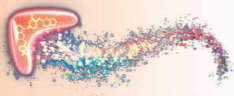




PURSUE PROGRESSION-FREE SURVIVAL WITH TUKYSA



TUKYSA + TRASTUZUMAB + CAPECITABINE

Indication¹

TUKYSA is indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.

Reference:

1. TUKYSA[®] Product Insert. Available at: Register of Therapeutic Products, Health Sciences Authority. <https://www.hsa.gov.sg/e-services/inforsarch>

Indications TUKYSA is indicated in combination with trastuzumab and capecitabine for treatment of patients with locally advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting. **Dosing** The recommended dose of TUKYSA is 300 mg (two 150 mg tablets) taken orally twice daily continuously in combination with trastuzumab and capecitabine. **Contraindications** Hypersensitivity to the active substance or to any of the excipients contained in TUKYSA. **Precautions/Warnings Hepatotoxicity** Hepatotoxicity has been reported during treatment with TUKYSA. The median time to onset of any grade increased ALT, AST, or bilirubin was 36 days; 84% of events resolved, with a median time to resolution of 22 days. Monitor ALT, AST, and bilirubin prior to initiation of treatment and every three weeks thereafter or as clinically indicated. Based on the severity of the adverse reaction, interrupt dose, then dose reduce or permanently discontinue TUKYSA. **Diarrhea** Diarrhea, including severe events resulting in dehydration, hypotension, acute kidney injury, and death, has been reported during treatment with TUKYSA. The median time to onset of any grade diarrhea was 12 days; 80% of diarrhea events resolved, with a median time to resolution of 8 days. Prophylactic use of antidiarrheals was not required. Antidiarrheals were used in less than half of treatment cycles where diarrhea events were reported. The median duration of antidiarrheal use was 3 days per cycle. If diarrhea occurs, administer antidiarrheals as clinically indicated. Based on the severity of the diarrhea, interrupt dose, then dose reduce or permanently discontinue TUKYSA. Perform diagnostic tests as clinically indicated to exclude other causes of diarrhea. **Embryo-Fetal Toxicity** Based on findings from animal studies and its mechanism of action, TUKYSA may cause fetal harm when administered to a pregnant woman. In animal reproduction studies, administration of tucatinib to pregnant rats and rabbits during organogenesis caused embryo-fetal mortality, reduced fetal weight and fetal abnormalities at maternal exposures \geq 1.3 times the human exposure (AUC) at the recommended dose. TUKYSA should not be used during pregnancy. If TUKYSA is used during pregnancy, or if the patient becomes pregnant while receiving this drug, the patients must be advised of the potential risk to the fetus. Advise females of reproductive potential to use effective contraception during treatment and for at least 1 week after the last dose. Advise males with female partners of reproductive potential to use effective contraception during treatment and for at least 1 week after the last dose of TUKYSA. **Adverse Reactions** The following clinically significant adverse reactions are described in : • Hepatotoxicity [see Warnings and Precautions] • Diarrhea [see Warnings and Precautions]. **Before prescribing TUKYSA, please consult full prescribing information. Full prescribing information is available upon request.**

MSD Pharma (Singapore) Pte Ltd.

5 Battery Road, MYP Centre, #17-01, Singapore 049510.

Tel: +65 6887 1330 | www.msd-singapore.com

Copyright © 2023 Merck & Co., Inc., Rahway, NJ, USA, and its affiliates. All right reserved.

SG-KEY-00666 Jun/2023