Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 401, 3 Oktober 2024

Products approved for additional indication (DCA 401 – 3 Oktober 2024)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
1.	Rexulti 4mg film-coated tablets [Brexpiprazole 4mg] Rexulti 3mg film-coated tablets [Brexpiprazole 3mg] Rexulti 2mg film-coated tablets [Brexpiprazole 2mg] Rexulti 1mg film-coated tablets [Brexpiprazole 1mg] Rexulti 0.5mg film-coated tablets [Brexpiprazole 0.5mg] Rexulti 0.25mg film-coated tablets [Brexpiprazole 0.25mg]	**INDICATION :** Brexpiprazole is indicated in adult patients for: • Treatment of agitation associated with Alzheimer's dementia (AAD) Limitations of Use: REXULTI is not indicated as an as needed ("prn") treatment for agitation associated with dementia due to Alzheimer's disease. **POSOLOGY :** Treatment of Agitation Associated with Alzheimer's Dementia The recommended starting dosage for REXULTI for the treatment of AAD is 0.5 mg taken orally once daily on Days 1 to 7. The dosage should be titrated on Days 8 through 14 to 1 mg, and on Day 15 to 2 mg. The recommended target dose range is 2 mg to 3 mg once daily. After at least 14 days at 2 mg once daily, the dose can be increased to the maximum recommended daily dose of 3 mg, if clinically warranted.	**LUNDBECK MALAYSIA SDN. BHD.** A-05-01, Oasis Square, Jalan PJU 1A/7A, Ara Damansara, 47301 Petaling Jaya, Selangor.

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Rafinlar 50mg Hard Capsule [Dabrafenib mesylate 59.25 mg (equivalent to Dabrafenib 50mg)] Rafinlar 75mg Hard Capsule [Dabrafenib mesylate 88.88 mg (equivalent to Dabrafenib 75mg)]	**INDICATION:** 1.4 BRAF V600E Mutation-Positive Unresectable or Metastatic Solid Tumors RAFINLAR is indicated, in combination with trametinib, for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. 1.5 Limitations of Use • RAFINLAR is not indicated for treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. • RAFINLAR is not indicated for treatment of patients with wild-type BRAF solid tumors. **POSOLOGY :** Patient Selection <u>Melanoma</u> • Confirm the presence of BRAF V600E or V600K mutation in tumor specimens prior to initiation of treatment with RAFINLAR as a single agent. • Confirm the presence of BRAF V600E or V600K mutation in tumor specimens prior to initiation of treatment with RAFINLAR and trametinib <u>Solid Tumors</u> • Confirm the presence of BRAF V600E mutation in tumor specimens prior to initiation of treatment with RAFINLAR and trametinib.	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

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<table>
<tr><th>No.</th><th>Product
[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
Recommended Dosage

<u>Adult Patients</u>

• The recommended dosage for RAFINLAR capsules in adult patients is 150 mg taken orally twice daily.

<u>Pediatric Patients (Solid Tumors Only)</u>

The recommended dosage for RAFINLAR capsules in pediatric patients who weigh at least 26 kg is based on body weight (Table 1). A recommended dosage of RAFINLAR capsules has not been established in patients who weigh less than 26 kg.

Table 1. Recommended Dosage for RAFINLAR Capsules in Pediatric Patients (Weight-based)
<table>
<tr><th>Body Weight</th><th>Recommended Dosage</th></tr>
<tr><td>26 to 37 kg</td><td>75 mg orally twice daily</td></tr>
<tr><td>38 to 50 kg</td><td>100 mg orally twice daily</td></tr>
<tr><td>51 kg or greater</td><td>150 mg orally twice daily</td></tr>
</table>
• The recommended duration of treatment for patients with unresectable or metastatic melanoma or solid tumors is until disease progression or unacceptable toxicity.
</td><td></td></tr>
</table>

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Products approved for additional indication (DCA 401 – 3 Oktober 2024)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
3.	Meqsel 0.5mg Film-Coated Tablet [Trametinib dimethyl sulfoxide equivalent to 0.5 mg of trametinib] Meqsel 2mg Film-Coated Tablet [Trametinib dimethyl sulfoxide equivalent to 2mg of trametinib]	**INDICATION :** 1.3 BRAF V600E Mutation-Positive Unresectable or Metastatic Solid Tumors MEQSEL is indication, in combination with dabrafenib, for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. 1.4 Limitations of Use MEQSEL is not indication indicated for treatment of patients with colorectal cancer because of known intrinsic resistance to BRAF inhibition. **POSOLOGY :** <u>Patient Selection</u> <u>Melanoma</u> • Confirm the presence of BRAF V600E or V600K mutation in tumor specimens prior to initiation of treatment with MEQSEL as a single agent or in combination with dabrafenib. <u>Solid Tumors</u> • Confirm the presence of BRAF V600E mutation in tumor specimens prior to initiation of treatment with MEQSEL and dabrafenib. Recommended Dosage	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

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[Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td></td><td></td><td>
<u>Adult Patients</u>

The recommended dosage for MEQSEL tablets in adult patients is 2 mg orally taken once daily.

<u>Pediatric Patients (Solid Tumors Only)</u>

The recommended dosage for MEQSEL tablets in pediatric patients who weigh at least 26 kg is based on body weight (Table 1). A recommended dosage of MEQSEL tablets has not been established in patients who weigh less than 26 kg.

Table 1. Recommended Dosage for MEQSEL Tablets in Pediatric Patients (Weight-based)
<table>
<tr><th>Body Weight</th><th>Recommended Dosage</th></tr>
<tr><td>26 to 37 kg</td><td>1 mg orally once daily</td></tr>
<tr><td>38 to 50 kg</td><td>1.5 mg orally once daily</td></tr>
<tr><td>51 kg or greater</td><td>2 mg orally once daily</td></tr>
</table>
The recommended duration of treatment for patients with unresectable or metastatic melanoma or solid tumors is until disease progression or unacceptable toxicity.
</td><td></td></tr>
</table>