Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 418, 5 Mac 2026

Products approved for additional indication (DCA 418 – 5 March 2026)

<table>
<tr><th>No.</th><th>Product [Active Ingredient]</th><th>Additional Indication</th><th>Product Registration Holder (PRH)</th></tr>
<tr><td>1.</td><td>BOTOX (BOTULINUM TOXIN TYPE A) IM INJECTION

[Clostridium Botulinum Toxin Type A]</td><td>
INDICATION:

BOTOX® is indicated in the management of focal spasticity:

▪ upper and lower limb spasticity in adults

POSOLOGY:

Focal Upper Limb Spasticity in Adults

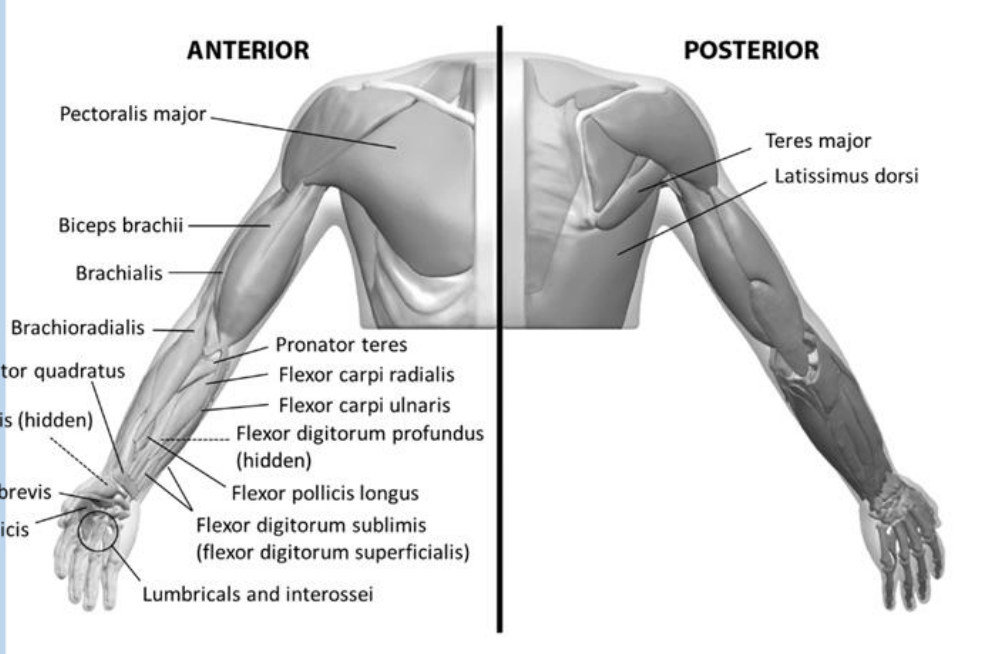
The recommended dose for treating upper limb spasticity in adults is up to 400 Units divided among the affected muscles (see Table and Figure below).

Table: BOTOX® Dosing by Muscle for Adult Upper Limb Spasticity
<table>
<tr><th>Muscle</th><th>Recommended Dose; Number of Sites</th></tr>
<tr><td>Shoulder*
Pectoralis major
Teres major
Latissimus dorsi</td><td>
75 – 125 Units; 3 sites
30 – 50 Units; 2 sites
45 – 75 Units; 3 sites</td></tr>
<tr><td>Elbow
Biceps brachii
Brachioradialis
Brachialis</td><td>
60 – 200 Units; 2 to 4 sites
45 – 75 Units; 1 to 2 sites
30 – 50 Units; 1 to 2 sites</td></tr>
<tr><td>Forearm
Pronator quadratus
Pronator teres</td><td>
10 – 50 Units; 1 site
15 – 25 Units; 1 site</td></tr>
</table>
</td><td>ABBVIE SDN BHD
9th Floor Menara Lien Hoe,
No.8, Persiaran Tropicana,
Tropicana Golf & Country Resort,
47410 Petaling Jaya,
Selangor.</td></tr>
</table>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 418, 5 Mac 2026

Products approved for additional indication (DCA 418 – 5 March 2026)

<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>
<table>
<tr><th>Muscle</th><th>Recommended Dose; Number of Sites</th></tr>
<tr><td>Wrist
Flexor carpi radialis
Flexor carpi ulnaris</td><td>
15 – 60 Units; 1 to 2 sites
10 – 50 Units; 1 to 2 sites</td></tr>
<tr><td>Fingers/Hand
Flexor digitorum profundus
Flexor digitorum sublimis/ superficialis
Lumbricals**
Interossei**</td><td>
15 – 50 Units; 1 to 2 sites
15 – 50 Units; 1 to 2 sites
5 – 10 Units; 1 site
5 – 10 Units; 1 site</td></tr>
<tr><td>Thumb
Adductor pollicis
Flexor pollicis longus
Flexor pollicis brevis
Opponens pollicis</td><td>
20 Units; 1 to 2 sites
20 Units; 1 to 2 sites
5 – 25 Units; 1 site
5 – 25 Units; 1 site</td></tr>
</table>
*When injecting the shoulder muscles in combination, the recommended maximum dose is 250 U.
** When injecting both lumbricals and/or interossei, the recommended maximum dose is 50 U per hand.
</td><td></td></tr>
</table>

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Figure: Muscles Injected for Adult Upper Limb Spasticity  The maximum dose at a single treatment session of BOTOX® is 400 Units; re injections should not occur before 12 weeks. Improvement in muscle tone occurred within two weeks, with the peak effect generally seen within four to six weeks. If it is deemed appropriate by the treating physician or healthcare provider, repeat doses may be administered, when the effect of the previous injection has diminished.	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 418, 5 Mac 2026

Products approved for additional indication (DCA 418 – 5 March 2026)

<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>
The degree and pattern of muscle spasticity at the time of re-injection may necessitate alterations in the dose of BOTOX® and muscles to be injected. The lowest effective dose should be used.

Focal Lower Limb Spasticity in Adults

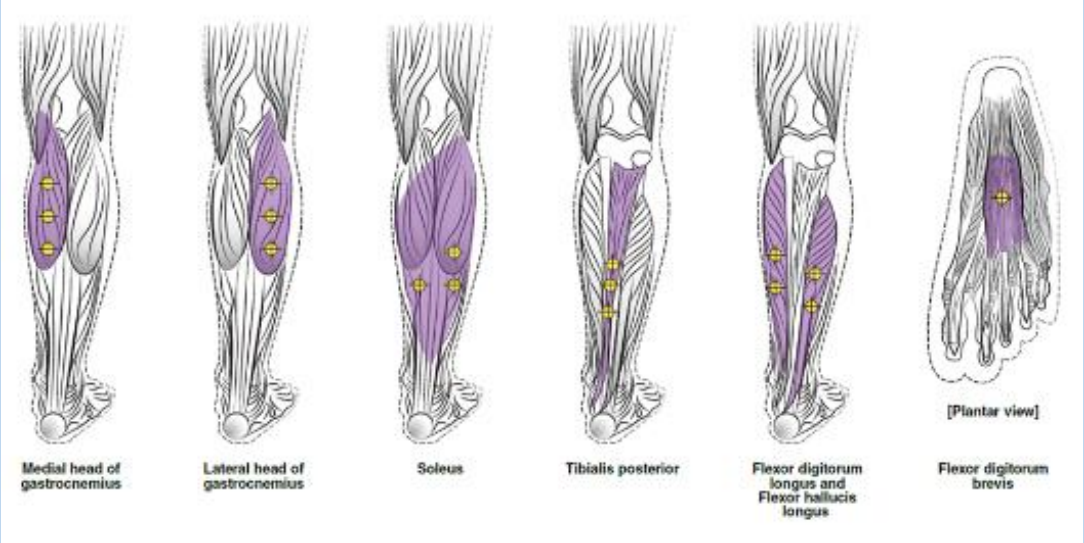
The recommended dose for treating adult lower limb spasticity involving the ankle and toes is 300 Units to 400 Units divided among affected muscles (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, flexor digitorum longus and flexor digitorum brevis) (see table and figure below).

BOTOX® Dosing by Muscle for Lower Limb Spasticity
<table>
<tr><th>Muscle</th><th>Recommended Dose

Total Dosage; Number of Sites</th></tr>
<tr><td>Gastrocnemius Medial head</td><td>75 Units; 3 sites</td></tr>
<tr><td>Gastrocnemius Lateral head</td><td>75 Units; 3 sites</td></tr>
<tr><td>Soleus</td><td>75 Units; 3 sites</td></tr>
<tr><td>Tibialis posterior</td><td>75 Units; 3 sites</td></tr>
<tr><td>Flexor hallucis longus</td><td>50 Units; 2 sites</td></tr>
<tr><td>Flexor digitorum longus</td><td>50 Units; 2 sites</td></tr>
<tr><td>Flexor digitorum brevis</td><td>25 Units; 1 site</td></tr>
</table>
</td><td></td></tr>
</table>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 418, 5 Mac 2026

Products approved for additional indication (DCA 418 – 5 March 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Figure: Injection Sites for Lower Limb Spasticity  	
2.	Fycompa 4mg Film-coated Tablets [Perampanel 4.2 mg (equivalent to anhydrous base 4.0 mg)]	**INDICATION:** Fycompa (perampanel) is indicated for the monotherapy treatment of • partial seizures (including secondarily generalized seizures) in patients with epilepsy from 4 years and older **POSOLOGY:** Partial-Onset Seizures [Monotherapy]	**EISAI (MALAYSIA) SDN. BHD.** Unit 701D, Level 7, Tower D, Uptown 5, No.5, Jalan SS21/39, Damansara Uptown, 47400 Petaling Jaya, Selangor.

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 418, 5 Mac 2026

Products approved for additional indication (DCA 418 – 5 March 2026)

<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>Fycompa 2mg Film-coated Tablets

[Perampanel 2.1 mg (equivalent to anhydrous base 2.0 mg)]</td><td>The following table summarises the recommended posology for adults, adolescents, and children from 4 years of age.

More details are provided below the table.
<table>
<tr><th></th><th rowspan="2">Adult/ adolescent (12 years and older)</th><th colspan="3">Children (4 – 11 years); weighing:</th></tr>
<tr><th>≥ 30 kg</th><th>20 - < 30 kg</th><th>< 20 kg</th></tr>
<tr><td>Recommended starting dose</td><td>2 mg/day</td><td>2 mg/day</td><td>1 mg/day</td><td>1 mg/day</td></tr>
<tr><td>Titration (incremental steps)</td><td>2 mg/day (no more frequently than intervals of 2 weeks)</td><td>2 mg/day (no more frequently than intervals of 2 weeks)</td><td>1 mg/day (no more frequently than intervals of 2 weeks)</td><td>1 mg/day (no more frequently than intervals of 2 weeks)</td></tr>
<tr><td>Recommended maintenance dose</td><td>4 –8mg/ day</td><td>4 –8mg/ day</td><td>4 –6mg/ day</td><td>2 –4mg/ day</td></tr>
<tr><td>Recommended maximum dose</td><td>8 mg/day</td><td>8 mg/day</td><td>6 mg/day</td><td>4 mg/day</td></tr>
</table></td><td></td></tr>
</table>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 418, 5 Mac 2026

Products approved for additional indication (DCA 418 – 5 March 2026)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Adults, adolescents age ≥12 years The starting oral dose is 2 mg once daily as Fycompa at bedtime, and the daily dose may then be increased by 2 mg at intervals of 2 weeks or longer. The maintenance dose is 4-8 mg once daily. Dosage may be increased or decreased as necessary by 2 mg or less at intervals of 2 weeks or longer based on individual clinical response and tolerability, but the maximum daily dose should not be over 8 mg. Children (from 4 to 11 years) weighing ≥30 kg The starting oral dose is 2 mg once daily as Fycompa at bedtime, and the daily dose may then be increased by 2 mg at intervals of 2 weeks or longer. The maintenance dose is 4-8 mg once daily. Dosage may be increased or decreased as necessary by 2 mg or less at intervals of 2 weeks or longer based on individual clinical response and tolerability, but the maximum daily dose should not be over 8 mg. Children (from 4 to 11 years of age) weighing 20 kg and <30 kg The starting oral dose is 1 mg once daily as Fycompa at bedtime, and the daily dose may then be increased by 1 mg at intervals of 2 weeks or longer. The maintenance dose is 4-6 mg once daily. Dosage may be increased or decreased as necessary by 1 mg or less at intervals of 2 weeks or longer based on individual clinical response and tolerability, but the maximum daily dose should not be over 6 mg. Children (from 4 to 11 years of age) weighing <20 kg The starting oral dose is 1 mg once daily as Fycompa at bedtime, and the daily dose may	

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		then be increased by 1 mg at intervals of 2 weeks or longer. The maintenance dose is 2-4 mg once daily. Dosage may be increased or decreased as necessary by 1 mg or less at intervals of 2 weeks or longer based on individual clinical response and tolerability, but the maximum daily dose should not be over 4 mg.	
3.	Kryxana 200mg Film-coated Tablets [Ribociclib succinate 254.40mg (corresponds to 200mg of ribociclib free base)]	**INDICATION:** <u>Early Breast Cancer</u> KRYXANA is indicated in combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative stage II and III early breast cancer at high risk of recurrence. **POSOLOGY:** <u>Important Dosing Administration Instructions</u> KRYXANA can be taken with or without food. Pre/perimenopausal women, or men, treated with the combination KRYXANA plus an aromatase inhibitor or fulvestrant, should be treated with a luteinizing hormone-releasing hormone (LHRH) agonist according to current clinical practice standards. Patients should take their dose of KRYXANA at approximately the same time each day, preferably in the morning. If the patient vomits after taking the dose, or misses a dose, no additional dose should be taken that day. The next prescribed dose should be taken at the usual time. KRYXANA	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		tablets should be swallowed whole (tablets should not be chewed, crushed or split prior to swallowing). No tablet should be ingested if it is broken, cracked, or otherwise not intact. <u>Early Breast Cancer</u> The recommended dosage of KRYXANA is 400 mg (two 200 mg film-coated tablets) taken orally, once daily for 21 consecutive days followed by 7 days off in 28-day treatment cycles. KRYXANA should be given in combination with an aromatase inhibitor. Refer to the Full Prescribing Information for the recommended dosage of the aromatase inhibitor. In patients with early breast cancer, treatment with KRYXANA should continue for 3 years or until disease recurrence or unacceptable toxicity occurs. <u>Dose Modifications for Adverse Reactions</u> The recommended dose modifications for adverse reactions are listed in Table 1.	

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 418, 5 Mac 2026

Products approved for additional indication (DCA 418 – 5 March 2026)

<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>Table 1: Recommended Dose Modification for Adverse Reactions
<table>
<tr><th>Level</th><th colspan="2">KYRXANA</th></tr>
<tr><th></th><th>Dose</th><th>Number of tablets</th></tr>
<tr><td><u>Early breast cancer</u></td><td></td><td></td></tr>
<tr><td>Starting dose</td><td>400mg/day</td><td>two 200 mg tablets</td></tr>
<tr><td>Dose reduction</td><td>200mg/day*</td><td>one 200 mg tablet</td></tr>
<tr><td><u>Advanced or metastatic breast cancer</u></td><td></td><td></td></tr>
<tr><td>Starting dose</td><td>600mg/day</td><td>three 200 mg tablets</td></tr>
<tr><td>First Dose reduction</td><td>400mg/day*</td><td>two 200 mg tablets</td></tr>
<tr><td>Second Dose reduction</td><td>200mg/day*</td><td>one 200 mg tablet</td></tr>
<tr><td colspan="3">*If dose reduction below 200 mg/day is required, discontinue KYRXANA</td></tr>
</table></td><td></td></tr>
</table>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 418, 5 Mac 2026

Products approved for additional indication (DCA 418 – 5 March 2026)

<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>
Table 4: Dose Modification and Management for QT Prolongation
<table>
<tr><th>QTcF* prolongation</th><th>Early breast cancer</th><th>Advanced or metastatic breast cancer</th></tr>
<tr><td rowspan="3">>480 ms and ≤ 500 ms</td><td colspan="2">Interrupt KRYXANA treatment and wait until QTcF resolves to < 480 ms</td></tr>
<tr><td>Resume at the same dose</td><td>Reduce to the next lower dose level</td></tr>
<tr><td colspan="2">If QTcF > 480 ms recurs, interrupt KRYXANA treatment and wait until QTcF resolves to < 480 ms, then resume at next lower dose level</td></tr>
<tr><td>> 500ms</td><td colspan="2">Interrupt KRYXANA treatment and wait until QTcF resolves to < 480 ms, then resume at next lower dose level.

If QTcF > 500 ms recurs, discontinue KRYXANA.</td></tr>
</table>
Permanently discontinue KRYXANA if QTcF interval prolongation is either > 500 ms or > 60 ms change from baseline AND associated with any of the following: Torsades de Pointes, polymorphic ventricular tachycardia, syncope, or signs/symptoms of serious arrhythmia.

Note: If dose reduction below 200 mg/day is required, discontinue KRYXANA.

Electrocardiograms (ECGs) should be assessed prior to initiation of treatment in all patients.

Repeat ECGs at approximately Day 14 of the first cycle, and as clinically indicated.

In case of QTcF prolongation at any given time during treatment, monitor ECG more frequently, and as clinically indicated

*QTcF = QT interval corrected by Fridericia’s formula.
</td><td></td></tr>
</table>

<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>
Table 8: Dose Modification for Use with Strong CYP3A Inhibitors
<table>
<tr><th>Indication</th><th>Co-administration with Strong CYP3A Inhibitors</th></tr>
<tr><td>Early breast cancer</td><td>Reduce the KRYXANA dose to 200 mg once daily.</td></tr>
<tr><td>Advanced or metastatic breast cancer</td><td>Reduce the KRYXANA dose to 400 mg once daily.</td></tr>
</table>
If the strong inhibitor is discontinued, change the KRYXANA dose (after at least 5 half-lives of the strong CYP3A inhibitor) to the dose used prior to the initiation of the strong CYP3A inhibitor.

<u>Dose Modification for Hepatic Impairment</u>

The recommended dose modifications for patients with hepatic impairment are shown in Table 9.
</td><td></td></tr>
</table>

Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 418, 5 Mac 2026

Products approved for additional indication (DCA 418 – 5 March 2026)

<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>Table 9: Dose Modification for Hepatic Impairment
<table>
<tr><th>Indication</th><th>Mild hepatic impairment
(Child-Pugh class A)</th><th>Moderate and severe hepatic impairment
(Child-Pugh class B or C)</th></tr>
<tr><td>Early breast cancer</td><td>No dose adjustment is necessary</td><td>No dose adjustment is necessary</td></tr>
<tr><td>Advanced or metastatic breast cancer</td><td>No dose adjustment is necessary</td><td>KRYXANA 400 mg once daily</td></tr>
</table>
Review the Full Prescribing Information for the co-administered aromatase inhibitor or fulvestrant for dose modifications related to hepatic impairment</td><td></td></tr>
</table>