Maklumat tambahan indikasi
Year 2020
Products Approved For Additional Indication (DCA 350 – 2 November 2020)

	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Symbicort Turbuhaler 160/4.5 mcg/dose** [Budesonide 160mcg / Formoterol fumarate dihydrate 4.5mcg]	➢ Posology: ***Asthma*** *Symbicort Turbuhaler can be used according to different treatment approaches:* *A. Symbicort anti-inflammatory reliever therapy (patients with mild disease).* *B. Symbicort anti-inflammatory reliever plus maintenance therapy.* *C. Symbicort maintenance therapy (fixed dose).* ***A. Symbicort anti-inflammatory reliever therapy (patients with mild disease)*** *Symbicort Turbuhaler 160/4.5 µg/inhalation is taken as needed for the relief of asthma symptoms when they occur and as a preventative* *treatment of symptoms in those circumstances recognised by the patient to precipitate an asthma attack. Patients should be advised to always have Symbicort Turbuhaler 160/4.5 µg/inhalation available for relief of symptoms.* *Preventative use of Symbicort Turbuhaler 160/4.5 µg/inhalation for allergen- or exercise-induced bronchoconstriction (AIB/EIB) should be discussed between physician and patient; the recommended dose frequency should take into consideration both allergen exposure and exercise patterns.* *<u>Adults and adolescents (12 years and older)</u>* *Patient should take 1 inhalation of Symbicort Turbuhaler 160/4.5 µg/inhalation as needed in response to symptoms. If symptoms persist after a few minutes, an additional inhalation should be taken. No more than 6 inhalations should be taken **on any single***	**ASTRAZENECA SDN. BHD.** Level 11 & 12, Nucleus Tower No. 10, Jalan PJU 7/6, Mutiara Damansara 47800 Petaling Jaya, Selangor

occasion.

A total daily dose of more than 8 inhalations is normally not needed, however a total daily dose of up to 12 inhalations can be used temporarily. If the patient experiences a three-day period of deteriorating symptoms after taking additional as needed inhalation, the patient should be reassessed for alternative explanations of persisting symptoms.

Symbicort Turbuhaler 80/4.5 mcg/inhalation should NOT be used as Symbicort Anti-inflammatory Reliever Therapy.

<u>Children under 12 years</u>
Symbicort anti-inflammatory reliever therapy is not recommended for children.

B. Symbicort anti-inflammatory reliever plus maintenance therapy
Patients take a daily maintenance dose of Symbicort and in addition take Symbicort as needed in response to symptoms. Patients should be advised to always have Symbicort available for rescue use.

Symbicort anti-inflammatory reliever plus maintenance therapy should especially be considered for patients with:

- *inadequate asthma control and in frequent need of reliever medication*
- *asthma exacerbations in the past requiring medical intervention*

Close monitoring for dose-related adverse effects is needed in patients who frequently take high numbers of Symbicort as-needed inhalations.

Preventative use of Symbicort Turbuhaler 160/4.5 µg/inhalation for AIB/EIB should be discussed between physician and patient; the recommended dose frequency should take into consideration both allergen exposure and exercise patterns.

		General information *If patients take Symbicort Turbuhaler as anti-inflammatory reliever (either alone or in combination with maintenance therapy) physicians should discuss allergen exposure and exercise patterns with the patients and take these into consideration when recommending the dose frequency for asthma treatment.*	
2.	2.1 **Xofluza Film-Coated Tablet 20mg** [Baloxavir marboxil 20mg] 2.2 **Xofluza Film-Coated Tablet 40mg** [Baloxavir marboxil 40mg]	➢ *Indication:* *Xofluza is indicated for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and who are <u>at high risk of developing influenza-related complications.</u>*	**ROCHE (MALAYSIA) SDN. BHD.** Level 21, The Pinnacle Persiaran Lagoon, Bandar Sunway 47500 Subang Jaya, Selangor
3.	3.1 **Tecentriq 60mg/ml concentrate for solution for infusion** [Atezolizumab 60mg/ml]	➢ *Indication:* *<u>Non-small cell lung cancer</u>* *Tecentriq, in combination with nab-paclitaxel and carboplatin, is indicated for first-line treatment of patients with metastatic non-squamous NSCLC who do not have EGFR or ALK genomic tumour aberrations.* ➢ *Posology:* *Tecentriq in combination nab-paclitaxel and carboplatin* *During the induction phase, the recommended dose of Tecentriq is 1200 mg administered by intravenous (IV) infusion, followed by nab-paclitaxel and carboplatin every 3 weeks for four or six cycles. For each 21-day cycle, Tecentriq, nab-paclitaxel and carboplatin is administered on day 1. In addition, nab-paclitaxel is administered on days 8 and 15.* *The induction phase is followed by a maintenance phase without chemotherapy in which 1200 mg Tecentriq is administered by IV infusion every 3 weeks.*	**ROCHE (MALAYSIA) SDN. BHD.** Level 21, The Pinnacle Persiaran Lagoon, Bandar Sunway 47500 Subang Jaya, Selangor

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<td>4.</td>
<td>4.1 Nimenrix Powder And Solvent For Solution For Injection
[Neisseria meningitidis serogroups polysaccharide*
A 5 µg
C 5 µg
W-135 5 µg
Y 5 µg
*conjugated to tetanus toxoid carrier protein 44 µg]</td>
<td>➢ Indication:
Active immunisation of individuals from 6 weeks of age against invasive meningococcal diseases caused by Neisseria meningitidis group A, C, W-135, and Y.

➢ Posology:

<table>
<tr><th>Age Group</th><th>Primary Immunisation</th><th>Booster</th></tr>
<tr><td>Infants from 6 weeks to less than 6 months of age</td><td>Two doses, each of 0.5 ml, with the first dose given from 6 weeks of age, with an interval of 2 months between doses</td><td>At 12 months of age</td></tr>
<tr><td>Unvaccinated infants from 6 months to less than 12 months of age*</td><td>One dose of 0.5 ml given from 6 months of age</td><td>At 12 months of age with a minimum interval of at least 2 months after the primary dose</td></tr>
<tr><td>Children from 12 months of age, adolescents and adults*</td><td>One dose of 0.5 ml</td><td>Not routinely administered</td></tr>
</table>

*In some situations, consideration may be given to administering an additional primary dose or a booster dose of Nimenrix.

Nimenrix may be given as a booster dose to individuals who have previously received primary vaccination with Nimenrix or other conjugated or plain polysaccharide meningococcal vaccines.

Nimenrix should be used in accordance with available official recommendations.</td>
<td>PFIZER (MALAYSIA) SDN. BHD.
Level 10 & 11, Wisma Averis, Tower 2
Avenue 5, Bangsar South
No.8, Jalan Kerinchi,
59200 Kuala Lumpur</td>
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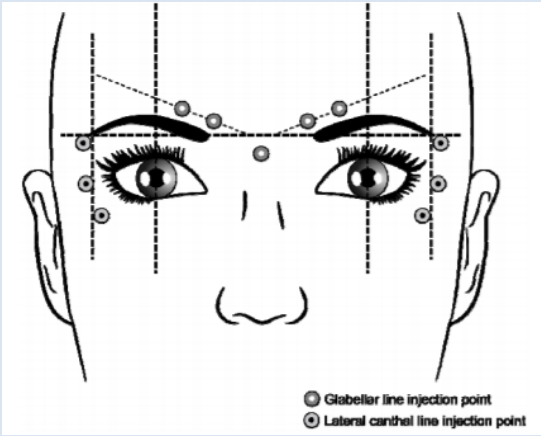
<td>5.</td>
<td>5.1 Accentrix 10mg/ml solution for Injection
[Ranibizumab 10 mg/ml]</td>
<td>➢ Indication:
Accentrix is indicated for:
the treatment of proliferative diabetic retinopathy (PDR)</td>
<td>NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.
Level 22, Tower B, Plaza 33</td>
</tr>
</table>

		➢ *Posology* *The recommended dose for Accentrix is 0.5 mg given as a single intravitreal injection. This corresponds to an injection volume of 0.05 mL. The interval between two doses injected into the same eye should be at least four weeks.* *Treatment is initiated with one injection per month until maximum visual acuity is achieved and/or there are no signs of disease activity i.e. no change in visual acuity and in other signs and symptoms of the disease under continued treatment. In patients with wet AMD, DME, PDR, and RVO, initially, three or more consecutive, monthly injections may be needed.* *If patients are being treated according to a treat-and-extend regimen, once maximum visual acuity is achieved and/or there are no signs of disease activity, the treatment intervals can be extended stepwise until signs of disease activity or visual impairment recur. The treatment interval should be extended by no more than two weeks at a time for wet AMD and may be extended by up to one month at a time for DME. For PDR and RVO, treatment intervals may also be gradually extended, however there are insufficient data to conclude on the length of these intervals. If disease activity recurs, the treatment interval should be shortened accordingly.*	No. 1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor
6.	6.1 **Dysport Powder For Injection** [Clostridium Botulinum Toxin Type A-haemagglutinin complex]	➢ *Indication:* *Dysport is indicated for the temporary improvement in the appearance of moderate to severe lateral canthal lines (crow's feet lines) seen at maximum smile in adult patients under 65 years, when the severity of these lines has an important psychological impact on the patient.* ➢ *Posology:* *Dysport should only be administered by appropriately trained physicians.* *The units of Dysport are specific to the preparation and are not interchangeable with other preparations of botulinum toxin.* *The treatment interval depends on the individual patient's response after*	**EP PLUS GROUP SDN BHD** Block C-3-1, Plaza Mont Kiara No 2, Jalan Kiara, Mont Kiara 50480 Kuala Lumpur

assessment.
Treatment interval with Dysport should not be more frequent than every three months.

Remove any make-up and disinfect the skin with a local antiseptic.
Intramuscular injections should be performed using a sterile 29 - 30 gauge needle.
The recommended injection points for glabellar lines and lateral canthal lines is described below:



Moderate to Severe Lateral canthal lines:
The recommended dose per side is 30 units (60 units for both sides, 0.30 ml of reconstituted solution) of Dysport, to be divided into 3 injection sites; 10 units (0.05 ml of reconstituted solution) are to be administered intramuscularly into each injection point.
Injection should be lateral (20 - 30° angle) to the skin and very superficial.
All injection points should be at the external part of the orbicularis oculi muscle and sufficiently far from the orbital rim (approximately 1 - 2 cm) as shown above.
The anatomical landmarks can be more readily identified if observed and palpated at maximal smile. Care must be taken to avoid injecting the zygomaticus major/minor muscles to avoid lateral mouth drop and asymmetrical smile.

The efficacy and safety, of repeat injections of Dysport, has been evaluated in glabellar lines up to 24 months and up to 8 repeat treatment cycles and for lateral canthal lines up to 12 months and up to 5 repeat treatment cycles.

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<td><u>Method of administration</u>
For moderate to severe glabellar lines or lateral canthal lines, Dysport is reconstituted with sodium chloride injection BP (0.9 % w/v) to yield a solution containing 200 units per ml of Dysport. Dysport is administered by intramuscular injection as described above.</td>
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<td>7.</td>
<td>7.1 Imfinzi
concentrate for solution for intravenous infusion 50mg/ml
[Durvalumab 50mg/ml]</td>
<td>➢ Indication:

Small Cell Lung Cancer (SCLC)
IMFINZI in combination with etoposide and either carboplatin or cisplatin is indicated for the first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC).

➢ Posology:

The recommended dose of IMFINZI depends on the indication as presented in Table 1. IMFINZI is administered as an intravenous infusion over 1 hour.

Table 1. Recommended dosage of IMFINZI
<table>
<tr><th>Indication</th><th>Recommended IMFINZI dosage</th><th>Duration of Therapy</th></tr>
<tr><td>ES-SCLC</td><td>1500 mg[a] in combination with chemotherapy[b,c] every 3 weeks (21 days) for 4 cycles, followed by 1500 mg every 4 weeks as monotherapy</td><td>Until disease progression or unacceptable toxicity</td></tr>
</table>
[a] Patients with a body weight of 30 kg or less must receive weight-based dosing, equivalent to IMFINZI 20 mg/kg in combination with chemotherapy every 3 weeks (21 days) for 4 cycles, followed by 20 mg/kg every 4 weeks as monotherapy until weight increases to greater than 30 kg.
[b] Administer IMFINZI prior to chemotherapy when given on the same day.
[c] When IMFINZI is administered in combination with chemotherapy, refer to the Prescribing Information for etoposide and carboplatin or cisplatin for dosing information.</td>
<td>ASTRAZENECA SDN. BHD.
Level 11 & 12, Nucleus Tower
No. 10, Jalan PJU 7/6, Mutiara Damansara,
47800 Petaling Jaya, Selangor</td>
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