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KISQALI - Home - HCP

Prescribing information

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Help your eligible HR+/HER2– aBC patients achieve their treatment goals[1–9]

Indications:[1]

- KISQALI is indicated for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine

therapy

- In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist

KISQALI is not recommended to be used in combination with tamoxifen.

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1L KISQALI + AI increased mOS by >1 year (12.5 months) vs placebo + AI in postmenopausal patients[3]

- mOS at median 80-month follow-up was 63.9 months with KISQALI + AI vs 51.4 months with AI alone (HR=0.76; 95% CI: 0.63–0.93; p=0.008)[3]

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KISQALI + ET* preserved QoL (EoRTC or TTD) across all three Phase III trials vs placebo + ET[†6–9]

- Patient-reported outcomes for health-related QoL were secondary endpoints[6–9]

- MONALEESA-2: KISQALI + AI maintained QoL (mTTD ≥10%) for 27.7 months vs 27.6 months with placebo + AI (HR=0.944; 95% CI: 0.720–1.237).[7] MONALEESA-3: KISQALI + fulvestrant maintained QoL (mTTD ≥10%) for 35.9 months vs 33.1 months with placebo + fulvestrant alone (HR=0.81; 95% CI: 0.62–1.06).[8] MONALEESA-7: KISQALI + ET + LHRH maintained QoL (mTTD ≥10%) for 35.8 months vs 23.3 months with placebo + AI + LHRH (HR=0.67; 95% CI: 0.52–0.86)[9]

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In HR+/HER2– aBC, KISQALI + ET* is the only CDK4/6i with significant 1L OS benefit across three Phase III trials vs placebo + ET.[3–5]

MONALEESA-2: At 60-month follow-up, the Kaplan–Meier estimate of OS was 52.3% (95% CI, 46.5–57.7) in the KISQALI + AI group (n=334) and 43.9% (95% CI, 38.3–49.4) in the placebo group; at 72-month follow-up, was 44.2% (95% CI, 38.5 to 49.8) and 32.0% (95% CI, 26.8 to 37.3), respectively. Analysis showed a significant and clinically meaningful increase in OS of 12.5 months with 1L KISQALI + AI vs placebo + AI in postmenopausal patients with HR+/HER2- aBC.[3]

MONALEESA-3: KISQALI + fulvestrant (n=484) showed a significant OS benefit over placebo + fulvestrant. The estimated OS at 42-month follow-up was 57.8% (95% CI: 52.0 to 63.2) in the KISQALI group and 45.9% (95% CI, 36.9 to 54.5) in the placebo group, (HR=0.72; 95% CI:0.57 to 0.92; P=0.00455).[10]

MONALEESA-7: The estimated OS at 42-month follow-up was 70.2% (95% CI: 63.5 to 76.0) in the KISQALI + ET group (n=335) and 46.0% (95% CI: 32.0 to 58.9) in the placebo + ET group (HR for death, 0.71; 95% CI, 0.54 to 0.95; P=0.00973 by log-rank test).[11]

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KISQALI received an ESMO-MCBS score of 5/5 when used in combination with LHRH and with ET[‡13]

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SAFETY PROFILE

An established safety profile with KISQALI + ET*[1,12,14]

Discover more on KISQALI’s safety profile

Please consult your local Summary of Product Characteristics for the full KISQALI safety and tolerability profile.

Postmenopausal women with HR+/HER2– aBC

Postmenopausal women with HR+/HER2– aBC

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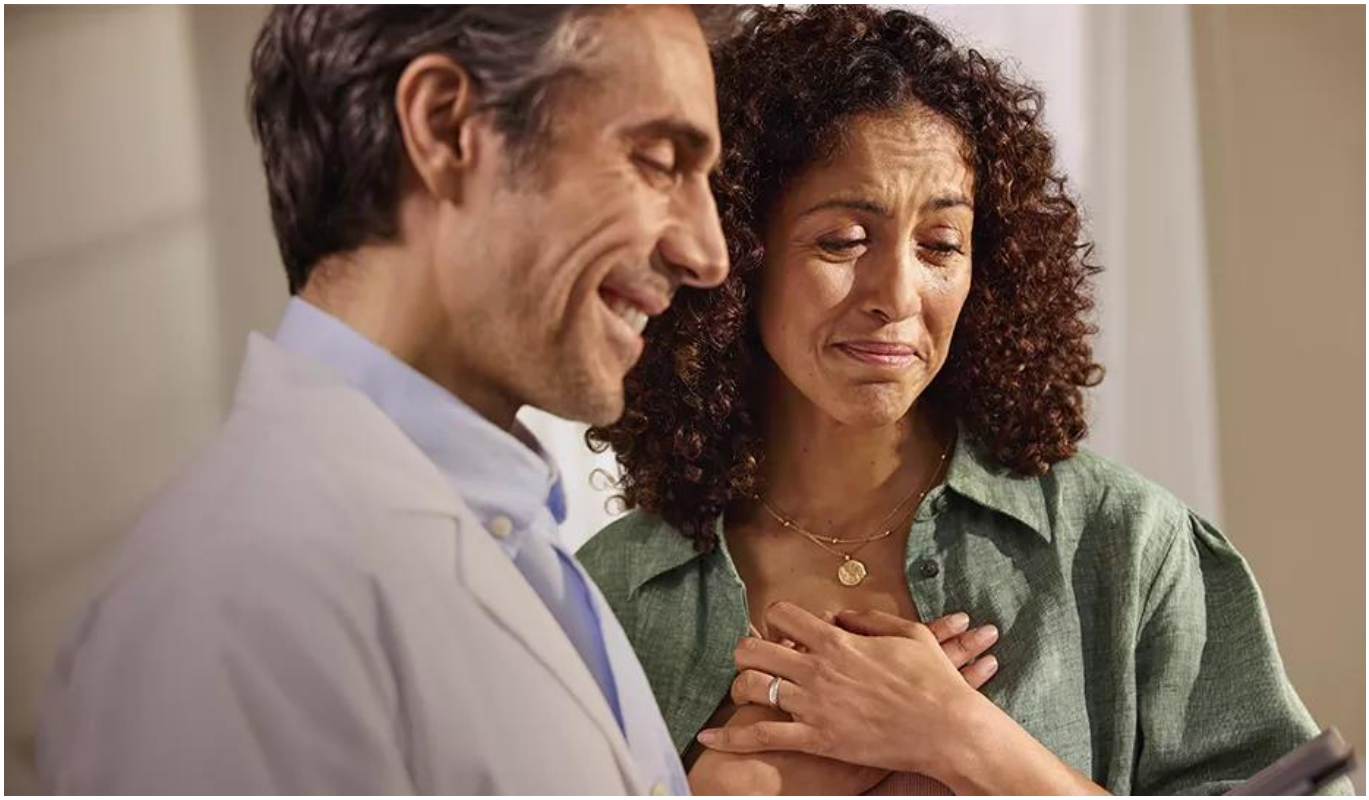

Pre/perimenopausal women with HR+/HER2– aBC

Pre/perimenopausal women with HR+/HER2– aBC

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*ET is defined as AI and LHRH or fulvestrant.[3–5]
[†]QoL was assessed using the EORTC QLQ-C30 questionnaire: a validated tool used worldwide to assess QoL in patients with cancer. Time to definitive deterioration 10% (TTD; defined as ≥10% worsening of the scale score relative to baseline, with no later improvement above this threshold observed during the treatment period, or death due to any cause) in the global health status/QoL score was investigated.[6–9]
[‡]The ESMO-MCBS is a standardised tool that quantifies the likely magnitude of clinical benefit. The scale considers overall survival, progression-free survival, disease-free survival, hazard ratio, response rate, QoL, prognosis of the condition and toxicity of patients in the non-curative setting, ranging from grade 1 to 5, with 4 and 5 denoting substantial benefit. For further information, please refer to the ESMO-MCBS scorecard methodology.[15]

1L, first-line; aBC, advanced breast cancer; AI, aromatase inhibitor; CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; CI, confidence interval; eBC, early breast cancer; EORTC-

QLQ C30, European Organisation for Research and Treatment of Cancer Core Quality of Life questionnaire; ESMO-MCBS, European Society for Medical Oncology magnitude of clinical benefit scale; ET, endocrine therapy; HER2–, human epidermal growth receptor 2 negative; HR+, hormone receptor-positive; HR, hazard ratio; LHRH, luteinising hormone-releasing hormone; mOS, median overall survival; mTTD, median time to deterioration; OS, overall survival; QoL, quality of life; TTD, time to deterioration.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Novartis online through the pharmacovigilance intake (PVI) tool at www.novartis.com/report, or alternatively email medinfo.uk@novartis.com or call 01276 698370.
