**Maklumat tambahan indikasi untuk upload pada laman web**
**Year 2015**
**Products Approved For Additional Indication (DCA 287 – 30 April 2015)**

| NO | PRODUCT (ACTIVE INGREDIENT) | ADDITIONAL INDICATION | MARKETING AUTHORIZATION HOLDER |
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| 1. | **1.1 ACTEMRA 20 MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION**<br>[Tocilizumab 20 mg/ml] | ➢ Indication:<br><br>*Polyarticular Juvenile Idiopathic Arthritis (pJIA)*<br>*Tocilizumab in combination with methotrexate (MTX) is indicated for the treatment of juvenile idiopathic polyarthritis (rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX.*<br>*Tocilizumab can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.*<br><br>➢ Posology:<br><br>*The recommended dose of tocilizumab for patients with pJIA is:*<br>• *10 mg/kg for patients < 30 kilograms (kgs),*<br>• *8 mg/kg for patients ≥ 30 kilograms (kgs),*<br>*given once every four weeks as an IV infusion. A change in dose should only be based on a consistent change in the patient's body weight over time. Tocilizumab can be used alone or in combination with MTX.*<br><br>*Dose Modification Recommendations for pJIA:*<br>*Dose interruptions of tocilizumab for the following laboratory abnormalities are recommended in pJIA patients in the tables below. If appropriate, the dose of concomitant MTX and/or other medications should be modified or dosing stopped and tocilizumab dosing interrupted until the clinical situation has been evaluated. As there are many co-morbid conditions that may affect laboratory values in pJIA, the decision to discontinue tocilizumab for a laboratory abnormality should be based upon the medical assessment of the individual patient.* | **ROCHE (MALAYSIA) SDN. BHD.**<br>Level 21, The Pinnacle<br>Persiaran Lagoon,<br>Bandar Sunway<br>47500 Subang Jaya,<br>Selangor |

- *Liver enzyme abnormalities*

| *Laboratory Value* | *Action* |
|---|---|
| *> 1 to 3 x ULN* | *Dose modify concomitant MTX if appropriate*<br>*For persistent increases in this range, interrupt tocilizumab until ALT/AST have normalized.* |
| *> 3 x ULN to 5x ULN* | *Dose modify concomitant MTX if appropriate*<br>*Interrupt tocilizumab dosing until < 3x ULN and follow recommendations above for >1 to 3x ULN* |
| *> 5x ULN* | *Discontinue tocilizumab.*<br>*The decision to discontinue tocilizumab in pJIA for a laboratory abnormality should be based on the medical assessment of the individual patient.* |

- *Low absolute neutrophil count (ANC)*

| *Laboratory Value (cells x $10^9$/L)* | *Action* |
|---|---|
| *ANC > 1* | *Maintain dose* |
| *ANC 0.5 to 1* | *Interrupt tocilizumab dosing*<br>*When ANC increases to > 1 x $10^9$/ L resume tocilizumab.* |
| *ANC < 0.5* | *Discontinue tocilizumab.*<br>*The decision to discontinue tocilizumab in pJIA for a laboratory abnormality should be based on the medical assessment of the individual patient.* |

- *Low platelet count*

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| | | <table><tr><th>*Laboratory Value (cells x $10^3/\mu L$)*</th><th>*Action*</th></tr><tr><td>*50 to 100*</td><td>*Dose modify concomitant MTX if appropriate*<br>*Interrupt tocilizumab dosing*<br>*When platelet count is > 100 x $10^3/\mu L$ resume tocilizumab*</td></tr><tr><td>*< 50*</td><td>*Discontinue tocilizumab.*<br>*The decision to discontinue tocilizumab in pJIA for a laboratory abnormality should be based on the medical assessment of the individual patient.*</td></tr></table><br>*Reduction of tocilizumab dose due to laboratory abnormalities has not been studied in pJIA patients.*<br>*Available data suggest that clinical improvement is observed within 12 weeks of initiation of treatment with tocilizumab. Continued therapy should be carefully reconsidered in a patient exhibiting no improvement within this timeframe.* | |
| 2. | **2.1 DIPHERELINE P.R. 11.25MG POWDER FOR SUSPENSION FOR INTRAMUSCULAR INJECTION**<br>[Triptorelin pamoate] | ➢ Indication:<br><br>*Precocious puberty (before 8 years in girls and 10 years in boys).*<br><br>➢ Posology:<br><br>*Precocious puberty*<br>*One intramuscular injection should be administered every 3 months.*<br><br>*The treatment of children with Diphereline P.R. 11.25mg should be under the overall supervision of a paediatric endocrinologist or of a paediatrician or endocrinologist with expertise in the treatment of central precocious puberty.*<br><br>*Treatment should be stopped around the physiological age of puberty in boys and girls and should not be continued in* | **A. MENARINI SINGAPORE PTE. LTD.**<br>Level 2, No. 10<br>Jalan Bersatu 13/4<br>46200 Petaling Jaya,<br>Selangor |

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| | | *girls with a bone maturation of more than 12 years. There are limited data available in boys relating to the optimum time to stop treatment based on the bone age, however it is advised that treatment is stopped in boys with a bone maturation age of 13-14 years.* | |
| 3. | **3.1 OZURDEX® 700 MICROGRAMS INTRAVITREAL IMPLANT IN APPLICATOR**<br>[Dexamethasone] | ➢ Indication:<br><br>*OZURDEX® is indicated for the treatment of adult patients with visual impairment due to diabetic macular oedema (DME) who are pseudophakic or who are considered insufficiently responsive to, or unsuitable for non-corticosteroid therapy.*<br><br>➢ Posology:<br><br><u>DME</u><br>*Patients treated with OZURDEX® who have experienced an initial response and in the physician's opinion may benefit from retreatment without being exposed to significant risk should be considered for retreatment.*<br><br>*Retreatment may be performed after approximately 6 months if the patient experiences decreased vision and/or increase in retinal thickness, secondary to recurrent or worsening diabetic macular oedema.*<br><br>*There is currently no experience of the efficacy or safety of repeat administrations in DME beyond 7 implants.*<br><br><u>Paediatric population</u><br>*There is no relevant use of OZURDEX® in the paediatric population in*<br>• *diabetic macular oedema* | **ALLERGAN MALAYSIA SDN BHD**<br>Level 5-02, Block A, PJ8 No.23, Jalan Barat, Seksyen 8<br>46050 Petaling Jaya, Selangor |
| 4. | **4.1 Forxiga 5mg Film-Coated Tablet**<br>[Dapagliflozin propanediol monohydrate 5mg]<br><br>**4.2 Forxiga 10mg Film-Coated Tablet**<br>[Dapagliflozin propanediol monohydrate 10mg] | ➢ Indication:<br><br><u>Add-on combination therapy</u><br>*Forxiga is indicated in patients with type 2 diabetes mellitus to improve glycaemic control:*<br>• *in combination with metformin and a sulfonylurea when existing therapy, along with diet and exercise, does not provide adequate glycaemic control.* | **ASTRAZENECA SDN. BHD.**<br>Level 12, Surian Tower<br>1 Jalan PJU 7/3<br>Mutiara Damansara<br>47810 Petaling Jaya, Selangor |

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| 5. | **5.1 PRADAXA 110MG, HARD CAPSULES**<br>[Dabigatran etexilate mesilate] | ➢ Indication:<br><br>*110mg capsule:*<br>*Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults.* | **BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.**<br>Suite 15-5 Level 15<br>Wisma UOA Damansara II<br>No 6, Jalan Changkat Semantan<br>Damansara Heights<br>50490 Kuala Lumpur |
| 6. | **6.1 Spiriva Respimat 2.5 microgram, Solution for Inhalation**<br>[Tiotropium bromide monohydrate] | ➢ Indication:<br><br>*Asthma*<br>*Spiriva Respimat is indicated as an add-on maintenance bronchodilator treatment in adult patients with asthma who are currently treated with the maintenance combination of inhaled corticosteroids (≥800µg budesonide/day or equivalent) and long-acting β2 agonists and who experienced one or more severe exacerbations in the previous year.*<br><br>➢ Posology:<br><br>*In the treatment of asthma, the full benefit will be apparent after several doses of Spiriva Respimat.*<br><br>*The recommended dose for adults is 5 microgram tiotropium given as two puffs from the Respimat inhaler once daily, at the same time of the day.*<br><br>*<u>Paediatric population:</u>*<br>*<u>Asthma</u>*<br>*The efficacy and safety of Spiriva Respimat in children and adolescents has not yet been established.* | **BOEHRINGER INGELHEIM (MALAYSIA) SDN. BHD.**<br>Suite 15-5 Level 15<br>Wisma UOA Damansara II<br>No 6, Jalan Changkat Semantan<br>Damansara Heights<br>50490 Kuala Lumpur |

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| 7. | **7.1 Ritalin LA Modified-release Capsule 20mg**<br>[Methylphenidate hydrochloride 20mg]<br><br>**7.2 Ritalin LA Modified-release Capsule 30mg**<br>[Methylphenidate hydrochloride 30mg]<br><br>**7.3 Ritalin LA Modified-release Capsule 40mg**<br>[Methylphenidate hydrochloride 40mg] | ➢ Indication:<br><br>*Ritalin LA capsules are indicated for the treatment of ADHD.*<br><br>*Continuation of Treatment in Adolescent and Special Diagnostic Considerations for ADHD in adults*<br>*There is limited information to guide clinicians about how long older adolescents should continue to receive treatment with drugs for attention deficit hyperactivity disorder (ADHD). The decision should be based on the extent to which symptoms of ADHD and social functioning have improved to a point that medication is no longer needed. If older adolescents have been largely symptoms-free for a year and are functioning well, a trial without medication is warranted. This should be undertaken at times of low stress such as during holidays or in a period when a school routine is well established.*<br><br>*ADHD needs to be considered in adults who present with longstanding symptoms suggestive of ADHD (inattention, impulsivity, disorganization) that appear to have started in childhood and are persisting into adult life. Further, people with personality disorder and/or problems with drug use accompanied by a significant level of impulsivity and inattention should be referred for evaluation by a psychiatrist with the training and skills required to assess and treat ADHD. This expertise is necessary due to the overlap of ADHD symptoms with anxiety, mood and personality disorders.*<br><br>➢ Posology:<br><br>*Pre-treatment screening*<br>*Treatment should only be initiated by specialist physicians with experience in the use of the drug. Before initiating Ritalin 10/Ritalin LA treatment, patients should be assessed for pre-existing cardiovascular and psychiatric disorders and a family history of sudden death, ventricular arrhythmia and psychiatric disorders (see sections CONTRAINDICATIONS and WARNINGS AND PRECAUTIONS).* | **NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.**<br>Level 22, Tower B,<br>Plaza 33<br>No. 1, Jalan Kemajuan,<br>Seksyen 13<br>46200 Petaling Jaya,<br>Selangor |

*Dosage*
*The dosage of Ritalin 10/ Ritalin LA should be individualized according to the patient's clinical needs and responses.*
*Treatment with Ritalin 10/ Ritalin LA should be initiated at a low dose, with increments at weekly intervals.*

*<u>ADHD</u>*
*In the treatment of ADHD, an attempt should be made to time administration of the drug to coincide with periods of greatest academic, behavioral, or social difficulties for the patient.*

*If symptoms do not improve after dose titration over a one–month period, the drug should be discontinued.*

*If symptoms worsen or other adverse effects occur, the dosage should be reduced or, if necessary, the drug discontinued.*

*If the effect of the drug wears off too early in the evening, disturbed behaviour and/or inability to go to sleep may recur. A small evening dose of the Ritalin 10mg tablet may help to solve this problem.*

*Periodic assessment of the treatment in ADHD*
*Drug treatment needs not be indefinite. Physicians should periodically re-evaluate the treatment with trial periods off medication to assess the patient's functioning without pharmacotherapy. Improvement may be sustained when the drug is either temporarily or permanently discontinued. When used in children with ADHD, treatment can usually be discontinued during or after puberty.*

*If therapy is interrupted for reasons other than those stated above, it should not be restarted at the dose that had been reached prior to treatment interruption, but should be re-titrated.*

*Adults*
*Only the Ritalin LA formulation should be used for the treatment of ADHD in adults.*

*Ritalin LA capsules*

*Maximum daily doses:*

*Daily doses above 80mg are not recommended for the treatment of ADHD in adults.*

*Patients new to methylphenidate*

*The recommended starting dose of Ritalin LA in patients who are not currently taking methylphenidate is 20 mg once daily.*

*Patients currently using methylphenidate*

*Treatment may be continued with the same daily dose. If the patient was previously treated with an immediate release formulation, a conversion to an appropriate recommended dose of Ritalin LA should be made (see below SWITCHING PATIENT TREATMENT FROM RITALIN 10 TO RITALIN LA CAPSULES).*

*There are no differences recommended in dosing between male and female adult patients.*

*Use in Elderly*

*Use of Ritalin LA in patients over 60 years of age has not been studied in controlled trials.*

*Switching patient's treatment from Ritalin 10 to Ritalin LA capsules*

*The recommended dose of Ritalin LA should be equal to the total daily dose of the immediate-release formulation not exceeding a total dose of 60 mg in children and 80 mg in adults. An example in patients being switched from Ritalin 10 immediate-release tablets is provided in table below.*

*Table 1 Recommended daily dose when switching treatment to Ritalin LA*

| *Previous dose of Ritalin 10 tablets* | *Recommended dose of Ritalin LA capsules* |
|---|---|
| *10 mg twice daily* | *20 mg once daily* |
| *15 mg twice daily* | *30 mg once daily* |
| *20 mg twice daily* | *40 mg once daily* |

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| | | *For other methylphenidate regimens, clinical judgement should be used when selecting the starting dose.*<br><br>*Ritalin LA dosage may be adjusted at weekly intervals in 10 mg increments for children and in 20 mg increments for adults.*<br><br>*Administration*<br><br>*<u>Ritalin LA</u>*<br>*Ritalin LA capsules should be administered orally once daily in the morning.*<br><br>*Ritalin LA may be swallowed as whole capsules or alternatively may be administered by sprinkling the capsule contents on a small amount of soft food (see specific instructions below). Ritalin LA capsules and/or their contents should not be crushed, chewed or divided.*<br><br>*The capsules may be administered with or without food. A high fat breakfast may slow the rate of absorption and therefore onset of action. Dosage should, therefore, be standardised in relation to food to ensure consistency of effect.*<br><br>*Ritalin LA administered as a single daily dose provides comparable overall exposure (AUC) of methylphenidate compared to the same total dose of immediate release tablets administered twice daily.*<br><br>*<u>Sprinkling Ritalin LA capsule contents on food</u>*<br>*Carefully open the Ritalin LA capsule(s) and sprinkle the beads over apple sauce. The food should not be warm because it could affect the modified-release properties of the formulation. All of the mixture of drug and food should be immediately swallowed, unchewed. The drug and food mixture should not be stored for future use.* | |

8.

**8.1 Eliquis 2.5mg film-coated tablets**
[Apixaban 2.5mg]

**8.2 Eliquis 5mg film-coated tablets**
[Apixaban 5mg]

- Indication:

*For 2.5mg and 5mg*
*Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE), and prevention of recurrent DVT and PE in adults (see section 4.4 for haemodynamically unstable PE patients).*

- Posology:

*<u>Treatment of DVT, treatment of PE and prevention of recurrent DVT and PE (VTEt)</u>*
*The recommended dose of Eliquis for the treatment of acute DVT and treatment of PE is 10 mg taken orally twice daily for the first 7 days followed by 5 mg taken orally twice daily. As per available medical guidelines, short duration of treatment (at least 3 months) should be based on transient risk factors (e.g. recent surgery, trauma, immobilisation).*

*The recommended dose of Eliquis for the prevention of recurrent DVT and PE is 2.5 mg taken orally twice daily. When prevention of recurrent DVT and PE is indicated, the 2.5 mg twice daily dose should be initiated following completion of 6 months of treatment with Eliquis 5 mg twice daily or with another anticoagulant, as indicated in Table 1 below.*

*Table 1:*

| | *Dosing schedule* | *Maximum daily dose* |
|---|---|---|
| *Treatment of DVT or PE* | *10 mg twice daily for the first 7 days* | *20mg* |
| | *Followed by 5 mg twice daily* | *10mg* |
| *Prevention of recurrent DVT and/or PE following completion of 6 months of treatment for DVT or PE* | *2.5 mg twice daily* | *5mg* |

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| | | *The duration of overall therapy should be individualised after careful assessment of the treatment benefit against the risk for bleeding.*<br><br>*<u>Prevention of VTE (VTEp): elective hip or knee replacement surgery</u>*<br>*<u>Treatment of DVT, treatment of PE and prevention of recurrent DVT and PE (VTEt)</u>*<br>*For the prevention of VTE in elective hip or knee replacement surgery (VTEp), for the treatment of DVT, treatment of PE and prevention of recurrent DVT and PE (VTEt) apixaban is to be used with caution.*<br><br>*<u>Body weight</u>*<br>*VTEp and VTEt – No dose adjustment required.*<br><br>*<u>Elderly</u>*<br>*VTEp and VTEt – No dose adjustment required.* | |
| 9. | **9.1 EPIDUO 0.1%/ 2.5% GEL**<br>[Adapalene 1mg and Benzoyl Peroxide 25mg] | ➢ Indication:<br><br>*For cutaneous treatment of Acne vulgaris when comedones, papules and pustules are present in patients aged 9 years and older.*<br><br>➢ Posology:<br><br>*The safety and effectiveness of EPIDUO have not been studied in children below 9 years of age.* | **ZUELLIG PHARMA SDN BHD**<br>No. 15, Persiaran Pasak Bumi, Sek. U8<br>Perindustrian Bukit Jelutong<br>40150 Shah Alam, Selangor |