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Year 2014
Products Approved For Additional Indication (DCA 281 – 24 November 2014)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	**PREVENAR 13 SUSPENSION FOR INJECTION** [1 dose (0.5ml) contains: Pneumococcal polysaccharide serotype 1^1 2.2µg Pneumococcal polysaccharide serotype 3^1 2.2µg Pneumococcal polysaccharide serotype $4^1$2.2µg Pneumococcal polysaccharide serotype $5^1$2.2µg Pneumococcal polysaccharide serotype $6A^1$ 2.2µg Pneumococcal polysaccharide serotype $6B^1$4.4µg Pneumococcal polysaccharide serotype $7F^1$ 2.2µg Pneumococcal polysaccharide serotype $9V^1$ 2.2µg Pneumococcal polysaccharide serotype $14^1$2.2µg Pneumococcal polysaccharide serotype $18C^1$ 2.2µg Pneumococcal polysaccharide serotype $19A^1$ 2.2µg Pneumococcal polysaccharide serotype $19F^1$ 2.2µg Pneumococcal polysaccharide serotype $23F^1$ 2.2µg ^{1}Conjugated to CRM_{197} carrier protein and adsorbed on aluminium phosphate (0.125mg aluminium)]	➢ Indication: *Active immunisation for the prevention of pneumococcal disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F in adults aged 18-49 years old.* ➢ Posology: *<u>Adults aged 18 years and older</u>* *Prevenar 13 is to be administered as a single dose to adults 18 years and older including those previously vaccinated with a pneumococcal polysaccharide vaccine.* *The need for revaccination with a subsequent dose of Prevenar 13 has not been established.* *Regardless of prior pneumococcal vaccination status, if the use of 23-valent pneumococcal polysaccharide vaccine is considered appropriate, Prevenar 13 should be given first.*	**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.	**CERVARIX SUSPENSION FOR INJECTION** [Each dose of 0.5ml contains: - Human Papillomavirustype 16 L1 protein 20 mcg - Human Papillomavirustype 18 L1 protein 20mcg]	➢ Indication: *Cervarix is indicated in females from 10 to 45 years of age for the prevention of premalignant genital (cervical, vulvar and vaginal) lesions and cervical cancer caused by human papillomavirus types 16 and 18. Immunogenicity studies have been conducted in females aged 10 to 14 years and 26 to 45 years to link efficacy in females aged 15 to 25 years to other populations.* ➢ Posology: *The vaccination schedule depends on the age of the subject.*	**GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.** Level 6, Quill 9 No. 112, Jalan Semangat NO.8, Persiaran Tropicana 46300 Petaling Jaya, Selangor

Age at the time of the first injection	*Immunization and schedule*	*Flexibility for immunization if required*
10 to and including 14 years	*Two doses each of 0.5ml at 0, 6 months*	*Second dose between 5 and 7 months after the 1st dose*
From 15 years and above	*Three doses each of 0.5ml at 0, 1, 6 months*	*Second dose between 1 and 2.5 months after 1st dose* *Third dose between 5 and 12 months after the 1st dose*

If at any age the second vaccine dose is administered before the 5th month after the first dose, the third dose should always be administered.
The need for a booster dose has not been established.
It is recommended that subjects who receive a first dose of Cervarixcomplete the vaccination course with Cervarix.

Pediatric population
Cervarix is not recommended for use in girls below 10 years of age due to lack of data on safety and immunogenicity in this age-group.

<u>Method of administration</u>
Cervarix is for intramuscular injection in the deltoid region.

3.	**GARDASIL SUSPENSION FOR INJECTION** [Each 0.5ml dose contains: Human Papillomavirus type: 6 L1 protein 20 mcg/0.5ml 11L1 protein 40 mcg/0.5ml 16 L1 protein40 mcg/0.5ml 18 L1 protein 20mcg/0.5ml]	➢ Posology: *Alternatively, in individuals 9 through 13 years of age, Gardasil can be administered according to a 2-dose (0, 6 months) schedule.* *The use of Gardasil should be in accordance with official recommendations.* *It is recommended that individuals who receive a first dose of Gardasil complete the vaccination course with Gardasil.* *The need for a booster dose has not been established.*	**MERCK SHARP &DOHME (MALAYSIA) SDN. BHD.** T2-9, Jaya 33, No.3 (Lot 33) Jalan Semangat, Seksyen 13 46100 Petaling Jaya, Selangor
4.	**NEXAVAR FILM-COATED TABLETS 200 MG** [Sorafenib Tosylate 274mg (equivalent to 200mg sorafenib)]	➢ Indication: *Nexavar is indicated for the treatment of patients with locally advanced or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine.* ➢ Posology: *Recommended dose* *No changes to the recommended dose.* *Dose Reduction for Differentiated Thyroid Carcinoma* *Management of suspected adverse drug reactions may require temporary interruption and/or dose reduction of sorafenib therapy.* *When dose reduction is necessary during the treatment of differentiated thyroid carcinoma, the sorafenib dose should be reduced to 600mg daily in divided doses (two tablets of 200mg and one tablet of 200mg twelve hours apart).* *If additional dose reduction is necessary, sorafenib may be reduced to one tablet of 200mg twice daily, followed by one tablet of 200mg once daily. After improvement of non-hematological adverse reactions, the dose of sorafenib may be increased.*	**BAYER CO. (M) SDN BHD** **T1-14, Jaya 33,** No. 3 Jalan Semangat Seksyen 13 46200 Petaling Jaya, Selangor

Recommended Dose Modifications for Dermatologic Toxicities for Patients with Differentiated Thyroid Carcinoma:

Dermatologic Toxicity Grade	*Occurrence*	*NEXAVAR Dose Modification*
Grade 1: Numbness, dysesthesia, paresthesia, tingling, painless swelling, erythema or discomfort of the hands or feet which does not disrupt the patient's normal activities	*Any occurrence*	*Continue treatment with NEXAVAR*
Grade 2: Painful erythema and swelling of the hands or feet and/or discomfort affecting the patient's normal activities	*1st occurrence*	*Decrease NEXAVAR dose to 600 mg daily. If no improvement within 7 days, see below*
	No improvement within 7 days at reduced dose or 2nd occurrence	*Interrupt NEXAVAR until resolved or improved to grade 1. If NEXAVAR is resumed, decrease dose (See "Dose Reduction for Differentiated Thyroid Carcinoma").*
	3rd occurrence	*Interrupt NEXAVAR until*

		resolved or improved to grade 1 If NEXAVAR is resumed, decrease dose.
	4th occurrence	*Discontinue NEXAVAR permanently*
Grade 3: Moist desquamation, ulceration, blistering, or severe pain of the hands or feet, resulting in inability to work or perform activities of daily living	*1st occurrence*	*Interrupt NEXAVAR until resolved or improved to grade 1 If NEXAVAR is resumed, decrease dose by one dose level (See "Dose Reduction for Differentiated Thyroid Carcinoma").*
	2nd occurrence	*Interrupt NEXAVAR until resolved or improved to grade 1 When NEXAVAR is resumed, decrease dose by 2 dose levels (See "Dose Reduction for Differentiated Thyroid Carcinoma")*
	3rd	*Discontinue*

			occurrence	*NEXAVAR permanently*

5.	**ZONEGRAN TABLETS 100MG** [Zonisamide 100mg]	➢ Indication: *Zonegran is indicated as monotherapy in the treatment of partial seizures, with or without secondary generalisation, in adults with newly diagnosed epilepsy.* ➢ Posology: *Posology - Adults* *<u>Dosage escalation and maintenance</u>* *Zonegran may be taken as monotherapy or added to existing therapy in adults. The dose should be titrated on the basis of clinical effect. Recommended escalation and maintenance doses are given in Table 1. Some patients, especially those not taking CYP3A4-inducing agents, may respond to lower doses.* *<u>Withdrawal</u>* *When Zonegran treatment is to be discontinued, it should be withdrawn gradually (see section 4.4). In clinical studies of adult patients, dose reductions of 100 mg at weekly intervals have been used with concurrent adjustment of other antiepileptic medicine doses (where necessary).*	**EISAI (M) SDN. BHD.** Lot 6.1, 6th Floor Menara Lien Hoe No.8, Persiaran Tropicana 47410 Petaling Jaya, Selangor

Table 1: Adults – recommended dosage escalation and maintenance regimen

Treatment Regimen	*Titration Phase*			*Usual Maintenance Dose*
Monotherapy - Newly diagnosed adult patients	*Week 1 + 2* *100 mg/day (once a day)*	*Week 3 + 4* *200 mg /day (once a day)*	*Week 5 + 6* *300 mg / day (once a day)*	*300 mg per day (once a day).* *If a higher dose is required: increase at two-weekly intervals in increments of 100 mg up to a maximum of 500 mg.*

General dosing recommendations for Zonegran in special patient populations

		<u>Elderly</u> *Caution should be exercised at initiation of treatment in elderly patients as there is limited information on the use of Zonegran in these patients. Prescribers should also take account of the safety profile of Zonegran.* *<u>Patients with renal impairment</u>* *Caution must be exercised in treating patients with renal impairment, as there is limited information on use in such patients and a slower titration of Zonegran might be required. Since zonisamide and its metabolites are excreted renally, it should be discontinued in patients who develop acute renal failure or where a clinically significant sustained increase in serum creatinine is observed.* *In subjects with renal impairment, renal clearance of single doses of zonisamide was positively correlated with creatinine clearance. The plasma AUC of zonisamide was increased by 35% in subjects with creatinine clearance < 20 ml/min.* *<u>Patients with hepatic impairment</u>* *Use in patients with hepatic impairment has not been studied. Therefore use in patients with severe hepatic impairment is not recommended. Caution must be exercised in treating patients with mild to moderate hepatic impairment, and a slower titration of Zonegran may be required.* *<u>Method of administration</u>* *Zonegran tablets are for oral use.* *<u>Effect of food</u>* *Zonegran may be taken with or without food.*	