limited to, carbamazepine,

phenobarbital, phenytoin, rifabutin, rifampicin and St. John's Wort (Hypericum perforatum). If a strong CYP3A4 inducer must be used concomitantly with sonidegib, consideration should be given to increasing the daily dose of sonidegib to 400-800 mg.. Monitor patients carefully for adverse drug reactions with concomitant use of substrates of CYP2B and CYP2C9 enzymes or BCRP transporter, especially those with a narrow therapeutic range. Due to overlapping toxicities, patients taking Odomzo who are also taking medications known to increase the risk of muscle-related toxicity may be at increased risk of developing muscle-related adverse events. Patients should be closely monitored and dose adjustments should be considered if muscle symptoms develop. ▪ Odomzo has no or negligible influence on the ability to drive and use machines. ▪ Patients should be monitored closely for adverse events and given appropriate supportive measures in all cases of overdose. ▪ **PACK SIZE:** 30 capsules. ▪ **CLASSIFICATION:** POM

REFERENCES: Odomzo Summary of Product Characteristics. May 2020.