Maklumat tambahan indikasi
Year 2019
Products Approved For Additional Indication (DCA 331 – 31 January 2019)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Onglyza Tablet 2.5mg** [Saxagliptin hydrochloride 2.79 mg, equivalent to Saxagliptin 2.5 mg] 1.2 **Onglyza Tablet 5mg** [Saxagliptin hydrochloride 5.58 mg, equivalent to Saxagliptin 5 mg]	➢ Indication: *Monotherapy and Combination Therapy* *ONGLYZA is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus [see Clinical Studies].* *Limitation of Use* *ONGLYZA is not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis, as it would not be effective in these settings.*	**ASTRAZENECA SDN. BHD.** Level 12, Surian Tower, 1 Jalan PJU 7/3 Mutiara Damansara 47810 Petaling Jaya, Selangor
2.	2.1 **Kombiglyze XR Tablet 2.5/1000mg** [Saxagliptin hydrochloride 2.79 mg, equivalent to Saxagliptin 2.5 mg/Metformin 1000 mg] 2.2 **Kombiglyze XR Tablet 5/1000mg** [Saxagliptin hydrochloride 5.58 mg, equivalent to Saxagliptin 5 mg/Metformin 1000 mg] 2.3 **Kombiglyze XR Tablet 5/500mg** [Saxagliptin hydrochloride 5.58 mg, equivalent to Saxagliptin 5 mg/Metformin 500 mg]	➢ Indication: *KOMBIGLYZE XR is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate [see Clinical Studies].* *Limitation of Use* *KOMBIGLYZE XR is not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.*	**ASTRAZENECA SDN. BHD.** Level 12, Surian Tower, 1 Jalan PJU 7/3 Mutiara Damansara 47810 Petaling Jaya, Selangor
3.	3.1 **BOTOX (BOTULINUM TOXIN TYPE A) IM INJECTION** [Pertuzumab 30mg/ml]	➢ Indication : *BOTOX is indicated in the management of focal spasticity:* ○ *Including ankle and foot disability due to lower limb spasticity associated with stroke in adults*	**ALLERGAN MALAYSIA SDN. BHD.** Level 5-02, Block A, PJ8 No.23, Jalan Barat, Seksyen 8 46050 Petaling Jaya, Selangor

- Posology:

The exact dosage and number of injection sites should be tailored to the individual based on the size, number and location of muscles involved, the severity of spasticity, presence of local muscle weakness, and the patient response to previous treatment.

The recommended dilution is 200 Units/4mL or 100 Units/2mL with preservative-free 0.9% Sodium Chloride injection (see Dilution Tables). A 25, 27 or 30 gauge needle may be used for superficial muscles, and a 22-gauge needle may be used for deeper musculature. Localisation of the involved muscles with electromyographic guidance or nerve stimulation techniques may be useful.

Multiple injection sites allow BOTOX to have more uniform contact with the innervation areas of the muscle and are especially useful in larger muscles.

If it is deemed appropriate by the treating physician, repeat BOTOX treatment may be administered when the effect of a previous injection has diminished, but generally no sooner than 12 weeks after the previous injection. The degree of muscle spasticity at the time of reinjection may necessitate alterations in the dose of BOTOX and muscles to be injected.

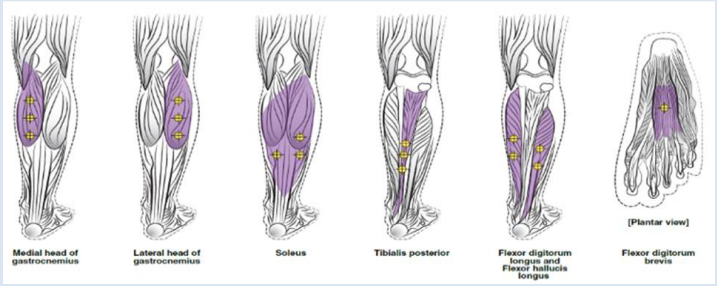
Lower Limb Spasticity

The recommended dose for treating lower limb spasticity involving the ankle and foot is 300 Units to 400 Units divided among up to 6 muscles (gastrocnemius, soleus, tibialis posterior, flexor hallucis longus, flexor digitorum longus and flexor digitorum brevis) (see table and figure below).

BOTOX Dosing by Muscle for Lower Limb Spasticity Muscle

Muscle	*Recommended Dose Total Dosage (Number of Sites)*
Gastrocnemius medial head	*75 Units divided in 3 sites*
Gastrocnemius lateral head	*75 Units divided in 3 sites*
Soleus	*75 Units divided in 3 sites*
Tibialis Posterior	*75 Units divided in 3 sites*
Flexor hallucis longus	*50 Units divided in 2 sites*
Flexor digitorum longus	*50 Units divided in 2 sites*
Flexor digitorum brevis	*25 Units in 1 site*

Injection Sites for Lower Limb Spasticity



4.	4.1 **DARZALEX™ 20MG/ML CONCENTRATE FOR SOLUTION FOR INFUSION** [DARATUMUMAB 20 MG/ML]	➢ Indication: *DARZALEX is indicated* • *in combination with bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.* • *in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy.* • *as monotherapy, for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.* ➢ *Posology:* *DARZALEX should be administered by a healthcare professional, with immediate access to emergency equipment and appropriate medical support to manage infusion-related reactions (IRRs) if they occur.* *Pre- and post-infusion medications should be administered (see Recommended concomitant medications below).* *<u>Dosage – Adults (≥18 years)</u>* *Recommended dose* *Newly Diagnosed Multiple Myeloma* *<u>Dosing schedule in combination with bortezomib, melphalan and prednisone (6-week cycle dosing regimens) for patients ineligible for autologous stem cell transplant</u>* *The recommended dose is DARZALEX 16 mg/kg body weight administered as an intravenous infusion according to the following dosing schedule in Table 1.* *Table 1: DARZALEX dosing schedule in combination with bortezomib, melphalan and prednisone ([VMP]; 6-week cycle dosing regimen)*	**JOHNSON & JOHNSON SDN. BHD.** Lot 3 & 5, Jalan Tandang 46050 Petaling Jaya, Selangor

Weeks	*Schedule*
Weeks 1 to 6	*Weekly (total of 6 doses)*
Weeks 7 to 54[a]	*Every three weeks (total of 16 doses)*
Week 55 onwards until disease progression[b]	*Every four weeks*

[a] *First dose of the every-3-week dosing schedule is given at Week 7*
[b] *First dose of the every-4-week dosing schedule is given at Week 55*

Bortezomib is given twice weekly at Weeks 1, 2, 4 and 5 for the first 6-week cycle, followed by once weekly at Weeks 1, 2, 4 and 5 for eight more 6-week cycles. For information on the VMP dose and dosing schedule when administered with DARZALEX, see Clinical Studies.

Relapsed/Refractory Multiple Myeloma
Monotherapy and combination therapy with lenalidomide and low-dose dexamethasone (4-week cycle regimen)
The recommended dose is DARZALEX 16 mg/kg body weight administered as an intravenous infusion according to the following dosing schedule in Table 2:

Table 2: DARZALEX dosing schedule for monotherapy and in combination with lenalidomide (4-week cycle dosing regimen)

Weeks	*Schedule*
Weeks 1 to 8	*weekly (total of 8 doses)*
Weeks 9 to 24[a]	*every two weeks (total of 8 doses)*
Week 25 onwards until disease progression[b]	*every four weeks*

[a] *First dose of the every-2 week-dosing schedule is given at week 9*
[b] *First dose of the every-4 week-dosing schedule is given at week 25*

Combination therapy with bortezomib and dexamethasone (3-

week cycle regimen)
The recommended dose is DARZALEX 16mg/kg body weight administered as an intravenous infusion according to the following dosing schedule in Table 3:

Table 3: DARZALEX dosing schedule with bortezomib (3-week cycle dosing regimen)

Weeks	*Schedule*
Weeks 1 to 9	*weekly (total of 9 doses)*
Weeks 10 to 24[a]	*every three weeks (total of 5 doses)*
Week 25 onwards until disease progression [b]	*every four weeks*

[a] *First dose of the every-3 week dosing schedule is given at week 10*
[b] *First dose of the every-4 week dosing schedule is given at week 25*

For dosing instructions for medicinal products administered with DARZALEX see Clinical Studies and manufacturer's prescribing information.

5.	5.1 **XGEVA 120 MG SOLUTION FOR INJECTION** [DENOSUMAB 70 MG/ML]	➢ Indication: *Prevention of skeletal related events (pathological fracture, radiation to bone, spinal cord compression or surgery to bone) in adults with multiple myeloma and in patients with bone metastases from solid tumours.* ➢ Posology: *Prevention of skeletal related events in adults with multiple myeloma and bone metastases from solid tumours* *The recommended dose is 120 mg administered as a single subcutaneous injection once every 4 weeks into the thigh, abdomen or upper arm.*	**ZUELLIG PHARMA SDN. BHD.** No. 15, Persiaran Pasak Bumi, Seksyen U8 Perindustrian Bukit Jelutong 40150 Shah Alam, Selangor