Maklumat tambahan indikasi
Year 2017
Products Approved For Additional Indication (DCA 315 – 29 August 2017)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **KIVEXA TABLETS** [ABACAVIR 600MG & LAMIVUDINE 300MG]	➢ Indication: *Kivexa is indicated in antiretroviral combination therapy for the treatment of Human Immunodeficiency Virus (HIV) infection in adults, adolescents and children weighing at least 25kg.* *Before initiating treatment with abacavir, screening for carriage of the HLA-B*5701 allele should be performed in any HIV-infected patient, irrespective of racial origin. Abacavir should not be used in patients known to carry the HLA-B*5701 allele.* ➢ Posology: *Adults, adolescents and children weighing at least 25 kg:* *The recommended dose of Kivexa is one tablet once daily.* *Children Under 25 kg:* *Kivexa should not be administered to children who weigh less than 25 kg because it is a fixed-dose tablet that cannot be dose reduced.* *Kivexa is a fixed-dose tablet and should not be prescribed for patients requiring dose adjustments. Separate preparations of abacavir or lamivudine are available in cases where discontinuation or dose adjustment of one of the active substances is indicated. In these cases the physician should refer to the individual product information for these medicinal products.* *Special Populations* *Paediatric population:* *The safety and efficacy of Kivexa in children weighing less than 25 kg has not been established.* *Currently available data are described in section 4.8, 5.1 and 5.2 but no recommendation on posology can be made.*	**GLAXOSMITHKLINE PHARMACEUTICAL SDN. BHD.** Level 6, Quill 9 112, Jalan Semangat 46300 Petaling Jaya, Selangor

2.	2.1 **LUCENTIS 10 MG/ML SOLUTION FOR INJECTION IN PRE-FILLED SYRINGE** [RANIBIZUMAB 10 MG/ML]	➢ Indication: *Lucentis is indicated for:* • *the treatment of visual impairment due to choroidal neovascularization (CNV).* ➢ Posology: ***Dosage*** *Lucentis must be administered by a qualified ophthalmologist experienced in intravitreal injections.* *The recommended dose for Lucentis is 0.5 mg given as a single intravitreal injection. This corresponds to an injection volume of 0.05 mL. The interval between two doses injected into the same eye should be at least four weeks.* *Treatment is initiated with one injection per month until maximum visual acuity is achieved and/or there are no signs of disease activity i.e. no change in visual acuity and in other signs and symptoms of the disease under continued treatment. In patients with wet AMD, DME and RVO, initially, three or more consecutive, monthly injections may be needed.* *Thereafter, monitoring and treatment intervals should be determined by the physician and should be based on disease activity, as assessed by visual acuity and/or anatomical parameters.* *If, in the physician's opinion, visual and anatomic parameters indicate that the patient is not benefiting from continued treatment, Lucentis should be discontinued.* *Monitoring for disease activity may include clinical examination, functional testing or imaging techniques (e.g. optical coherence tomography or fluorescein angiography).* *If patients are being treated according to a treat-and-extend regimen, once maximum visual acuity is achieved and/or there are no signs of disease activity, the treatment intervals can be extended stepwise until signs of disease activity or visual impairment recur. The treatment interval should be extended by no more than two weeks at a time for wet AMD and may be extended by up to one month at a time for DME. For RVO, treatment intervals may also be gradually extended, however there are insufficient data to conclude on the length of these intervals. If disease activity recurs, the treatment interval should be shortened accordingly.* *The treatment of visual impairment due to CNV should be determined individually*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 22, Tower B, Plaza 33, No.1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor

per patient based on disease activity.Some patients may only need one injection during the first 6 months; others may need monthly treatment. For CNV secondary to PM, many patients may only need one or two injections during the first year, while some patients may need more frequent treatment(see section CLINICAL PHARMACOLOGY).

Lucentis and laser photocoagulation in DME and in macular oedema secondary to BRVO
There is some experience of Lucentis administered concomitantly with laser photocoagulation (see section PHARMACODYNAMICS). When given on the same day, Lucentis should be administered at least 30 minutes after laser photocoagulation. Lucentis can be administered in patients who have received previous laser photocoagulation.

Lucentis and Visudyne photodynamic therapy in CNV secondary to PM
There is no experience of concomitant administration of Lucentis and Visudyne.

Special populations

Hepatic impairment
Lucentis has not been studied in patients with hepatic impairment. However, no special considerations are needed in this population.

Renal impairment
Dose adjustment is not needed in patients with renal impairment (see section PHARMACOKINETICS).

Paediatric population
The safety and efficacy of Lucentis in children and adolescents below 18 years of age have not been established. Available data in adolescent patients aged 12 to 17 years with visual impairment due to CNV are described in section CLINICAL STUDIES.

Elderly
No dose adjustment is required in the elderly. There is limited experience in patients older than 75 years with DME.

Method of administration
Lucentis should be inspected visually for particulate matter and discoloration prior to administration.
The injection procedure should be carried out under aseptic conditions, which includes the use of surgical hand disinfection, sterile gloves, a sterile drape and a sterile eyelid speculum (or equivalent) and the availability of sterile paracentesis (if required). The patient's medical history for hypersensitivity reactions should be

		carefully evaluated prior to performing the intravitreal procedure (see section WARNINGS AND PRECAUTIONS). Adequate anaesthesia and a broad-spectrum topical microbicide to disinfect the periocular skin, eyelid and ocular surface should be administered prior to the injection, in accordance with local practice. *For information on preparation of Lucentis, see section INSTRUCTIONS FOR USE AND HANDLING.* *The injection needle should be inserted 3.5 to 4.0 mm posterior to the limbus into the vitreous cavity, avoiding the horizontal meridian and aiming towards the centre of the globe. The injection volume of 0.05 mL is then delivered; a different scleral site should be used for subsequent injections.*	
3.	3.1 **ACCENTRIX 10MG/ML SOLUTION FOR INJECTION** [RANIBIZUMAB 10 MG/ML]	➢ Indication: *Accentrix is indicated for:* • *the treatment of visual impairment due to choroidal neovascularization (CNV).* ➢ Posology: ***Dosage*** *Accentrix must be administered by a qualified ophthalmologist experienced in intravitreal injections.* *The recommended dose for Accentrix is 0.5 mg given as a single intravitreal injection. This corresponds to an injection volume of 0.05 mL. The interval between two doses injected into the same eye should be at least four weeks.* *Treatment is initiated with one injection per month until maximum visual acuity is achieved and/or there are no signs of disease activity i.e. no change in visual acuity and in other signs and symptoms of the disease under continued treatment. In patients with wet AMD, DME and RVO, initially, three or more consecutive, monthly injections may be needed.* *Thereafter, monitoring and treatment intervals should be determined by the physician and should be based on disease activity, as assessed by visual acuity and/or anatomical parameters.* *If, in the physician's opinion, visual and anatomic parameters indicate that the patient is not benefiting from continued treatment, Accentrix should be discontinued.* *Monitoring for disease activity may include clinical examination, functional testing or imaging techniques (e.g. optical coherence tomography or fluorescein*	**ALCON LABORATORIES (MALAYSIA) SDN. BHD.** Level 20-1, Tower B, Plaza 33, No.1, Jalan Kemajuan, Seksyen 13 46200 Petaling Jaya, Selangor

angiography).

If patients are being treated according to a treat-and-extend regimen, once maximum visual acuity is achieved and/or there are no signs of disease activity, the treatment intervals can be extended stepwise until signs of disease activity or visual impairment recur. The treatment interval should be extended by no more than two weeks at a time for wet AMD and may be extended by up to one month at a time for DME. For RVO, treatment intervals may also be gradually extended, however there are insufficient data to conclude on the length of these intervals. If disease activity recurs, the treatment interval should be shortened accordingly.

The treatment of visual impairment due to CNV should be determined individually per patient based on disease activity. Some patients may only need one injection during the first 6 months; others may need monthly treatment. For CNV secondary to PM, many patients may only need one or two injections during the first year, while some patients may need more frequent treatment (see section CLINICAL PHARMACOLOGY).

Accentrix and laser photocoagulation in DME and in macular oedema secondary to BRVO
There is some experience of Accentrix administered concomitantly with laser photocoagulation (see section PHARMACODYNAMICS). When given on the same day, Accentrix should be administered at least 30 minutes after laser photocoagulation. Accentrix can be administered in patients who have received previous laser photocoagulation.

Accentrix and Visudyne photodynamic therapy in CNV secondary to PM
There is no experience of concomitant administration of Accentrix and Visudyne.

Special populations

Hepatic impairment
Accentrix has not been studied in patients with hepatic impairment. However, no special considerations are needed in this population.

Renal impairment
Dose adjustment is not needed in patients with renal impairment (see section PHARMACOKINETICS).

Paediatric population
The safety and efficacy of Accentrix in children and adolescents below 18 years of age have not been established. Available data in adolescent patients aged 12 to 17 years with visual impairment due to CNV are described in section CLINICAL STUDIES.

		Elderly *No dose adjustment is required in the elderly. There is limited experience in patients older than 75 years with DME.* ***Method of administration*** *Accentrix should be inspected visually for particulate matter and discoloration prior to administration.* *The injection procedure should be carried out under aseptic conditions, which includes the use of surgical hand disinfection, sterile gloves, a sterile drape and a sterile eyelid speculum (or equivalent) and the availability of sterile paracentesis (if required). The patient's medical history for hypersensitivity reactions should be carefully evaluated prior to performing the intravitreal procedure (see section WARNINGS AND PRECAUTIONS). Adequate anaesthesia and a broad-spectrum topical microbicide to disinfect the periocular skin, eyelid and ocular surface should be administered prior to the injection, in accordance with local practice.* *For information on preparation of Accentrix, see section INSTRUCTIONS FOR USE AND HANDLING.* *The injection needle should be inserted 3.5 to 4.0 mm posterior to the limbus into the vitreous cavity, avoiding the horizontal meridian and aiming towards the centre of the globe. The injection volume of 0.05 mL is then delivered; a different scleral site should be used for subsequent injections.*	