

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

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

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)								
1.	<p>BOTOX (BOTULINUM TOXIN TYPE A) IM INJECTION</p> <p>[Clostridium Botulinum Toxin Type A]</p>	<p>INDICATION:</p> <p>BOTOX® is indicated in the management of focal spasticity:</p> <ul style="list-style-type: none"> ▪ upper and lower limb spasticity in adults <p>POSOLGY:</p> <p>Focal Upper Limb Spasticity in Adults</p> <p>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).</p> <p>Table: BOTOX® Dosing by Muscle for Adult Upper Limb Spasticity</p> <table border="1"> <thead> <tr> <th>Muscle</th> <th>Recommended Dose; Number of Sites</th> </tr> </thead> <tbody> <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> </tbody> </table>	Muscle	Recommended Dose; Number of Sites	Shoulder* Pectoralis major Teres major Latissimus dorsi	75 – 125 Units; 3 sites 30 – 50 Units; 2 sites 45 – 75 Units; 3 sites	Elbow Biceps brachii Brachioradialis Brachialis	60 – 200 Units; 2 to 4 sites 45 – 75 Units; 1 to 2 sites 30 – 50 Units; 1 to 2 sites	Forearm Pronator quadratus Pronator teres	10 – 50 Units; 1 site 15 – 25 Units; 1 site	<p>ABBVIE SDN BHD 9th Floor Menara Lien Hoe, No.8, Persiaran Tropicana, Tropicana Golf & Country Resort, 47410 Petaling Jaya, Selangor.</p>
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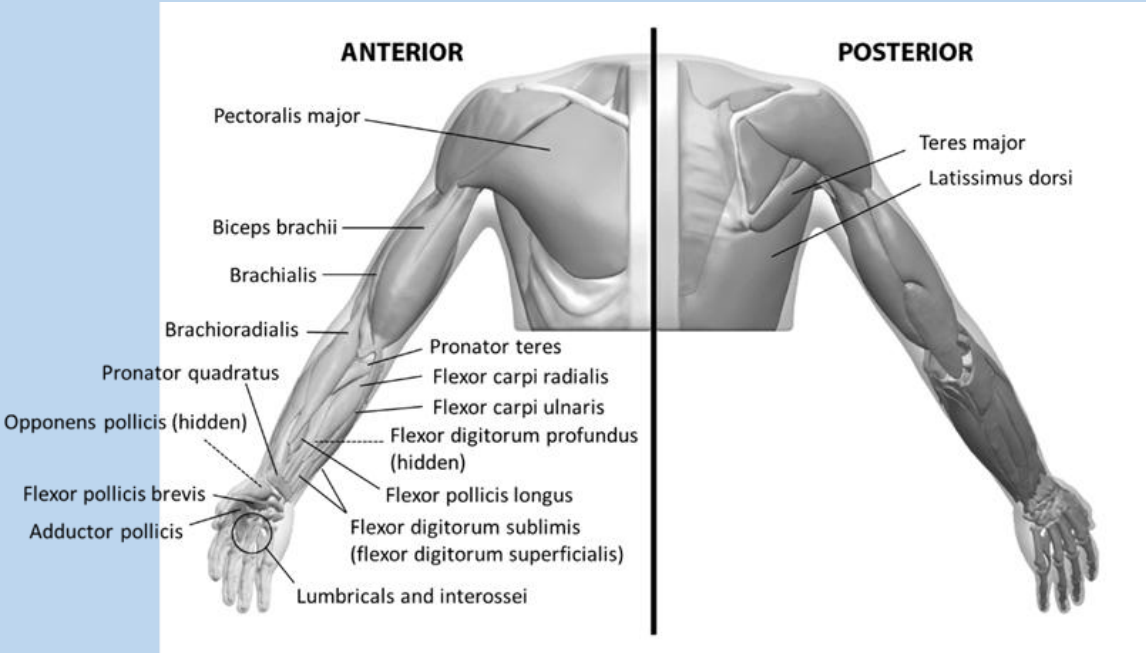
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		Wrist Flexor carpi radialis Flexor carpi ulnaris	15 – 60 Units; 1 to 2 sites 10 – 50 Units; 1 to 2 sites		
		Fingers/Hand Flexor digitorum profundus Flexor digitorum sublimis/ superficialis Lumbricals** Interossei**	15 – 50 Units; 1 to 2 sites 15 – 50 Units; 1 to 2 sites 5 – 10 Units; 1 site 5 – 10 Units; 1 site		
		Thumb Adductor pollicis Flexor pollicis longus Flexor pollicis brevis Opponens pollicis	20 Units; 1 to 2 sites 20 Units; 1 to 2 sites 5 – 25 Units; 1 site 5 – 25 Units; 1 site		
		<p>[^]When injecting the shoulder muscles in combination, the recommended maximum dose is 250 U.</p> <p>^{**} When injecting both lumbricals and/or interossei, the recommended maximum dose is 50 U per hand.</p>			

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		<p>Figure: Muscles Injected for Adult Upper Limb Spasticity</p>  <p>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.</p> <p>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.</p> <p>The degree and pattern of muscle spasticity at the time of re-injection may necessitate</p>	

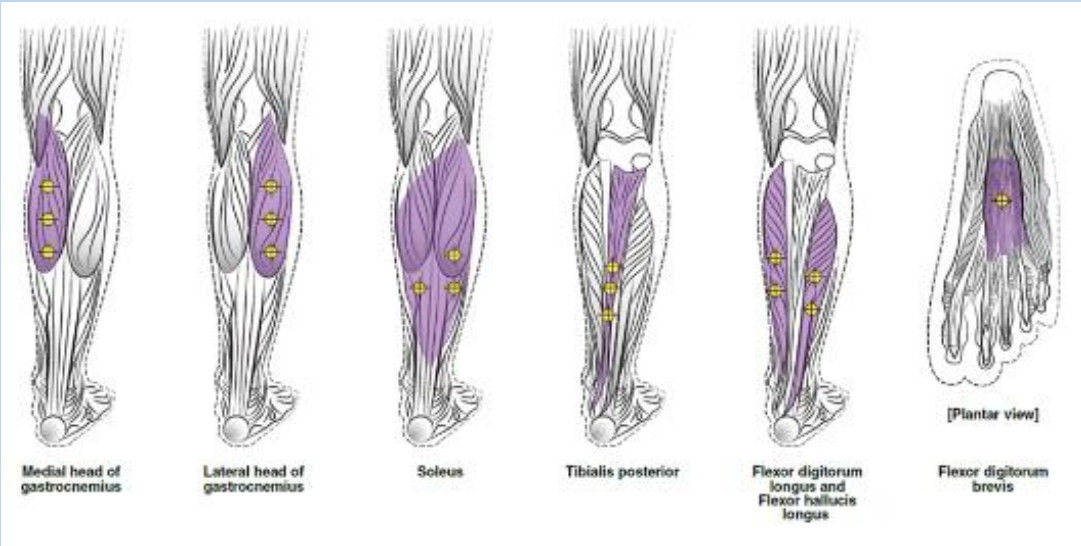
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		<p>alterations in the dose of BOTOX® and muscles to be injected. The lowest effective dose should be used.</p> <p>Focal Lower Limb Spasticity in Adults</p> <p>The recommended dose for treating adult lower limb spasticity involving the ankle and toes 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).</p> <p>BOTOX® Dosing by Muscle for Lower Limb Spasticity</p> <table border="1" data-bbox="539 831 1711 1398"> <thead> <tr> <th data-bbox="539 831 1059 956">Muscle</th> <th data-bbox="1059 831 1711 956">Recommended Dose Total Dosage; Number of Sites</th> </tr> </thead> <tbody> <tr> <td data-bbox="539 956 1059 1018">Gastrocnemius Medial head</td> <td data-bbox="1059 956 1711 1018">75 Units; 3 sites</td> </tr> <tr> <td data-bbox="539 1018 1059 1080">Gastrocnemius Lateral head</td> <td data-bbox="1059 1018 1711 1080">75 Units; 3 sites</td> </tr> <tr> <td data-bbox="539 1080 1059 1142">Soleus</td> <td data-bbox="1059 1080 1711 1142">75 Units; 3 sites</td> </tr> <tr> <td data-bbox="539 1142 1059 1204">Tibialis posterior</td> <td data-bbox="1059 1142 1711 1204">75 Units; 3 sites</td> </tr> <tr> <td data-bbox="539 1204 1059 1267">Flexor hallucis longus</td> <td data-bbox="1059 1204 1711 1267">50 Units; 2 sites</td> </tr> <tr> <td data-bbox="539 1267 1059 1329">Flexor digitorum longus</td> <td data-bbox="1059 1267 1711 1329">50 Units; 2 sites</td> </tr> <tr> <td data-bbox="539 1329 1059 1391">Flexor digitorum brevis</td> <td data-bbox="1059 1329 1711 1391">25 Units; 1 site</td> </tr> </tbody> </table>	Muscle	Recommended Dose Total Dosage; Number of Sites	Gastrocnemius Medial head	75 Units; 3 sites	Gastrocnemius Lateral head	75 Units; 3 sites	Soleus	75 Units; 3 sites	Tibialis posterior	75 Units; 3 sites	Flexor hallucis longus	50 Units; 2 sites	Flexor digitorum longus	50 Units; 2 sites	Flexor digitorum brevis	25 Units; 1 site	
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		<p>Figure: Injection Sites for Lower Limb Spasticity</p> 	
2.	<p>Fycompa 4mg Film-coated Tablets</p> <p>[Perampanel 4.2 mg (equivalent to anhydrous base 4.0 mg)]</p>	<p>INDICATION:</p> <p>Fycompa (perampanel) is indicated for the monotherapy treatment of</p> <ul style="list-style-type: none"> • partial seizures (including secondarily generalized seizures) in patients with epilepsy from 4 years and older 	<p>EISAI (MALAYSIA) SDN. BHD.</p> <p>Unit 701D, Level 7, Tower D, Uptown 5, No.5, Jalan SS21/39, Damansara Uptown, 47400 Petaling Jaya, Selangor.</p>

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	Fycompa 2mg Film-coated Tablets [Perampanel 2.1 mg (equivalent to anhydrous base 2.0 mg)]	<p>POSOLGY:</p> <p>Partial-Onset Seizures</p> <p>[Monotherapy]</p> <p>The following table summarises the recommended posology for adults, adolescents, and children from 4 years of age.</p> <p>More details are provided below the table.</p> <table border="1" data-bbox="524 691 1693 1431"> <thead> <tr> <th data-bbox="524 691 777 831"></th> <th data-bbox="777 691 1039 831">Adult/ adolescent (12 years and older)</th> <th colspan="3" data-bbox="1039 691 1693 751">Children (4 – 11 years); weighing:</th> </tr> <tr> <th data-bbox="524 751 777 831"></th> <th data-bbox="777 751 1039 831"></th> <th data-bbox="1039 751 1272 831">≥ 30 kg</th> <th data-bbox="1272 751 1464 831">20 - < 30 kg</th> <th data-bbox="1464 751 1693 831">< 20 kg</th> </tr> </thead> <tbody> <tr> <td data-bbox="524 831 777 935">Recommended starting dose</td> <td data-bbox="777 831 1039 935">2 mg/day</td> <td data-bbox="1039 831 1272 935">2 mg/day</td> <td data-bbox="1272 831 1464 935">1 mg/day</td> <td data-bbox="1464 831 1693 935">1 mg/day</td> </tr> <tr> <td data-bbox="524 935 777 1193">Titration (incremental steps)</td> <td data-bbox="777 935 1039 1193">2 mg/day (no more frequently than intervals of 2 weeks)</td> <td data-bbox="1039 935 1272 1193">2 mg/day (no more frequently than intervals of 2 weeks)</td> <td data-bbox="1272 935 1464 1193">1 mg/day (no more frequently than intervals of 2 weeks)</td> <td data-bbox="1464 935 1693 1193">1 mg/day (no more frequently than intervals of 2 weeks)</td> </tr> <tr> <td data-bbox="524 1193 777 1334">Recommended maintenance dose</td> <td data-bbox="777 1193 1039 1334">4 –8mg/ day</td> <td data-bbox="1039 1193 1272 1334">4 –8mg/ day</td> <td data-bbox="1272 1193 1464 1334">4 –6mg/ day</td> <td data-bbox="1464 1193 1693 1334">2 –4mg/ day</td> </tr> <tr> <td data-bbox="524 1334 777 1431">Recommended maximum dose</td> <td data-bbox="777 1334 1039 1431">8 mg/day</td> <td data-bbox="1039 1334 1272 1431">8 mg/day</td> <td data-bbox="1272 1334 1464 1431">6 mg/day</td> <td data-bbox="1464 1334 1693 1431">4 mg/day</td> </tr> </tbody> </table>		Adult/ adolescent (12 years and older)	Children (4 – 11 years); weighing:					≥ 30 kg	20 - < 30 kg	< 20 kg	Recommended starting dose	2 mg/day	2 mg/day	1 mg/day	1 mg/day	Titration (incremental steps)	2 mg/day (no more frequently than intervals of 2 weeks)	2 mg/day (no more frequently than intervals of 2 weeks)	1 mg/day (no more frequently than intervals of 2 weeks)	1 mg/day (no more frequently than intervals of 2 weeks)	Recommended maintenance dose	4 –8mg/ day	4 –8mg/ day	4 –6mg/ day	2 –4mg/ day	Recommended maximum dose	8 mg/day	8 mg/day	6 mg/day	4 mg/day	
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		<p><u>Adults, adolescents age ≥ 12 years</u></p> <p>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.</p> <p><u>Children (from 4 to 11 years) weighing ≥ 30 kg</u></p> <p>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.</p> <p><u>Children (from 4 to 11 years of age) weighing 20 kg and < 30 kg</u></p> <p>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.</p> <p><u>Children (from 4 to 11 years of age) weighing < 20 kg</u></p> <p>The starting oral dose is 1 mg once daily as Fycompa at bedtime, and the daily dose may</p>	

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		<p>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.</p>	
3.	<p>Kryxana 200mg Film-coated Tablets</p> <p>[Ribociclib succinate 254.40mg (corresponds to 200mg of ribociclib free base)]</p>	<p>INDICATION:</p> <p><u>Early Breast Cancer</u></p> <p>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.</p> <p>POSOLGY:</p> <p><u>Important Dosing Administration Instructions</u></p> <p>KRYXANA can be taken with or without food.</p> <p>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.</p> <p>Patients should take their dose of KRYXANA at approximately the same time each day, preferably in the morning.</p> <p>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</p>	<p>NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.</p> <p>Level 18, Imazium, No.8, Jalan SS21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.</p>

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		<p>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.</p> <p><u>Early Breast Cancer</u></p> <p>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.</p> <p>In patients with early breast cancer, treatment with KRYXANA should continue for 3 years or until disease recurrence or unacceptable toxicity occurs.</p> <p><u>Dose Modifications for Adverse Reactions</u></p> <p>The recommended dose modifications for adverse reactions are listed in Table 1.</p>	

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		<p>Table 1: Recommended Dose Modification for Adverse Reactions</p> <table border="1" data-bbox="521 371 1682 983"> <thead> <tr> <th data-bbox="521 371 1104 432">Level</th> <th colspan="2" data-bbox="1104 371 1682 432">KYRXANA</th> </tr> <tr> <td></td> <th data-bbox="1104 432 1384 493">Dose</th> <th data-bbox="1384 432 1682 493">Number of tablets</th> </tr> </thead> <tbody> <tr> <td colspan="3" data-bbox="521 493 1682 553"><u>Early breast cancer</u></td> </tr> <tr> <td data-bbox="521 553 1104 614">Starting dose</td> <td data-bbox="1104 553 1384 614">400mg/day</td> <td data-bbox="1384 553 1682 614">two 200 mg tablets</td> </tr> <tr> <td data-bbox="521 614 1104 675">Dose reduction</td> <td data-bbox="1104 614 1384 675">200mg/day*</td> <td data-bbox="1384 614 1682 675">one 200 mg tablet</td> </tr> <tr> <td colspan="3" data-bbox="521 675 1682 735"><u>Advanced or metastatic breast cancer</u></td> </tr> <tr> <td data-bbox="521 735 1104 796">Starting dose</td> <td data-bbox="1104 735 1384 796">600mg/day</td> <td data-bbox="1384 735 1682 796">three 200 mg tablets</td> </tr> <tr> <td data-bbox="521 796 1104 857">First Dose reduction</td> <td data-bbox="1104 796 1384 857">400mg/day*</td> <td data-bbox="1384 796 1682 857">two 200 mg tablets</td> </tr> <tr> <td data-bbox="521 857 1104 917">Second Dose reduction</td> <td data-bbox="1104 857 1384 917">200mg/day*</td> <td data-bbox="1384 857 1682 917">one 200 mg tablet</td> </tr> <tr> <td colspan="3" data-bbox="521 917 1682 983">*If dose reduction below 200 mg/day is required, discontinue KYRXANA</td> </tr> </tbody> </table>	Level	KYRXANA			Dose	Number of tablets	<u>Early breast cancer</u>			Starting dose	400mg/day	two 200 mg tablets	Dose reduction	200mg/day*	one 200 mg tablet	<u>Advanced or metastatic breast cancer</u>			Starting dose	600mg/day	three 200 mg tablets	First Dose reduction	400mg/day*	two 200 mg tablets	Second Dose reduction	200mg/day*	one 200 mg tablet	*If dose reduction below 200 mg/day is required, discontinue KYRXANA			
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		<p>Table 4: Dose Modification and Management for QT Prolongation</p> <table border="1" data-bbox="519 370 1682 975"> <thead> <tr> <th data-bbox="519 370 833 474">QTcF* prolongation</th> <th data-bbox="833 370 1256 474">Early breast cancer</th> <th data-bbox="1256 370 1682 474">Advanced or metastatic breast cancer</th> </tr> </thead> <tbody> <tr> <td data-bbox="519 474 833 815" rowspan="3">>480 ms and ≤ 500 ms</td> <td colspan="2" data-bbox="833 474 1682 572">Interrupt KRYXANA treatment and wait until QTcF resolves to ≤ 480 ms</td> </tr> <tr> <td data-bbox="833 572 1256 671">Resume at the same dose</td> <td data-bbox="1256 572 1682 671">Reduce to the next lower dose level</td> </tr> <tr> <td colspan="2" data-bbox="833 671 1682 815">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 data-bbox="519 815 833 975">> 500ms</td> <td colspan="2" data-bbox="833 815 1682 975">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> </tbody> </table> <p data-bbox="519 975 1682 1102">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.</p> <hr/> <p data-bbox="519 1102 1682 1142">Note: If dose reduction below 200 mg/day is required, discontinue KRYXANA.</p> <p data-bbox="519 1142 1682 1182">Electrocardiograms (ECGs) should be assessed prior to initiation of treatment in all patients.</p> <p data-bbox="519 1182 1682 1222">Repeat ECGs at approximately Day 14 of the first cycle, and as clinically indicated.</p> <p data-bbox="519 1222 1682 1342">In case of QTcF prolongation at any given time during treatment, monitor ECG more frequently, and as clinically indicated</p> <p data-bbox="519 1342 1682 1420">*QTcF = QT interval corrected by Fridericia's formula.</p>	QTcF* prolongation	Early breast cancer	Advanced or metastatic breast cancer	>480 ms and ≤ 500 ms	Interrupt KRYXANA treatment and wait until QTcF resolves to ≤ 480 ms		Resume at the same dose	Reduce to the next lower dose level	If QTcF > 480 ms recurs, interrupt KRYXANA treatment and wait until QTcF resolves to ≤ 480 ms, then resume at next lower dose level		> 500ms	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.		
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		<p>Table 8: Dose Modification for Use with Strong CYP3A Inhibitors</p> <table border="1" data-bbox="521 371 1720 596"> <thead> <tr> <th data-bbox="521 371 1021 432">Indication</th> <th data-bbox="1021 371 1720 432">Co-administration with Strong CYP3A Inhibitors</th> </tr> </thead> <tbody> <tr> <td data-bbox="521 432 1021 494">Early breast cancer</td> <td data-bbox="1021 432 1720 494">Reduce the KRYXANA dose to 200 mg once daily.</td> </tr> <tr> <td data-bbox="521 494 1021 596">Advanced or metastatic breast cancer</td> <td data-bbox="1021 494 1720 596">Reduce the KRYXANA dose to 400 mg once daily.</td> </tr> </tbody> </table> <p>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.</p> <p><u>Dose Modification for Hepatic Impairment</u></p> <p>The recommended dose modifications for patients with hepatic impairment are shown in Table 9.</p>	Indication	Co-administration with Strong CYP3A Inhibitors	Early breast cancer	Reduce the KRYXANA dose to 200 mg once daily.	Advanced or metastatic breast cancer	Reduce the KRYXANA dose to 400 mg once daily.	
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Products approved for additional indication (DCA 418 – 5 Mac 2026)

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		<p>Table 9: Dose Modification for Hepatic Impairment</p> <table border="1" data-bbox="521 371 1720 775"> <thead> <tr> <th data-bbox="521 371 833 533">Indication</th> <th data-bbox="833 371 1229 533">Mild hepatic impairment (Child-Pugh class A)</th> <th data-bbox="1229 371 1720 533">Moderate and severe hepatic impairment (Child-Pugh class B or C)</th> </tr> </thead> <tbody> <tr> <td data-bbox="521 533 833 635">Early breast cancer</td> <td data-bbox="833 533 1229 635">No dose adjustment is necessary</td> <td data-bbox="1229 533 1720 635">No dose adjustment is necessary</td> </tr> <tr> <td data-bbox="521 635 833 775">Advanced or metastatic breast cancer</td> <td data-bbox="833 635 1229 775">No dose adjustment is necessary</td> <td data-bbox="1229 635 1720 775">KRYXANA 400 mg once daily</td> </tr> </tbody> </table> <p data-bbox="504 836 1720 906">Review the Full Prescribing Information for the co-administered aromatase inhibitor or fulvestrant for dose modifications related to hepatic impairment</p>	Indication	Mild hepatic impairment (Child-Pugh class A)	Moderate and severe hepatic impairment (Child-Pugh class B or C)	Early breast cancer	No dose adjustment is necessary	No dose adjustment is necessary	Advanced or metastatic breast cancer	No dose adjustment is necessary	KRYXANA 400 mg once daily	
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