**Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 407, 25 Mac 2025**

***Products approved for additional indication (DCA 407 – 25 March 2025)***

| No. | Product [Active Ingredient] | Additional Indication | Product Registration Holder (PRH) |
|---|---|---|---|
| **1.** | Jardiance 10mg film coated tablets<br><br>[Empagliflozin 10mg]<br><br>Jardiance 25mg film coated tablets<br><br>[Empagliflozin 25mg] | **INDICATION :**<br><br><u>Type 2 diabetes mellitus</u><br><br>Glycaemic control<br><br>Jardiance is indicated in the treatment of type 2 diabetes mellitus to improve glycaemic control in adults and children aged 10 years and above as:<br><br><u>Monotherapy</u><br><br>When diet and exercise alone do not provide adequate glycaemic control in patients for whom use of metformin is considered inappropriate due to intolerance.<br><br><u>Add-on combination therapy</u><br><br>In combination with other glucose-lowering medicinal products including insulin, when these, together with diet and exercise, do not provide adequate glycaemic control (see sections 4.4, 4.5 and 5.1 for available data on different combinations).<br><br>**POSOLOGY:**<br><br>**<u>Paediatric population</u>**<br><br>Paediatric population:<br><br><u>Type 2 diabetes mellitus</u><br>The recommended starting dose of Jardiance is 10 mg once daily.<br>In patients tolerating empagliflozin 10 mg once daily and requiring additional glycaemic control, the dose can be increased to 25 mg once daily (see general information above in section 4.2 Dosage and Administration). | **BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.**<br>Level 23A, Mercu Aspire No. 3,<br>Jalan Bangsar KL Eco City,<br>59200 Kuala Lumpur,<br>Wilayah Persekutuan Kuala Lumpur. |

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| No. | Product [Active Ingredient] | Additional Indication | Product Registration Holder (PRH) |
|---|---|---|---|
| | | No data are available for children with eGFR <60 ml/min/1.73 m² and children below 10 years of age.<br><br><u>Heart failure</u><br>Safety and effectiveness of Jardiance for the treatment of heart failure in children under 18 years of age have not been established.<br><br><u>Chronic kidney disease</u><br>Safety and effectiveness of Jardiance for the treatment of CKD in children under 18 years of age have not been established. | |

**Tambahan Indikasi yang diluluskan dalam Mesyuarat PBKD 407, 25 Mac 2025**

***Products approved for additional indication (DCA 407 – 25 March 2025)***

| No. | Product [Active Ingredient] | Additional Indication | Product Registration Holder (PRH) |
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| **2.** | Jardiance Duo 5mg/ 500mg Film-coated tablets<br><br>[Empagliflozin 5mg/ Metformin 500mg]<br><br>Jardiance Duo 12.5mg/ 500mg Film-coated tablets<br><br>[Empagliflozin 12.5mg/ Metformin 500mg]<br><br>Jardiance Duo 12.5mg/ 850mg Film-coated tablets<br><br>[Empagliflozin 12.5mg/ Metformin 850mg]<br><br>Jardiance Duo 12.5mg/ 1000mg Film-coated tablets<br><br>[Empagliflozin 12.5mg/ Metformin 1000mg] | **INDICATION :**<br><br><u>Paediatric population</u><br>JARDIANCE DUO is indicated as an adjunct to diet and exercise to improve glycaemic control in children aged 10 years and above with type 2 diabetes mellitus:<br>- when treatment with both empagliflozin and metformin is appropriate<br>- inadequately controlled with metformin alone or in combination with insulin (see Clinical Trials)<br>- already treated with empagliflozin and metformin co-administered as separate tablets<br><br>**POSOLOGY :**<br><br><u>Paediatric population</u><br><br>The dosage should be individualised on the basis of the patient's current regimen, effectiveness, and tolerability. The recommended dose is one tablet twice daily.<br><br>The maximum recommended daily dose of JARDIANCE DUO is 25 mg of empagliflozin and 2000 mg of metformin. (See general information above in 4.2 Posology and method of administration)<br><br>No data are available for children with eGFR <60 ml/min/1.73 $m^2$ and children below 10 years of age. | **BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.**<br>Level 23A, Mercu Aspire No. 3,<br>Jalan Bangsar KL Eco City,<br>59200 Kuala Lumpur,<br>Wilayah Persekutuan Kuala Lumpur. |

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| No. | Product [Active Ingredient] | Additional Indication | Product Registration Holder (PRH) |
|---|---|---|---|
| **3.** | BLES (bovine lipid extract surfactant) 27 mg/ml Suspension for Intratracheal Instillation<br><br>[Bovine lipid extract surfactant (Phospholipid 27mg/ml & surfactant associated proteins SP-B and SP-C 176 - 500µg)] | **POSOLOGY :**<br><br>Addition of the subtitle to the currently approved posology:<br><u>INSURE (INtubate-SURfactant-Extubate) Procedure:</u><br>Addition of the new administration technique:<br><u>MIST (Minimally Invasive Surfactant Therapy) Procedure:</u><br>Note: Variations of the MIST procedure detailed below have been described in the literature. A common variation is the LISA (Less Invasive Surfactant Administration) procedure that uses Magill forceps for placement. Thin catheter placement should be performed according to established protocols of the healthcare centre.<br><br>BLES® may also be administered as per MIST techniques. It is recommended that for MIST delivery the neonate is ≥ 28 weeks and/ or ≥1000 grams, does not require intubation/ mechanical ventilation and meets the criteria for surfactant administration (i.e. oxygenation requirement met). Neonates should be kept on nasal continuous positive airway pressure (NCPAP) or non-invasive positive pressure ventilation (NIPPV) using nasal prongs or masks for the entire procedure.<br><br>To administer the dose via the MIST technique, guide a thin catheter (e.g. #5 Fr multi-access catheter) across the vocal cords to a depth of 6 cm + birth weight in kilograms as measured from the lip. This should ensure proper placement of the tip of the catheter mid-way between the vocal cords and carina. After catheter placement, keep the neonate's mouth closed for NCPAP / NIPPV delivery. Synchronize surfactant instillation with the neonate's inspiration using micro-boluses, over a period of 1 to 3 minutes. If unable to deliver the dose successfully using this technique in no more than three attempts, administer the dose via the INSURE method described above. | **AVERROES PHARMACEUTICALS SDN. BHD.**<br>3-08-01 & 03-09-01, Block 3,<br>Presint Alami, Worldwide Business Centre II,<br>Persiaran Akuatik,<br>Seksyen 13,<br>40100 Shah Alam,<br>Selangor. |

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| No. | Product [Active Ingredient] | Additional Indication | Product Registration Holder (PRH) |
|---|---|---|---|
| 4. | RINVOQ 15mg Extended Release Film Coated Tablets<br><br>[Upadacitinib Hemihydrate 15.4mg (Corresponds to 15 mg of upadacitinib)] | **INDICATION :**<br><br>Non-radiographic axial spondyloarthritis (nr-axSpA)<br>RINVOQ is indicated for the treatment of active non-radiographic axial spondyloarthritis in adult patients with objective signs of inflammation as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI), who have responded inadequately to nonsteroidal anti-inflammatory drugs (NSAIDs).<br><br>**POSOLOGY :**<br><br>Treatment with upadacitinib should be initiated and supervised by physicians experienced in the diagnosis and treatment of conditions for which upadacitinib is indicated.<br><br>Posology<br><br>Rheumatoid arthritis, psoriatic arthritis, non-radiographic axial spondyloarthritis and ankylosing spondylitis<br><br>The recommended dose of upadacitinib is 15 mg once daily.<br><br>Consideration should be given to discontinuing treatment in patients with non-radiographic axial spondyloarthritis and ankylosing spondylitis who have shown no clinical response after 16 weeks of treatment. Some patients with initial partial response may subsequently improve with continued treatment beyond 16 weeks. | **ABBVIE SDN. BHD.**<br>9th Floor Menara Lien Hoe,<br>No.8, Persiaran Tropicana,<br>Tropicana Golf & Country Resort,<br>47410 Petaling Jaya,<br>Selangor. |

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<tr><td></td><td></td><td>
<u>Special Populations</u><br><br>
Elderly<br>
Rheumatoid arthritis, psoriatic arthritis, <u>non-radiographic axial spondyloarthritis and</u> ankylosing spondylitis axial spondyloarthritis<br><br>
There are limited data in patients aged 75 years and older.<br><br>
Renal Impairment<br>
No dose adjustment is required in patients with mild or moderate renal impairment. There are limited data on the use of upadacitinib in subjects with severe renal impairment. Upadacitinib should be used with caution in patients with severe renal impairment. The use of upadacitinib has not been studied in subjects with end stage renal disease and is therefore not recommended for use in these patients.<br><br>
For patients with severe renal impairment, the following dose adjustments are recommended:<br><br>
Table 2. Recommended Dose for Severe Renal Impairment[a]
<table>
<tr><th></th><th>Indication</th><th>Recommended once daily dose</th></tr>
<tr><td rowspan="3">Severe renal impairment</td><td>Rheumatoid arthritis, psoriatic arthritis, <u>non-radiographic axial spondyloarthritis</u>, ankylosing spondylitis, atopic dermatitis</td><td>15 mg</td></tr>
<tr><td rowspan="2">Ulcerative Colitis<br>Crohn’s Disease</td><td>Induction: 30 mg</td></tr>
<tr><td>Maintenance: 15 mg</td></tr>
<tr><td colspan="3">[a]estimated glomerular filtration rate (eGFR) 15 to < 30 ml/min/1.73m$^2$</td></tr>
</table>
</td><td></td></tr>
</table>

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| | | Paediatric population<br>The safety and efficacy of RINVOQ in adolescents with atopic dermatitis weighing < 40 kg and in children with atopic dermatitis aged 0 to less than 12 years have not yet been established. No data are available.<br><br>The safety and efficacy of RINVOQ in children and adolescents with rheumatoid arthritis, psoriatic arthritis, non-radiographic axial spondyloarthritis, ankylosing spondylitis, ulcerative colitis and Crohn's disease aged 0 to less than 18 years have not yet been established. No data are available | |
| **5.** | VERORAB | **INDICATION :** | **SANOFI-AVENTIS** |

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| No. | Product [Active Ingredient] | Additional Indication | Product Registration Holder (PRH) |
|---|---|---|---|
| | VACCINE<br><br>[Inactivated Rabies Virus, 3.25 international units of rabies antigen] | VERORAB is indicated for pre-exposure and post-exposure prophylaxis of rabies in all age groups (see sections 4.2 and 5.1).<br><br>Verorab should be used according to official recommendations.<br><br>Pre-exposure prophylaxis should be offered to subjects at high risk of contamination by the rabies virus.<br><br>All those at permanent risk, such as the personnel of diagnostic, research or production laboratories working on the rabies virus, should be vaccinated.<br><br>Vaccination is also recommended for the following categories:<br>• chiropterologists and people regularly exposed to the bat rabies virus.<br>• exposed professionals (veterinary personnel, laboratory personnel handling equipment that is contaminated or likely to be contaminated, slaughterhouse butchers, pound personnel, naturalists, taxidermists, gamekeepers, forest rangers, slaughterhouse personnel).<br>• adults and children living in or travelling to enzootic areas.<br><br>**POSOLOGY :**<br><br>Posology<br>Intramuscular use (IM): the recommended dose is 0.5 mL of reconstituted vaccine.<br>Intradermal use (ID): the recommended dose is 0.1 mL of reconstituted vaccine per injection site.<br><br><u>Pre-exposure prophylaxis</u> | **(MALAYSIA) SDN. BHD.**<br>Unit TB-18-1, Level 18,<br>Tower B, Plaza 33,<br>No.1, Jalan Kemajuan,<br>Seksyen 13,<br>46200 Petaling Jaya,<br>Selangor. |

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<tr><td></td><td></td><td>
For pre-exposure immunisation, immunocompetent individuals can be vaccinated according to one of the vaccination schedules presented in table 1 and according to official recommendations.<br><br>
Table 1: Pre-exposure vaccination schedules
<table>
<tr><td></td><td>D0</td><td>D7</td><td>D21 or D28</td></tr>
<tr><td colspan="4">Intramuscular use (0.5 mL per dose)</td></tr>
<tr><td>Conventional regimen IM use – 0.5 mL</td><td>1 dose</td><td>1 dose</td><td>1 dose</td></tr>
<tr><td>1-week regimen [(a)]<br>IM use – 0.5 mL</td><td>1 dose</td><td>1 dose</td><td></td></tr>
<tr><td colspan="4">Intradermal use (0.1 mL per dose)</td></tr>
<tr><td>Conventional regimen ID use – 0.1 mL</td><td>1 dose</td><td>1 dose</td><td>1 dose</td></tr>
<tr><td>1-week regimen [(a)]<br>ID use - 0.1 mL</td><td>2 doses [(b)]</td><td>2 doses [(b)]</td><td></td></tr>
</table>
(a) This regimen should not be used for immunocompromised individuals (see sub-section "Immunocompromised individuals")<br>
(b) one injection in each anterolateral thigh (infants and toddlers) or in each arm (children and adults).<br>
Booster doses are determined based on the risk of exposure and on serological tests in accordance with official recommendations.<br><br>
VERORAB can be administered as a booster injection after primary vaccination with a cell culture rabies vaccine (a rabies vaccine prepared in VERO cells or prepared in human diploid cells (HDCV)).
</td><td></td></tr>
</table>

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| | | <u>Post-exposure prophylaxis</u><br>Post-exposure prophylaxis includes local non-specific treatment of the wound, vaccination and, where appropriate, passive immunization with rabies immunoglobulins.<br><br>Post-exposure prophylaxis should be initiated as soon as possible after suspected exposure to rabies. In all cases, proper wound care (careful washing of all bites and scratches with soap or detergent and copious amounts of water and/or virucidal agents) must be performed immediately or as soon as possible after exposure. It must be performed before administration of vaccine or rabies immunoglobulins, when they are indicated. Post-exposure prophylaxis should be adjusted to the exposure category, the condition of the animal (see Table 3) and the vaccination status of the patient, in accordance with official recommendations (see Table 2, WHO recommendations).<br><br>Post-exposure prophylaxis should be performed as soon as possible after exposure under medical supervision and only at a rabies centre.<br><br>If necessary, post-exposure prophylaxis can be supplemented by tetanus prophylaxis and antibiotic therapy to prevent the development of infections other than rabies.<br><br>Table 2: WHO Guide for post-exposure prophylaxis depending on severity of exposure (to be adapted according to local official recommendations). | |

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<tr><td></td><td></td><td>
<table>
<tr><th>Exposure category</th><th>Type of exposure to a domestic or wild animal, suspected or confirmed to be rabid or not available for testing</th><th>Post-exposure prophylaxis recommended</th></tr>
<tr><td>I</td><td>Touching or feeding of animals. Licks on intact skin (no exposure)</td><td>None if reliable case history is available.[a]</td></tr>
<tr><td>II</td><td>Nibbling of uncovered skin.<br>Minor scratches or abrasions without bleeding (exposure)</td><td>Administer vaccine immediately.<br>Discontinue treatment if the animal is in good health after the 10-day observation period[b] or if the rabies test performed using appropriate laboratory methods is negative.<br>Treat as category III if bat exposure involved.</td></tr>
</table>
</td><td></td></tr>
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<tr><td></td><td></td><td>
<table>
<tr><td>III</td><td>Single or multiple transdermal bites[c] or scratches, licks on broken skin or contamination of mucous membranes with saliva (licks), exposure to bats (severe exposure).</td><td>Administer the vaccine immediately and rabies immunoglobulin, preferably as soon as possible after initiation of post-exposure prophylaxis.<br>Rabies immunoglobulins can be injected up to 7 days after the first dose of vaccine is administered.<br>Discontinue treatment if the animal is in good health after the 10-day observation period[b] or if the rabies test performed using appropriate laboratory methods is negative.</td></tr>
</table>
([a]) If the animal is an apparently healthy dog or cat living in a low-risk area and placed under veterinary observation, treatment may be postponed (see Table 3).<br>([b]) This observation period only applies to cats and dogs. With the exception of endangered or threatened species, domestic animals and wild animals suspected to have rabies should be euthanised and their tissues examined using appropriate laboratory methods (see Table 3).<br>([c]) Bites, particularly to the head, neck, face, hands and genitals are classified as Category III exposure due to the extensive innervation of these parts of the body.<br><br>Table 3: Course of action after exposure depending on the condition of the animal (WHO recommendations to be adapted according to local recommendations)
</td><td></td></tr>
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<tr><td></td><td></td><td>
<table>
<tr><th rowspan="2">Circumstances</th><th colspan="2">Course of action regarding</th><th rowspan="2">Comments</th></tr>
<tr><th>The animal</th><th>The patient</th></tr>
<tr><td>Animal unavailable<br>Suspect or non-suspect circumstances</td><td></td><td>To be taken to a rabies centre for treatment</td><td>Treatment[b] is always completed.</td></tr>
<tr><td>Dead animal<br>Suspect or non-suspect circumstances</td><td>Send the brain to an approved laboratory for analysis</td><td>To be taken to a rabies centre for treatment</td><td>Treatment[b] is discontinued if the tests are negative or, otherwise, continued.</td></tr>
<tr><td>Live animal<br>Non-suspect circumstances</td><td>Place under veterinary supervision[a]</td><td>Postpone rabies treatment</td><td>Treatment[b] is continued based on veterinary supervision of the animal.</td></tr>
<tr><td>Live animal<br>Suspect circumstances</td><td>Place under veterinary supervision[a]</td><td>To be taken to a rabies centre for treatment</td><td>Treatment[b] is discontinued if veterinary supervision invalidates initial doubts, or, otherwise, continued.</td></tr>
</table>
([a]) According to WHO recommendations, the minimum observation period under veterinary supervision for dogs and cats is 10 days.<br>([b]) Treatment is recommended depending on the severity of exposure: see Table 2.
</td><td></td></tr>
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<tr><td></td><td></td><td>
<u>Post-exposure prophylaxis of non-immunised subjects</u><br>
Non-immunised subjects may be vaccinated according to one of the vaccination regimens by intramuscular use (IM) or by intradermal use (ID) presented in table 4.<br><br>
In all cases, refer to the local official recommendations.<br><br>
Table 4: Post-exposure prophylaxis of non-immunised subjects
<table>
<tr><th></th><th>D0</th><th>D3</th><th>D7</th><th>D14</th><th>D21</th><th>D28</th></tr>
<tr><td colspan="7">Intramuscular use (0.5 mL per dose)</td></tr>
<tr><td>IM Essen protocol<br>IM use – 0.5 mL/dose</td><td>1 dose</td><td>1 dose</td><td>1 dose</td><td>1 dose</td><td>-</td><td>1 dose</td></tr>
<tr><td>IM Zagreb protocol<br>IM use – 0.5 mL/dose</td><td>2 doses[a]</td><td>-</td><td>1 dose</td><td>-</td><td>1 dose</td><td>-</td></tr>
<tr><td colspan="7">Intradermal use (0.1 mL per dose)</td></tr>
<tr><td>New Thailand Red Cross (TRC) ID Regimen<br>ID use – 0.1 mL/dose</td><td>2 doses[b]</td><td>2 doses[b]</td><td>2 doses[b]</td><td>-</td><td>-</td><td>2 doses[b]</td></tr>
<tr><td>Institute Pasteur of Cambodia (IPC) ID regimen<br>ID use – 0.1 mL/dose</td><td>2 doses[b]</td><td>2 doses[b]</td><td>2 doses[b]</td><td>-</td><td>-</td><td>-</td></tr>
</table>
</td><td></td></tr>
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<tr><td></td><td></td><td>
<table>
<tr><td>4-site 1-week ID regimen<br>ID use – 0.1 mL/dose</td><td>4 doses[c]</td><td>4 doses[c]</td><td>4 doses[c]</td><td>-</td><td>-</td><td>-</td></tr>
</table>
([a]) one IM injection in the anterolateral region of each thigh (in infants and young children) or in each deltoid (in older children and adults).<br>
([b]) to be injected in 2 separate sites, contralateral if possible.<br>
([c]) to be injected in 4 separate sites.<br><br>
Whatever the regimen used, vaccination must not be discontinued unless the contact animal is declared free from rabies after veterinary supervision (see Table 3).<br><br>
Rabies immunoglobulins should be administered concomitantly with the vaccine, in case of category III exposure (WHO classification, see Table 2). If possible, the vaccine should be administered contralaterally to the immunoglobulin administration sites.<br><br>
Refer to the Summary of Characteristics of the rabies immunoglobulins used.<br><br>
<u>Post-exposure prophylaxis for already immunised subjects</u><br>
In accordance with official recommendations, this applies to subjects who have already received pre-exposure prophylaxis or post-exposure prophylaxis or who discontinued post-exposure prophylaxis after receiving at least two doses of vaccine prepared in cell culture.<br><br>
Subjects who have already been immunised must receive 1 dose of vaccine (0.5 mL intramuscularly or 0.1 mL intradermally) on D0 and 1 dose on D3.<br><br>
Alternatively, 4 intradermal injections of 0.1 mL may be administered in 4 separate sites on D0.
</td><td></td></tr>
</table>

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| | | Rabies immunoglobulins are not indicated in this case.<br><u>Immunocompromised subjects</u><br>• Pre-exposure prophylaxis<br>In immunocompromised subjects, conventional three-dose regimens should be used (see table 1) and blood tests for neutralising antibodies should be performed 2 to 4 weeks following the last dose of the vaccine to assess the possible need for an additional dose of the vaccine.<br><br>• Post-exposure prophylaxis<br>In immunocompromised subjects, a complete vaccine regimen should be administered (see table 4). Rabies immunoglobulins should be administered concomitantly with the vaccine in the event of any category II or III exposure (see table 2).<br><br>Paediatric population<br>Children should receive the same dose as adults (0.5 mL intramuscularly or 0.1 mL intradermally).<br><br>Method of administration<br>• **Intramuscular use (IM)**<br>The vaccine is administered in the anterolateral region of the thigh muscle in infants and young children and in the deltoid muscle in older children and adults.<br>• **Intradermal use (ID)**<br>The vaccine should ideally be administered in the upper arm or the forearm.<br><br>Do not inject in the buttocks region.<br>Do not inject via the intravascular route.<br>Precautions to be taken before handling or administering the medicinal product.<br>For instructions on reconstitution of the medicinal product before administration, see section 6.6. | |