Maklumat tambahan indikasi
Year 2017
Products Approved For Additional Indication (DCA 310 – 29 Mac 2017)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Fycompa 2mg Film-coated Tablets** [Perampanel 2.1mg (equivalent to anhydrous basis 2mg)] 1.2 **Fycompa 4mg Film-coated Tablets** [Perampanel 4.2mg (equivalent to anhydrous basis 4mg)] 1.3 **Fycompa 6mg Film-coated Tablets** [Perampanel 6.2mg (equivalent to anhydrous basis 6mg)] 1.4 **Fycompa 8mg Film-coated Tablets** [Perampanel 8.3mg (equivalent to anhydrous basis 8mg)] 1.5 **Fycompa 10mg Film-coated Tablets** [Perampanel 10.4mg (equivalent to anhydrous basis 10mg)] 1.6 **Fycompa 12mg Film-coated Tablets** [Perampanel 12.5mg (equivalent to anhydrous basis 12mg)]	➢ Indication: *Fycompa is indicated for the adjunctive treatment of primary generalised tonic-clonic seizures in adult and adolescent patients from 12 years of age with idiopathic generalised epilepsy.* ➢ Posology: *<u>Primary Generalised Tonic-Clonic Seizures</u>* *Perampanel at a dose up to 8 mg/day has been shown to be effective in primary generalised tonic-clonic seizures.* *Treatment with Fycompa should be initiated at a dose of 2 mg/day. The dose may be increased based on clinical response and tolerability by increments of 2 mg (either weekly or every 2 weeks, as per half-life considerations described below) to a maintenance dose of up to 8 mg/day. Depending upon individual clinical response and tolerability at a dose of 8 mg/day, the dose may be increased up to 12 mg/day, which may be effective in some patients (see section 4.4). Patients who are taking concomitant medicinal products that do not shorten the half-life of perampanel (see section 4.5) should be titrated no more frequently than at 2-week intervals. Patients who are taking concomitant medicinal products that shorten the half-life of perampanel (see section 4.5) should be titrated no more frequently than at 1-week intervals.*	**EISAI (MALAYSIA) SDN. BHD.** Lot 6.1, 6th Floor Menara Lien Hoe, No. 8, Persiaran Tropicana, 47410 Petaling Jaya, Malaysia.

2.	2.1 **TS-ONE Capsule 20** [Tegafur 20 mg Gimeracil 5.8 mg Oteracil potassium 19.6 mg equivalent to 15.8 mg oteracil free acid)] 2.2 **TS-ONE Capsule 25** [Tegafur 25 mg Gimeracil 7.25 mg Oteracil potassium 24.5 mg equivalent to 19.7 mg oteracil free acid]	➢ Indication: • *For the treatment of locally advanced or metastatic pancreatic cancer when given as monotherapy.* • *For the treatment of locally advanced or metastatic non-small cell lung cancer when given in combination with carboplatin.* • *For the treatment of metastatic colorectal cancer when given in combination with oxaliplatin as first-line treatment or in combination with irinotecan as second-line treatment.* ➢ Posology: ***Monotherapy*** *For the treatment of locally advanced or metastatic pancreatic cancer or for post operative adjuvant chemotherapy for locally advanced (stage II (excluding T1), IIA or IIIB) gastric cancer.* *The standard initial recommended dose for TS-ONE® is based on patient's BSA as per Table 1 and should be taken after meals twice daily, morning and evening, for 28 consecutive days followed by a 14-day rest (1 treatment cycle). This treatment cycle is repeated every 6 weeks.* *Based on the patient's condition, the dose may be reduced according to Table 2.* ***Combination Therapy*** *For the treatment of locally advanced or metastatic non-small cell lung cancer when given in combination with carboplatin* *The standard initial recommended dose of TS-ONE® is based on the patient's BSA as per Table 1. TS-ONE® should be given after meals twice daily, morning and evening, for 14 consecutive days in combination with carboplatin (AUC, 5 by Carvert) on Day 1. This treatment cycle is repeated every 3 weeks.* *For the treatment of metastatic colorectal cancer when given in combination with oxaliplatin as first-line treatment or in combination with irinotecan as second-line treatment* *The standard initial recommended dose of TS-ONE® is based on the patient's BSA as per Table 1.*	**DKSH MALAYSIA SDN. BHD.** B-11-01, The Ascent, Paradigm, No. 1, Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.

When used in combination with oxaliplatin, TS-ONE® should be given after meals twice daily, morning and evening, for 14 consecutive days, in combination with oxaliplatin 130mg/m^2 on Day 1 as a 2-hour intravenous infusion. This treatment cycle is repeated every 3 weeks.

When used in combination with irinotecan, TS-ONE® should be given after meals twice daily, morning and evening, for 14 consecutive days, in combination with irinotecan 125mg/m^2 on Day 1 and 15. This treatment is repeated every 4 weeks.

Adjustments during treatment

[Evaluator's note: Some parts of the information are updated with relevance to the additional indication (e.g., inclusion of new agents such as oxalipaltin, irinotecan and carboplatin)]

<u>General</u>

Toxicity due to TS-ONE® in combination with cisplatin, oxaliplatin, irinotecan or carboplatin administration should be managed with symptomatic treatment and/or treatment interruption or dose reduction. Patients taking TS-ONE® in combination with cisplatin, oxaliplatin, irinotecan or carboplatin should be informed of the risks and instructed to contact their physician immediately if moderate or severe toxicity occurs.

Doses omitted for toxicity are not replaced; and, if a patient vomits after taking a dose, this dose should not be replaced.

Once the TS-ONE® dose has been reduced, it should not be increased again.

<u>TS-ONE® dose modification criteria</u>

Dose modification for toxicity should be made according to Tables 2, 3, 4, 5 and 6. The initial dose can be decreased according to the patient's tolerability to the medication. The reduction of dose should be in 10mg intervals, with a lowest dose of 40mg. A maximum of two consecutive dose reductions can be applied in case of toxicity.

Table 2: Dose reductions (expressed as tegafur content)

Standard dose		*Dose reduction 1*		*Dose reduction 2*		*Dose reduction 3*
40 mg *50 mg* *60 mg*	→	*Drug rest* *40 mg* *50 mg*	→	*-* *Drug rest* *40 mg*	→	*-* *-* *Drug rest*

TS-ONE® dose modifications for toxicity when used in combination with cisplatin or other anti-cancer drugs can be made in two ways:

- *During the treatment cycle*
  During a treatment cycle, dose adjustment should be performed for each individual medicinal product that is considered to be causally related to toxicity, if such a distinction can be made. If both medicinal products are considered to be causing the toxicity or it is not possible to distinguish them, then dose reduction should be performed for both according to the recommended dose reduction schedule. Dose modification for toxicity of TS-ONE® and cisplatin should be made according to Table 2 and Table 3, respectively.

Table 3: Dose reductions for cisplatin

Standard dose		*Dose reduction 1*		*Dose reduction 2*
60mg/m²	→	*50mg/m²*	→	*40mg/m²*

For dose modification of irinotecan, oxaliplatin and carboplatin, refer to their SmPC respectively.

- *At the initiation of subsequent cycles of treatment*
  If a treatment delay is indicated for either TS-ONE® or the combination therapy anti-cancer drugs, then administration of both medicinal products should be delayed until the requirements for restarting both are met unless one of the medicinal products has been permanently discontinued.

3.	3.1 **Keytruda 100mg Solution for Infusion** [Pembrolizumab 100mg/vial]	➢ Indication: *KEYTRUDA is indicated for the first-line treatment of patients with metastatic non-small cell lung carcinoma (NSCLC) whose tumors express PD-L1 with a ≥50% tumor proportion score (TPS) as determined by a validated test, with no EGFR or ALK genomic tumor aberrations.* ➢ Posology: ***Patient Selection for Non-Small Cell Lung Carcinoma*** *Patients should be selected for treatment of advanced NSCLC with KEYTRUDA based on the presence of positive PD-L1 expression.* ***Recommended Dosing*** *KEYTRUDA is administered as an intravenous infusion over 30 minutes every 3 weeks.* *The recommended dose of KEYTRUDA is:* • *200mg for previously untreated NSCLC* • *2mg/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.*	**MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.** Lot No. B-22-1 & B-22-2, Level 22, The Ascent, Paradigm, No.1 Jalan SS7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor.