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KISQALI - ESMO rating - HCP

Prescribing information

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European Society for Medical Oncology Magnitude of Clinical Benefit Scale (ESMO-MCBS)

Indications:[1]

- KISQALI® (ribociclib) 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.

To learn more about the safety profile of KISQALI, visit our portal page here.

For full safety profile information, please refer to the KISQALI Summary of Product Characteristics.

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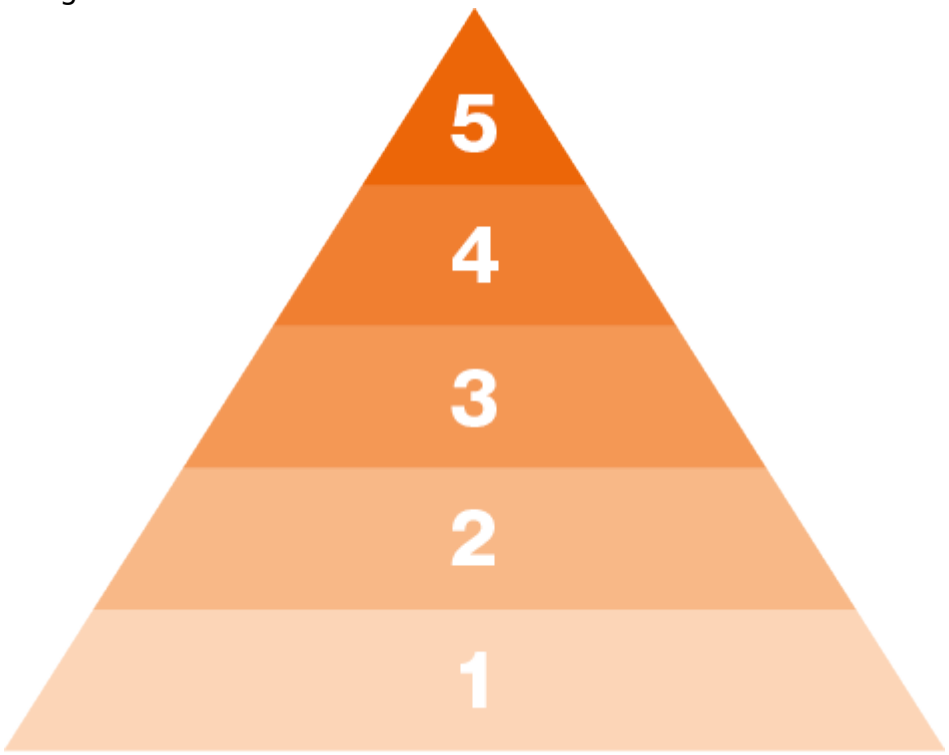

The ESMO-Magnitude of Clinical Benefit Scale (ESMO-MCBS) is a standardised tool that quantifies the likely magnitude of clinical benefit. The scale considers overall survival, progression-free survival, disease-free survival, hazard ratio, response rate, quality of life, prognosis of the condition and toxicity, of patients in the non-curative setting, ranging from grades 1 to 5, with 4 and 5 denoting substantial benefit.[2]

For further information, please refer to the ESMO-MCBS scorecard methodology.[2]

ESMO-MCBS: Scoring KISQALI

ESMO clinical practice guidelines:

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KISQALI received an ESMO-MCBS rating of 5/5 when used in combination with LHRH and with ET[3]

ET is defined as NSAI or tamoxifen and LHRH

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KISQALI + fulvestrant holds a rating of 4/5 as 1L/2L treatment of postmenopausal patients with HR+/HER2− aBC[3]

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KISQALI + AI holds a rating of 4/5 as 1L treatment of postmenopausal patients with HR+/HER2− aBC[3]

The ESMO-MCBS was developed to promote the scientific integrity of ESMO and of oncologists, and in particular to:[4]

- Reduce bias in data interpretation and analysis and enhance critical appraisal of the evidence
- Reduce hype
- Provide robust validation with strict adherence to standards for ‘accountability for reasonableness’
- Provide reliable and fair evaluation of benefit to assist in cancer planning, value-based priority setting and impact-oriented resource allocation decisions

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Find out more about the overall survival data of KISQALI

Discover more

Discover the quality of life data of KISQALI

Discover more

An established safety profile with KISQALI + ET[1,5,6]

ET is defined as AI or fulvestrant and LHRH

Discover more on KISQALI's safety profile

KISQALI is not recommended to be used in combination with tamoxifen.[1]

Across all three MONALEESA trials, progression-free survival was the primary endpoint, overall survival and quality of life were the secondary endpoints.[7–9]

1L, first-line; 2L, second-line; aBC, advanced breast cancer; AI, aromatase inhibitor; CDK4/6i, cyclin-dependent kinase 4/6 inhibitor; 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; LHRH, luteinising hormone-releasing hormone.

References:

1. KISQALI® (ribociclib) Summary of Product Characteristics.

2. European Society for Medical Oncology. ESMO-magnitude of clinical benefit scale. Available at: https://www.esmo.org/content/download/288502/5736211/1/esmo-mcbs-booklet.pdf [Accessed March 2025].

3. European Society for Medical Oncology. Ribociclib. Available at: https://www.esmo.org/guidelines/esmo-mcbs/esmo-mcbs-for-solid-tumours/esmo-mcbs-scorecards?mcbs_score_cards_form%5BsearchText%5D=ribociclib [Accessed March 2025].

4. European Society for Medical Oncology. About the ESMO-MCBS. Available at: https://www.esmo.org/guidelines/esmo-mcbs/about-the-esmo-mcbs [Accessed March 2025].

5. Borstnar S, et al. *Radiol Oncol* 2022;65(2):238–247.

6. Jackisch C, et al. Poster presentation P4-01-01. San Antonio Breast Cancer Symposium 2022, 6–10 December. San Antonio, USA.

7. Hortobagyi GN, et al. *N Engl J Med* 2016;375(18):1738-1748.

8. Slamon DJ, et al. *J Clin Oncol* 2018;36(24):2465–2472.

9. Tripathy MD, et al. *Lancet Oncol* 2018;19(7):904–915.

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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.
