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Year 2012
Products Approved For Additional Indication (DCA 259 – 27 Disember 2012)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **MABTHERA 100MG /10ML VIALS** [Rituximab 100mg/10 ml vials] 1.2 **MABTHERA 500MG /50ML VIALS** [Rituximab 500mg/ 50ml vials] 1.3 **MABTHERA 100MG /10ML VIALS** [Rituximab 100mg/10ml vials] 1.4 **MABTHERA 500MG /50ML VIALS** [Rituximab 500mg/ 50ml vials] 1.5 **MABTHERA VIALS 10MG /ML CONCENTRATE FOR SOLUTION FOR INFUSION** [Rituximab 10mg/vial]	➢ Indication: *(i) to restrict the indication only for severe active rheumatoid arthiritis(RA) and* *(ii) to add of the following statement in RA indication;* *Mabthera/Rituxan has been shown to reduce the rate of progression of joint damage as measured by x-ray, when given in combination with methotrexate.* ➢ Posology: ☐ *MabThera /Rituxan should be administered as an i.v. infusion through a dedicated line, in an environment where full resuscitation facilities are immediately available, and under the close supervision of an experienced physician.* *Do not administer the prepared infusion solutions as an i.v. push or bolus.* ☐ *Rheumatoid arthritis* *Premedication consisting af an analgesic/anti-pyretic (e.g. paracetamol) and an antihistaminic drug (e.g. diphenhydramine) should always be administered before each infusion of MabThera/ Rituxan.* *Premedication with glucocorticoids should also be considered, particularly if MabThera /Rituxan is not given in combination with steroid-containing chemotherapy.* *MabThera /Rituxan is not given in combination with steroid-containing chemotherapy.* *Patients should receive 100 mg IV methylprednisolone to be completed 30 minutes*	**ROCHE (M) SDN BHD** Level 56- 58, Vista Tower, The Intermark, 348, Jalan Tun Razak 50400 Kuala Lumpur.

		prior to each MabThera /Rituxan infusion (see section 2.4 Warnings and Precautions). *A course of MabThera /Rituxan consist of two 1000mg i.v infusions. The recommended dosage of MabThera/Rituxan is 1000mg by i.v infusion followed two weeks later by the second 1000mg i.v. infusion.* *The need for further courses should be evaluated 24 weeks following the previous course with retreatment given based on residual or disease activity returning to a level above a DAS28-ESR of 2.6 (treatment to remission).Patients may receive further courses no sooner than 16 weeks following the previous course.* *☐ First infusion of each course* *The recommended initial rate for infusion is 50mg/hr; after the first 30 minutes, it can be escalated in 50mg/hr increments every 30 minutes, to a maximum of 400mg/hr.* *☐ Second infusion of each course* *Subsequent doses of MabThera/Rituxan can be infused at an initial rate of 100mg/hr, and increased by 100 mg/hr increments at 30 minutes intervals, to a maximum of 400mg/hr*	
2.	2.1 **GARDASIL SUSPENSION FOR INJECTION** [1 dose (0.5ml) contains: Human Papillomavirus Type 6 L1 Protein 20mcg Human Papillomavirus Type 18 L1 Protein 20mcg Human Papillomavirus Type 11 L1 Protein 40mcg Human Papillomavirus Type 16 L1 Protein 40mcg]	➢ Indication: *The extension of indication for the prevention of anal cancer in girls, women, boys and men of 9-26 years of age.* ➢ Posology: *Gardasil should be administered intramuscularly as 3 separate 0.5-mL doses according to the following schedule:* *First dose: at elected date* *Second dose: 2 months after the first dose* *Third dose: 6 months after the first dose*	**MERCK SHARP & DOHME (MALAYSIA) SDN BHD** T2-9, Jaya 33, No.3 (Lot 33), Jalan Semangat, Seksyen 13, 46100 Petaling Jaya, Selangor.

Individuals are encouraged to adhere to the 0, 2, and 6 months vaccination schedule. However, in clinical studies, efficacy has been demonstrated in individuals who have received all 3 doses within a 1-year period. If an alternate vaccination schedule is necessary, the second dose should be administered at least 1 month after the first dose, and the third dose should be administered at least 3 months after the second dose.

☐ Method of Administration

Gardasil should be administered intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.
Gardasil must not be injected intravascularly. Neither subcutaneous nor intradermal administration has been studied. These methods of administration are not recommended.
The prefilled syringe is for single use only and should not be used for more than one individual.
For single-use vials a separate sterile syringe and needle must be used for each individual.
The vaccine should be used as supplied; no dilution or reconstitution is necessary. The full recommended dose of the vaccine should be used.
Shake well before use. Thorough agitation immediately before administration is necessary to maintain suspension of the vaccine.
After thorough agitation, Gardasil is a white, cloudy liquid. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Discard the product if particulates are present or if it appears discolored.

☐ Single-dose vial use
Withdraw the 0.5-ml dose of vaccine from the single-dose vial using a sterile needle and syringe free of preservatives, antiseptics, and detergents. Once the single-dose vial has been penetrated, the withdrawn vaccine should be used promptly, and

		the vial must be discarded. *☐ Prefilled syringe use* *Inject the entire contents of the syringe.*	
3.	3.1 **EPAXAL (SOLUTION FOR INTRAMUSCULAR INJECTION)** [1 dose (0.5ml) contains: At least 24 IU of Hepatitis A Virus Antigen (RG-SB strain)]	➢ Indication: *The extension of indication for active immunisations in children from one year of age.* ➢ Posology: ➢ *Basic immunization* *A single intramuscular injection of 0.5ml into the deltoid muscle constitutes basic immunization. Vaccine protection begins 14 days after vaccination.* ➢ *Simultaneous active and passive immunization* *If immediate protection against hepatitis A is necessary, Epaxal can be administered concomitantly with immunoglobulin preparations with elevated titer against hepatitis A which must be injected at another site. This provides immediate passive protection which merges fluently into active vaccine protection.* ➢ *Booster vaccination* *Since vaccine protection last at least 1 year, booster vaccination is only indicated if more than 1 year has passed since primary immunization. Booster vaccination with 0.5ml Epaxal is estimated to prolong the protective efficacy to at least 20 years for at least 95% of the vaccination subjects.*	**PROPHARM (M) SDN. BHD.** 640, 640-A & 638-A, 4th. Mile, Jalan Ipoh, 51200 Kuala Lumpur.

4.	4.1 **Kombiglyze XR Tablet 2.5/1000mg** [Saxagliptin Hydrochloride anhydrous 2.79mg (eq. to Saxagliptin 2.50mg) and Metformin Hydrochloride 1000.50mg (eq. to Metformin 1000mg)] 4.2 **Kombiglyze XR Tablet 5/1000mg** [Saxagliptin Hydrochloride anhydrous 5.58mg (eq. to Saxagliptin 5.00mg) and Metformin Hydrochloride 1000.50mg (eq. to Metformin 1000mg)] 4.3 **Kombiglyze XR Tablet 5/1000mg** [Saxagliptin Hydrochloride anhydrous 5.58mg (eq. to Saxagliptin 5.00mg) and Metformin Hydrochloride 1000.50mg (eq. to Metformin 1000mg)]	➢ Indication: *Removal of sentence:* *KOMBIGLYZE XR has not been studied in combination with insulin* ➢ Posology: *No change to approved posology but with the addition of the paragraph below:* • *Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin* • *When KOMBIGLYZE XR is used in combination with an insulin secretagogue (e.g., sulfonylurea) or with insulin, a lower dose of the insulin secretagogue or insulin may be required to minimize the risk of hypoglycaemia.*	**AstraZeneca SdnBhd,** Level 12, Surian Tower, 1 Jalan PJU 7/3, MutiaraDamansara, 47810 Petaling Jaya,Selangor.
5.	5.1 **GALVUS 50MG TABLETS** [Vildagliptin 50mg]	➢ Indication: *Galvus is indicated as an adjunct to diet and exercise to improve glycaemic control in patients with type 2 diabetes mellitus:* *As dual therapy in combination with* • *Insulin, in patients with insufficient glycaemic control.* ➢ Posology: *When used as dual combination with insulin, the recommended dose of vildagliptin is 50mg or 100mg daily. The 100mg dose should be administered as one dose of 50mg in the morning and one dose of 50mg in the evening.* ➢ Patients with renal impairment *No dosage adjustment is required in patients with mild renal impairment (creatinine clearance ≥ 50ml/min).*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 15, Crest, 3 Two Square, No.2, Jalan 19/1, 46300 Petaling Jaya, Selangor darul Ehsan.

		In patients with moderate to severe impairment or end-stage renal disease (ESRD), the recommended dose of Galvus is 50mg once daily.	