Maklumat tambahan indikasi
Year 2018
Products Approved For Additional Indication (DCA 324 – 31 Mei 2018)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Xalkori 200mg Hard Capsules** [Crizotinib 200 mg] 1.2 **Xalkori 250mg Hard Capsules** [Crizotinib 250 mg]	➢ Indication: *Crizotinib is indicated for the treatment of patients with metastatic NSCLC whose tumors are ROS1-positive* ➢ Posology: *Patient Selection* *Select patients for the treatment of metastatic NSCLC with Crizotinib based on the presence of ALK or ROS1positivity in tumor specimens.* *ALK Testing and ROS1 Testing* *An accurate and validated assay for either ALK or ROS1 is necessary for the selection of patients for treatment with Crizotinib.* *Either ALK-positive of ROS1-positive NSCLC status should be established prior to initiation of Crizotinib therapy. Assessment should be performed by laboratories with demonstrated proficiency in the specific technology being utilized.*	**Pfizer (Malaysia) Sdn. Bhd.** Level 9-2, 10 & 11, Wisma Averis, Tower 2, Avenue 5, Bangsar South, No.8, Jalan Kerinchi, 59200 Kuala Lumpur.
2.	2.1 **HALAVEN® 0.5 mg/ml solution for injection** [Eribulin mesylate 0.5 mg, equivalent to 0.44 mg eribulin]	➢ Indication: *(i)* <u>*Breast Cancer*</u> *HALAVEN® is indicated as monotherapy for the treatment of locally advanced or metastatic HER2 negative breast cancer after failure of one chemotherapeutic regimen for advanced disease. Patients should have received an anthracycline and a taxane unless these treatments were not suitable.*	**Eisai (Malaysia) Sdn Bhd** Lot 6.1, 6th.Floor Menara Lien Hoe, No. 8, PSN Tropicana, 47410 Petaling Jaya, Selangor.

(ii) *<u>Soft Tissue Sarcoma (Liposarcoma)</u>*
HALAVEN® is indicated for the treatment of inoperable liposarcoma after progression following prior chemotherapy for advanced or metastatic disease in adults. Patients should have received two previous chemotherapy treatments, one of which should have included an anthracycline unless this treatment is unsuitable.

- Posology:

HALAVEN should only be administered under the supervision of a qualified physician experienced in the appropriate use of cytotoxic medicinal products.

<u>Posology</u>

The recommended dose of eribulin mesilate as the ready to use solution is 1.4 mg/m^2 which should be administered intravenously over 2 to 5 minutes on Days 1 and 8 of every 21-day cycle.

Please note:

In the EU the recommended dose refers to the base of the active substance (eribulin). Calculation of the individual dose to be administered to a patient must be based on the strength of the ready to use solution that contains 0.44 mg/ml eribulin and the dose recommendation of 1.23 mg/m^2. The dose reduction recommendations shown below are also shown as the dose of eribulin to be administered based on the strength of the ready to use solution.

In the pivotal trials, the corresponding publication and in some other regions e.g. the US and Switzerland, the recommended dose is based on the salt form (eribulin mesilate).

Patients may experience nausea or vomiting. Antiemetic prophylaxis including corticosteroids should be considered.

Patients with renal impairment

Some patients with moderately or severely impaired renal function (creatinine clearance <50 ml/min) may have increased eribulin exposure and may need a reduction of the dose. For all patients with renal impairment, caution and close safety monitoring is advised. (See Pharmacokinetic properties).

Elderly patients

No specific dose adjustments are recommended based on the age of the patients (see PRECAUTIONS 6).

Paediatric population

There is no relevant use of HALAVEN in children and adolescents for the indication of breast cancer. The safety and efficacy of HALAVEN in children from birth to 18 years of age have not yet been established in soft tissue sarcoma. No data are available.

Method of administration

HALAVEN is for intravenous use. The dose may be diluted in up to 100 ml of sodium chloride 9 mg/ml (0.9%) solution for injection. It should not be diluted in glucose 5% infusion solution. For instructions on the dilution of the medicinal product before administration, (see Precaution concerning use). Good peripheral venous access, or a patent central line, should be ensured prior to administration. There is no evidence that eribulin mesilate is a vesicant or an irritant. In the event of extravasation, treatment should be symptomatic. For information relevant to the handling of cytotoxic drugs (see Precaution concerning use).

3.	3.1 **ACTEMRA 162MG/ 0.9ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE** [TOCILIZUMAB 162MG/ 0.9ML]	➢ Indication: <u>*Giant Cell Arteritis (GCA)*</u> *Tocilizumab is indicated for the treatment of giant cell arteritis (GCA) in adult patients.* ➢ Posology: <u>*Dosage and administration*</u> *(i) General* *Substitution by any other biological medicinal product requires the consent of the prescribing physician.* *For adult patients with RA, tocilizumab may be administered as SC injection.* *For adult patients with GCA, tocilizumab is administered as a SC injection.* *Tocilizumab SC formulation is not intended for intravenous administration.* *Tocilizumab SC formulation is administered with a single-use PFS + NSD. The first injection should be performed under the supervision of a qualified health care professional. The recommended injection sites (abdomen, thigh and upper arm) should be rotated and injections should never be given into moles, scars, or areas where the skin is tender, bruised, red, hard, or not intact.* *Patients transitioning from tocilizumab IV therapy to SC administration should administer the first SC dose at the time of the next scheduled IV dose under the supervision of a qualified health care professional.* *Assess suitability of patients for SC home use and instruct patients to inform a healthcare professional if they*	**Roche (Malaysia) Sdn. Bhd.** Level 21, The Pinnacle, Persiaran Lagoon, Bandar Sunway, 47500 Subang Jaya, Selangor.

experience symptoms of allergic reaction before administering the next dose. Patients should seek immediate medical attention if developing symptoms of serious allergic reactions.

(ii) Rheumatoid Arthritis
The recommended dose of tocilizumab for adult patients is 162 mg given once every week as a subcutaneous injection.

Tocilizumab can be used alone or in combination with MTX and/or other DMARDs.

(iii) Giant Cell Arteritis (GCA)
The recommended dose of tocilizumab for adult patients with GCA is 162 mg given once every week as a subcutaneous injection, in combination with a tapering with course of glucocorticoids. Tocilizumab can be used alone following discontinuation of glucocorticoids.

Based upon the chronic nature of GCA, treatment beyond 52 weeks should be guided by disease activity, physician discretion, and patient choice.

<u>Dose Modification Recommendations for RA and GCA</u>
(i) Liver enzyme abnormalities

Lab value	*Action*
> 1 to 3x ULN	*Dose modify concomitant DMARDs (RA) or immunomodulatory agents (GCA) if appropriate* *For patients on subcutaneous tocilizumab with persistent increases in this range, reduce tocilizumab injection frequency to every other week or interrupt tocilizumab until ALT/ AST have normalized.*

	Restart with weekly injection or injection every other week, as clinically appropriate.
> 3 to 5x ULN	*Interrupt tocilizumab dosing until < 3x ULN and follow recommendations above for > 1 to 3x ULN.* *For persistent increases > 3x ULN (confirmed by repeat testing), discontinue tocilizumab.*
> 5x ULN	*Discontinue tocilizumab.*

- *Low absolute neutrophil count (ANC)*
- *In patients not previously treated with Tocilizumab, initiation is not recommended in patients with an absolute neutrophil count (ANC) below 2 x 10^9/ L*

Lab value (cells x 10^9/ L)	*Action*
ANC > 1	*Maintain dose*
ANC 0.5 to 1	*Interrupt tocilizumab dosing* *For patients on subcutaneous tocilizumab, when ANC > 1 x 10^9/ L resume tocilizumab injection every other week and increase frequency to every week, as clinically appropriate.*
ANC < 0.5	*Discontinue tocilizumab*

		(ii) Low platelet count *Lab value (cells x 10^3/ µl)* — *Action* *50 to 100* — *Interrupt tocilizumab dosing. For patients on subcutaneous tocilizumab, when platelet count is > 100 x 10^3/ µl resume tocilizumab injection every other week and increase frequency to every week, as clinically appropriate.* *< 50* — *Discontinue tocilizumab*	
4.	4.1 **KEYTRUDA 100MG SOLUTION FOR INFUSION** [PEMBROLIZUMAB 100MG]	➢ Indication: *(i) <u>Urothelial Carcinoma</u>* *KEYTRUDA is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy. This indication is approved based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.* *(i) <u>Classical Hodgkin Lymphoma</u>* *KEYTRUDA as monotherapy is indicated for the treatment of patients with relapsed or refractory classical Hodgkin lymphoma (cHL) who have failed autologous stem cell transplant (ASCT) and brentuximabvedotin (BV), or who are transplant-ineligible and have failed BV.* *This indication is approved based on the overall response rate (ORR) and durability of response.*	**Merck Sharp & Dohme (Malaysia) Sdn. Bhd.** Lot B-22-1 & B22-2, Level 22 The Ascent, Paradigm No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

		Continued approval for this indication may be contingent upon the verification of the results from the confirmatory clinical studies. ➢ Posology: *KEYTRUDA is administered as an intravenous infusion over 30 minutes every 3 weeks.* *The recommended dose of KEYTRUDA is:* • *200 mg for head and neck cancer, urothelial carcinoma, classical Hodgkin Lymphoma or previously untreated NSCLC* • *2 mg/kg for melanoma or previously treated NSCLC.* *Patients should be treated with KEYTRUDA until disease progression or unacceptable toxicity. Atypical responses (i.e., an initial transient increase in tumor size or small new lesions within the first few months followed by tumor shrinkage) have been observed. Clinically stable patients with initial evidence of disease progression should remain on treatment until disease progression is confirmed.*	