Yulareb™
abemaciclib

Yulareb is now approved as a treatment option for HR+, HER2-, node-positive EBC at high risk of recurrence[1]

APPROVAL BASED ON RESULTS IN PATIENTS WITH CLINICAL AND PATHOLOGICAL RISK FACTORS (Cohort 1; n=5,120)[1]

Consider Yulareb + ET for your patients with HR+, HER2- EBC at

HIGH RISK OF RECURRENCE

1 TO 3 positive nodes **AND** tumor size ≥ 5 cm

OR

1 TO 3 positive nodes **AND** histological grade 3

OR

≥4 positive nodes

EBC=early breast cancer, ET=endocrine therapy, HER2=human epidermal growth factor 2, HR=hormone receptor.

ABBREVIATED PRESCRIBING INFORMATION

CONTENTS: 50 mg tablets, 100 mg,150 mg tablets: Tablets are provided as immediate-release oval white, beige, or yellow tablets. INDICATIONS: 1. For early breast cancer, in combination with endocrine therapy is indicated for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence (1.1, 2.1, 14.1). In pre- or perimenopausal women, aromatase inhibitor endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist 2. For metastatic breast cancer, in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer. 3. For metastatic breast cancer, in combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy. DOSAGE: When used in combination with fulvestrant tamoxifen, or an aromatase inhibitor, the recommended dose of YULAREB is 150 mg taken orally twice daily. Refer to the Full Prescribing Information for the recommended dose of the fulvestrant, tamoxifen, or aromatase inhibitor being used. 1. Early Breast Cancer: YULAREB should be taken continuously for two years, or until disease recurrence or unacceptable toxicity occurs. 2. Advanced or metastatic breast cancer: Continue treatment until disease progression or unacceptable toxicity. 3. Pre/perimenopausal women treated with the combination of YULAREB plus fulvestrant should be treated with a gonadotropin-releasing hormone agonist according to current clinical practice standards. 4. Pre/perimenopausal women treated with the combination of YULAREB, plus an aromatase inhibitor should be treated with a gonadotropin-releasing hormone agonist (GnRH) according to current clinical practice standards. ADMINISTRATION: Advise the patient that YULAREB may be taken with or without food. CONTRAINDICATIONS: Hypersensitivity to the active substance or to any of the excipients listed. SPECIAL WARNINGS AND PRECAUTIONS: 1. Diarrhea: YULAREB can cause severe cases of diarrhea, associated with dehydration and infection: Instruct patients at the first sign of loose stools to initiate antidiarrheal therapy, increase oral fluids, and notify their healthcare provider. 2. Neutropenia: Monitor complete blood counts prior to the start of YULAREB therapy, every 2 weeks for the first 2 months, monthly for the next 2 months, and as clinically indicated. 3. Interstitial Lung Disease (ILD)/Pneumonitis: Severe and fatal cases of ILD/pneumonitis have been reported. Monitor for clinical symptoms or radiological changes indicative of ILD/pneumonitis. Permanently discontinue YULAREB in all patients with Grade 3 or 4 ILD or pneumonitis. 4. Hepatotoxicity: Increases in serum transaminase levels have been observed. Perform liver function tests (LFTs) before initiating treatment with YULAREB. Monitor LFTs every two weeks for the first two months, monthly for the next 2 months, and as clinically indicated. 5. Venous Thromboembolism: Monitor patients for signs and symptoms of thrombosis and pulmonary embolism and treat as medically appropriate. 6. Embryo-Fetal Toxicity: Can cause fetal harm. Advise patients of potential risk to a fetus and to use effective contraception. ADVERSE REACTIONS: Most common adverse reactions (incidence ≥20%) were diarrhea, neutropenia, nausea, abdominal pain, infections, fatigue, anemia, leukopenia, decreased appetite, vomiting, headache, alopecia, and thrombocytopenia. DRUG INTERACTIONS: 1. CYP3A Inhibitors: Avoid concomitant use of ketoconazole. Reduce the YULAREB dose with concomitant use of other strong and moderate CYP3A inhibitors. 2. CYP3A Inducers: Avoid concomitant use of strong and moderate CYP3A inducers. PRESENTATION: YULAREB tablets are supplied in 7-day dose pack configurations as follows: 1. 150 mg dose pack (14 tablets) – each blister pack contains 7 tablets (150 mg per tablet) (150 mg twice daily) 2. 100 mg dose pack (14 tablets) – each blister pack contains 7 tablets (100 mg per tablet) (100 mg twice daily) 3. 50 mg dose pack (14 tablets) – each blister pack contains 7 tablets (50 mg per tablet) (50 mg twice daily) DATE OF REVISION: 9 Nov 2022 REFERENCE: Yulareb PI_USPI Oct 2021_EUSPC Apr2022_09 Nov 2022 pack contains 7 tablets (50 mg per tablet) (50 mg twice daily) DATE OF REVISION: 9 Nov 2022 REFERENCE: Yulareb PI_USPI Oct 2021_EUSPC Apr2022_09 Nov 2022.

Malaysia Adverse events should be reported to zpmypv@zuelligpharma.com

Before prescribing, please refer to the full prescribing information, which is available upon request.

For Healthcare Professionals Only MY-PM-LILLY-YULARE-ONA-HCP-000001-05-2023

References: **1**. Yulareb Package Insert (Malaysia). Last Updated: 09 Nov 2022.

ZP THERAPEUTICS
making healthcare more accessible

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