Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 394, 7 Mac 2024

Products approved for additional indication (DCA 394, 7 Mac 2024)

<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>Scemblix 20mg film-coated tablet

[Asciminib 20mg (corresponds to Asciminib hydrochloride 21.62mg)]

Scemblix 40mg film-coated tablet

[Asciminib 40mg (corresponds to Asciminib hydrochloride 43.24mg)]</td><td>INDICATION :

Scemblix is indicated for the treatment of adult patients with Ph+ CML in CP with the T315I mutation

POSOLOGY :

<u>Ph+ CML-CP habouring the T315I mutation</u>

The recommended dose is 200mg taken orally twice daily at approximately 12-hour intervals.

<u>Dose adjustments for adverse reactions</u>

For the management of adverse drug reactions, Scemblix dose can be reduced based on individual safety and tolerability, as described in Table 1. If adverse drug reactions are effectively managed, Scemblix may be resumed as described in Table 1.

Scemblix should be permanently discontinued in patients unable to tolerate a dose of 160 mg twice daily.

Table 1 Scemblix dosage modification
<table><tr><th>Starting dose</th><th>Reduced dose</th><th>Resumed dose</th></tr><tr><td>200mg twice daily</td><td>160mg twice daily</td><td>200mg twice daily</td></tr></table></td><td>NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
Level 18, Imazium,
No.8, Jalan Ss21/37,
Damansara Uptown,
47400 Petaling Jaya,
Selangor.</td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
2.	Revolade Film-Coated Tablet 50mg [Eltrombopag olamine 63.8 mg (equivalent to 50 mg of eltrombopag free acid)] Revolade Film-Coated Tablet 25mg [Eltrombopag olamine 31.9 mg (equivalent to 25 mg of eltrombopag free acid)]	**INDICATION :** Revolade is indicated for the treatment of adult patients with primary immune thrombocytopenia (ITP) who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). Revolade is indicated for the treatment of paediatric patients aged 6 years and above with primary immune thrombocytopenia (ITP) lasting 6 months or longer from diagnosis and who are refractory to other treatments (e.g. corticosteroids, immunoglobulins). **POSOLOGY :** There are no changes to currently approved posology.	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 18, Imazium, No.8, Jalan Ss21/37, Damansara Uptown, 47400 Petaling Jaya, Selangor.

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Products approved for additional indication (DCA 394, 7 Mac 2024)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)

3.	Clexane 2000 IU (20mg) / 0.2 mL (Pre-filled Syringe For Injection)
	
	[Enoxaparin Sodium (Heparin) 20mg]
	
	Clexane 4000 IU (40mg) / 0.4 mL (Pre-filled Syringe For Injection)
	
	[Enoxaparin Sodium (Heparin) 40mg]
	
	Clexane 6000 IU (60mg) / 0.6 mL (Pre-filled Syringe For Injection)
	
	[Enoxaparin Sodium (Heparin) 60mg]
		INDICATION :
		
		Extended treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of its recurrence in patients with active cancer.
		
		POSOLOGY : (additional posology highlighted in bold)
		
		<u>Prophylaxis of venous thromboembolic disease in moderate and high risk surgical patients</u>
		
		Individual thromboembolic risk for patients can be estimated using validated risk stratification model.
		
		• In patients at moderate risk of thromboembolism, the recommended dose of enoxaparin sodium is 2,000 IU (20 mg) once daily by subcutaneous (SC) injection. Preoperative initiation (2 hours before surgery) of enoxaparin sodium 2,000 IU (20 mg) was proven effective and safe in moderate risk surgery. In moderate risk patients, enoxaparin sodium treatment should be maintained for a minimal period of 7-10 days whatever the recovery status (e.g. mobility). Prophylaxis should be continued until the patient no longer has significantly reduced mobility.
		• In patients at high risk of thromboembolism, the recommended dose of enoxaparin sodium is 4,000 IU (40 mg) once daily given by SC injection preferably started 12 hours before surgery. If there is a need for earlier than 12 hours enoxaparin sodium preoperative prophylactic initiation (e.g. high risk patient waiting for a differed orthopaedic surgery), the last injection should be administered no later than 12 hours prior to surgery and resumed 12 hours after surgery.
		  ○ For patients who undergo major orthopaedic surgery an extended thromboprophylaxis up to 5 weeks is recommended.
		  ○ For patients with a high venous thromboembolism (VTE) risk who undergo abdominal or pelvic surgery for cancer an extended thromboprophylaxis up to 4 weeks is recommended.
			SANOFI-AVENTIS (MALAYSIA) SDN. BHD.
			Unit TB-18-1, Level 18, Tower B, Plaza 33, No.1, Jalan Kemajuan, Seksyen 13, 46200 Petaling Jaya, Selangor.

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Products approved for additional indication (DCA 394, 7 Mac 2024)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		<u>Prophylaxis of venous thromboembolism in medical patients</u> The recommended dose of enoxaparin sodium is 4,000 IU (40 mg) once daily by SC injection. Treatment with enoxaparin sodium is prescribed for at least 6 to 14 days whatever the recovery status (e.g. mobility). The benefit is not established for a treatment longer than 14 days. <u>Treatment of DVT and PE</u> Enoxaparin sodium can be administered SC either as a once daily injection of 150 IU/kg (1.5 mg/kg) or as twice daily injections of 100 IU/kg (1 mg/kg). The regimen should be selected by the physician based on an individual assessment including evaluation of the thromboembolic risk and of the risk of bleeding. The dose regimen of 150 IU/kg (1.5 mg/kg) administered once daily should be used in uncomplicated patients with low risk of VTE recurrence. The dose regimen of 100 IU/kg (1 mg/kg) administered twice daily should be used in all other patients such as those with obesity, with symptomatic PE, cancer, recurrent VTE or proximal (vena iliaca) thrombosis. Enoxaparin sodium treatment is prescribed for an average period of 10 days. Oral anticoagulant therapy should be initiated when appropriate (see “Switch between enoxaparin sodium and oral anticoagulants” at the end of section Posology and method of administration). **In the extended treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and prevention of its recurrence in patients with active cancer, physicians should carefully assess the individual thromboembolic and bleeding risks of the patient.** **The recommended dose is 100 IU/kg (1 mg/kg) administered twice daily by SC injections for 5 to10 days, followed by a 150 IU/kg (1.5 mg/kg) once daily SC injection up to 6 months. The benefit of continuous anticoagulant therapy should be reassessed after 6 months of treatment.**	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		<u>Prevention of thrombus formation during haemodialysis</u> The recommended dose is 100 IU/kg (1 mg/kg) of enoxaparin sodium. For patients with a high risk of haemorrhage, the dose should be reduced to 50 IU/kg (0.5 mg/kg) for double vascular access or 75 IU/kg (0.75 mg/kg) for single vascular access. During haemodialysis, enoxaparin sodium should be introduced into the arterial line of the circuit at the beginning of the dialysis session. The effect of this dose is usually sufficient for a 4-hour session; however, if fibrin rings are found, for example after a longer than normal session, a further dose of 50 IU to 100 IU/kg (0.5 to 1 mg/kg) may be given. No data are available in patients using enoxaparin sodium for prophylaxis or treatment and during haemodialysis sessions. <u>Acute coronary syndrome: treatment of unstable angina and NSTEMI and treatment of acute STEMI</u> • For treatment of unstable angina and NSTEMI, the recommended dose of enoxaparin sodium is 100 IU/kg (1 mg/kg) every 12 hours by SC injection administered in combination with antiplatelet therapy. Treatment should be maintained for a minimum of 2 days and continued until clinical stabilization. The usual duration of treatment is 2 to 8 days. Acetylsalicylic acid is recommended for all patients without contraindications at an initial oral loading dose of 150–300 mg (in acetylsalicylic acid-naive patients) and a maintenance dose of 75–325 mg/day long-term regardless of treatment strategy. • For treatment of acute STEMI, the recommended dose of enoxaparin sodium is a single intravenous (IV) bolus of 3,000 IU (30 mg) plus a 100 IU/kg (1 mg/kg) SC dose followed by 100 IU/kg (1 mg/kg) administered SC every 12 hours (maximum 10,000 IU (100 mg) for each of the first two SC doses). Appropriate antiplatelet therapy such as oral acetylsalicylic acid (75 mg to 325 mg once daily) should be administered concomitantly unless contraindicated. The recommended duration of treatment is 8 days or until hospital discharge, whichever comes first. When administered in conjunction with a thrombolytic (fibrin specific or non-fibrin specific), enoxaparin sodium should be given	

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Products approved for additional indication (DCA 394, 7 Mac 2024)

No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		between 15 minutes before and 30 minutes after the start of fibrinolytic therapy. o For dosage in patients ≥ 75 years of age, see paragraph “Elderly”. o For patients managed with PCI, if the last dose of enoxaparin sodium SC was given less than 8 hours before balloon inflation, no additional dosing is needed. If the last SC administration was given more than 8 hours before balloon inflation, an IV bolus of 30 IU/kg (0.3 mg/kg) enoxaparin sodium should be administered. <u>Paediatric population</u> The safety and efficacy of enoxaparin sodium in paediatric population have not been established. <u>Elderly</u> For all indications except STEMI, no dose reduction is necessary in the elderly patients, unless kidney function is impaired (see below “renal impairment” and section Special warnings and precautions for use). For treatment of acute STEMI in elderly patients ≥75 years of age, an initial IV bolus must not be used. Initiate dosing with 75 IU/kg (0.75 mg/kg) SC every 12 hours (maximum 7,500 IU (75 mg) for each of the first two SC doses only, followed by 75 IU/kg (0.75 mg/kg) SC dosing for the remaining doses). For dosage in elderly patients with impaired kidney function, see below “renal impairment” and section Special warnings and precautions for use). <u>Hepatic impairment</u> Limited data are available in patients with hepatic impairment (see sections Pharmacodynamics properties and Pharmacokinetic properties) and caution should be used in these patients (see section Special warnings and precautions for use).	

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<table>
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<tr><td></td><td></td><td>
<u>Renal impairment (see sections Special warnings and precautions for use and Pharmacokinetic properties)</u>

• Severe renal impairment
Enoxaparin sodium is not recommended for patients with end stage renal disease (creatinine clearance <15 mL/min) due to lack of data in this population outside the prevention of thrombus formation in extra corporeal circulation during haemodialysis.

Dosage table for patients with severe renal impairment (creatinine clearance [15-30] mL/min):
<table>
<tr><td>Indication</td><td>Dosing regimen</td></tr>
<tr><td>Prophylaxis of venous thromboembolic disease</td><td>2,000 IU (20 mg) SC once daily</td></tr>
<tr><td>Treatment of DVT and PE</td><td>100 IU/kg (1 mg/kg) body weight SC once daily</td></tr>
<tr><td>Extended treatment of DVT and PE in patients with active cancer</td><td>100 IU/kg (1 mg/kg) body weight SC once daily</td></tr>
<tr><td>Treatment of unstable angina and NSTEMI</td><td>100 IU/kg (1 mg/kg) body weight SC once daily</td></tr>
<tr><td>Treatment of acute STEMI (patients under 75)</td><td>1 x 3,000 IU (30 mg) IV bolus plus 100 IU/kg (1 mg/kg) body weight SC and then 100 IU/kg (1 mg/kg) body weight SC every 24 hours</td></tr>
<tr><td>Treatment of acute STEMI (patients over 75)</td><td>No IV initial bolus, 100 IU/kg (1 mg/kg) body weight SC and then 100 IU/kg (1 mg/kg) body weight SC every 24 hours</td></tr>
</table>
The recommended dosage adjustments do not apply to the haemodialysis indication.

• Moderate and mild renal impairment
Although no dose adjustment is recommended in patients with moderate (creatinine clearance 30-50 mL/min) and mild (creatinine clearance 50-80 mL/min) renal impairment, careful clinical monitoring is advised.
</td><td></td></tr>
</table>

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		<u>Method of administration</u> Clexane should NOT be administered by the intramuscular route. For the prophylaxis of venous thrombo-embolic disease following surgery, treatment of DVT and PE, **extended treatment of DVT and PE in patients with active cancer**, treatment of unstable angina and NSTEMI, Enoxaparin sodium should be administered by SC injection. • For acute STEMI, treatment is to be initiated with a single IV bolus injection immediately followed by a SC injection. • For the prevention of thrombus formation in the extra corporeal circulation during haemodialysis, it is administered through the arterial line of a dialysis circuit. The pre-filled disposable syringe is ready for immediate use. SC injection technique: Injection should be made preferably when the patient is lying down. Enoxaparin sodium is administered by deep SC injection. Do not expel the air bubble from the syringe before the injection to avoid the loss of drug when using pre-filled syringes. When the quantity of drug to be injected requires to be adjusted based on the patient's body weight, use the graduated pre-filled syringes to reach the required volume by discarding the excess before injection. Please be aware that in some cases it is not possible to achieve an exact dose due to the graduations on the syringe, and in such case the volume shall be rounded up to the nearest graduation. The administration should be alternated between the left and right anterolateral or posterolateral abdominal wall. The whole length of the need should be introduced vertically into a skin fold gently held between the thumb and index finger. The skin should not be released until the injection is complete. Do not rub the injection site after administration.	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		Note for the pre-filled syringes fitted with an automatic safety system: The safety system is triggered at the end of the injection (see instructions in section Special precautions for disposal and other handling). In case of self-administration, patient should be advised to follow instructions provided in the patient information leaflet included in the pack of this medicine. IV (bolus) injection (for acute STEMI indication only): Treatment is to be initiated with a single IV bolus injection immediately followed by a SC injection. Enoxaparin sodium should be administered through an IV line. It should not be mixed or co-administered with other medications. To avoid the possible mixture of enoxaparin sodium with other drugs, the IV access chosen should be flushed with a sufficient amount of saline or dextrose solution prior to and following the IV bolus administration of enoxaparin sodium to clear the port of drug. Enoxaparin sodium may be safely administered with normal saline solution (0.9%) or 5% dextrose in water. ○ Initial 3,000 IU (30 mg) bolus. For the initial 3,000 IU (30 mg) bolus, using an enoxaparin sodium graduated pre-filled syringe, expel the excessive volume to retain only 3,000 IU (30 mg) in the syringe. The 3,000 IU (30 mg) dose can then be directly injected into the IV line. ○ Additional bolus for PCI when last SC administration was given more than 8 hours before balloon inflation. An initial IV bolus injection of 3 000 IU followed by an SC injection of 100 IU/kg within 15 minutes, then every 12 hours (a maximum of 10000 IU for the 1st two SC doses). The 1st dose of enoxaparin should be administered between 15 minutes before and 30 minutes after the start of thrombolytic therapy (whether fibrin-specific or not).	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		The recommended duration of treatment is 8 days, or until the patient is discharged from hospital if the hospitalization is less than 8 days. Concomitant treatment: Aspirin therapy must be instituted as soon as possible after symptoms appear, and continued at a dose of between 75 mg and 325 mg daily for at least 30 days, unless otherwise indicated. For patients being managed with PCI, an additional IV bolus of 30 IU/kg (0.3 mg/kg) is to be administered if last SC administration was given more than 8 hours before balloon inflation. In order to assure the accuracy of the small volume to be injected, it is recommended to dilute the drug to 300 IU/mL (3 mg/mL). To obtain a 300 IU/mL (3 mg/mL) solution, using a 6,000 IU (60 mg) Enoxaparin sodium pre- filled syringe, it is recommended to use a 50 mL infusion bag (i.e. using either normal saline solution (0.9%) or 5% dextrose in water) as follows: Withdraw 30 mL from the infusion bag with a syringe and discard the liquid. Inject the complete contents of the 6,000 IU (60 mg) Enoxaparin sodium pre-filled syringe into the 20 mL remaining in the bag. Gently mix the contents of the bag. Withdraw the required volume of diluted solution with a syringe for administration into the IV line. After dilution is completed, the volume to be injected can be calculated using the following formula [Volume of diluted solution (mL) = Patient weight (kg) x 0.1] or using the table below. It is recommended to prepare the dilution immediately before use.	

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<table>
<tr><th>No.</th><th>Product
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<tr><td></td><td></td><td>Volume to be injected through IV line after dilution is completed at a concentration of 300 IU (3 mg)/ml.
<table>
<tr><th>Weight</th><th>Required dose
30 IU/kg (0.3 mg/kg)</th><th colspan="2">Volume to inject when diluted to a final concentration of300 IU (3 mg) / mL</th></tr>
<tr><td>[kg]</td><td>IU</td><td>[mg]</td><td>[ml]</td></tr>
<tr><td>45</td><td>1350</td><td>13.5</td><td>4.5</td></tr>
<tr><td>50</td><td>1500</td><td>15</td><td>5</td></tr>
<tr><td>55</td><td>1650</td><td>16.5</td><td>5.5</td></tr>
<tr><td>60</td><td>1800</td><td>18</td><td>6</td></tr>
<tr><td>65</td><td>1950</td><td>19.5</td><td>6.5</td></tr>
<tr><td>70</td><td>2100</td><td>21</td><td>7</td></tr>
<tr><td>75</td><td>2250</td><td>22.5</td><td>7.5</td></tr>
<tr><td>80</td><td>2400</td><td>24</td><td>8</td></tr>
<tr><td>85</td><td>2550</td><td>25.5</td><td>8.5</td></tr>
<tr><td>90</td><td>2700</td><td>27</td><td>9</td></tr>
<tr><td>95</td><td>2850</td><td>28.5</td><td>9.5</td></tr>
<tr><td>100</td><td>3000</td><td>30</td><td>10</td></tr>
<tr><td>105</td><td>3150</td><td>31.5</td><td>10.5</td></tr>
</table></td><td></td></tr>
</table>

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<tr><td></td><td></td><td>
<table>
<tr><td>110</td><td>3300</td><td>33</td><td>11</td></tr>
<tr><td>115</td><td>3450</td><td>34.5</td><td>11.5</td></tr>
<tr><td>120</td><td>3600</td><td>36</td><td>12</td></tr>
<tr><td>125</td><td>3750</td><td>37.5</td><td>12.5</td></tr>
<tr><td>130</td><td>3900</td><td>39</td><td>13</td></tr>
<tr><td>135</td><td>4050</td><td>40.5</td><td>13.5</td></tr>
<tr><td>140</td><td>4200</td><td>42</td><td>14</td></tr>
<tr><td>145</td><td>4350</td><td>43.5</td><td>14.5</td></tr>
<tr><td>150</td><td>4500</td><td>45</td><td>15</td></tr>
</table>

Arterial line injection:
It is administered through the arterial line of a dialysis circuit for the prevention of thrombus formation in the extra corporeal circulation during haemodialysis.

<u>Switch between enoxaparin sodium and oral anticoagulants</u>

Switch between enoxaparin sodium and vitamin K antagonists (VKA)
Clinical monitoring and laboratory tests [prothrombin time expressed as the International Normalized Ratio (INR)] must be intensified to monitor the effect of VKA.

As there is an interval before the VKA reaches its maximum effect, enoxaparin sodium therapy should be continued at a constant dose for as long as necessary in order to maintain the INR within the desired therapeutic range for the indication in two successive tests.
</td><td></td></tr>
</table>

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		For patients currently receiving a VKA, the VKA should be discontinued and the first dose of enoxaparin sodium should be given when the INR has dropped below the therapeutic range. Switch between enoxaparin sodium and direct oral anticoagulants (DOAC) For patients currently receiving enoxaparin sodium, discontinue enoxaparin sodium and start the DOAC 0 to 2 hours before the time that the next scheduled administration of enoxaparin sodium would be due as per DOAC label. For patients currently receiving a DOAC, the first dose of enoxaparin sodium should be given at the time the next DOAC dose would be taken. <u>Administration in spinal/epidural anaesthesia or lumbar puncture</u> Should the physician decide to administer anticoagulation in the context of epidural or spinal anaesthesia/analgesia or lumbar puncture, careful neurological monitoring is recommended due to the risk of neuraxial haematomas (see section Special warnings and precautions for use). - At doses used for prophylaxis A puncture-free interval of at least 12 hours shall be kept between the last injection of enoxaparin sodium at prophylactic doses and the needle or catheter placement. For continuous techniques, a similar delay of at least 12 hours should be observed before removing the catheter. For patients with creatinine clearance [15-30] mL/min, consider doubling the timing of puncture/catheter placement or removal to at least 24 hours. The 2 hours preoperative initiation of enoxaparin sodium 2,000 IU (20 mg) is not compatible with neuraxial anaesthesia.	

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No.	Product [Active Ingredient]	Additional Indication	Product Registration Holder (PRH)
		- At doses used for treatment A puncture-free interval of at least 24 hours shall be kept between the last injection of enoxaparin sodium at curative doses and the needle or catheter placement (see also section Contraindications). For continuous techniques, a similar delay of 24 hours should be observed before removing the catheter. For patients with creatinine clearance [15-30] mL/min, consider doubling the timing of puncture/catheter placement or removal to at least 48 hours. Patients receiving the twice daily doses (i.e. 75 IU/kg (0.75 mg/kg) twice daily or 100 IU/kg (1 mg/kg) twice-daily) should omit the second enoxaparin sodium dose to allow a sufficient delay before catheter placement or removal. Anti-Xa levels are still detectable at these time points, and these delays are not a guarantee that neuraxial hematoma will be avoided. Likewise, consider not using enoxaparin sodium until at least 4 hours after the spinal/epidural puncture or after the catheter has been removed. The delay must be based on a benefit-risk assessment considering both the risk for thrombosis and the risk for bleeding in the context of the procedure and patient risk factors.	