Maklumat tambahan indikasi untuk upload pada laman web
Year 2013
Products Approved For Additional Indication (DCA 265 – 27 Jun 2013)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **NESP Injection Syringe 20mcg** [Darbepoetin alfa 20mcg] 1.2 **NESP Injection Syringe 30mcg** [Darbepoetin alfa 30mcg] 1.3 **NESP Injection Syringe 40mcg** [Darbepoetin alfa 40mcg] 1.4 **NESP Injection Syringe 120mcg** [Darbepoetin alfa 120mcg]	➢ Indication: *Nesp is indicated for the treatment of anemia associated with chronic renal failure, including patients on dialysis and patients not on dialysis.* ➢ Posology: *Hemodialysis patients:* *Initial dose* *The usual dose of Nesp in adult patients is 20 µg as darbepoetin alfa (genetical recombination), to be administered as a single intravenous injection once weekly.* *Initial dose at the switching from erythropoietin preparations (epoetin alfa (genetical recombination), epoetin beta (genetical recombination), etc). The usual dose of Nesp in adult patients is 15-60 µg as darbepoetin alfa (genetical recombination), to be administered as a single intravenous injection once weekly.* *Maintenance dose* *When correction of anemia is achieved, the usual dose of Nesp in adult patients is 15-60 µg as darbepoetin alfa (genetical recombination), to be administered as a single intravenous injection once weekly. If alleviation of anemia is maintained by once weekly injection, the frequency of administration can be changed to once every two weeks with an initial dose set to be two-fold of the dose in the once weekly injection. In this case, the usual dose in adult patients is 30-120 µg*	**SMART MEDICINE SDN BHD** No.2, Jalan SS13/5, 47500 Subang Jaya, Selangor Darul Ehsan.

		administered as a single intravenous injection once every two weeks. *In all cases, the dose should be adjusted in view of the degree of anemic symptoms and the patient's age, and should not exceed 180μg as a single injection.* *Peritoneal dialysis patients and patients with chronic kidney disease not on dialysis:* *Initial dose* *The usual dose of Nesp in adult patients is 30 μg as darbepoetin alfa (genetical recombination), to be administered as a single injection once every two weeks subcutaneously or intravenously.* *Initial dose at the switching from erythropoietin preparations (epoetin alfa (genetical recombination), epoetin beta (genetical recombination), etc).* *The usual dose of Nesp in adult patients is 30-120 μg as darbepoetin alfa (genetical recombination), to be administered as a single injection once every two weeks subcutaneously or intravenously.* *Maintenance dose* *When correction of anemia is achieved, the usual dose of Nesp in adult patients is 30-120 μg as darbepoetin alfa (genetical recombination), to be administered as a single injection once every two weeks subcutaneously or intravenously. If alleviation of anemia is maintained by once every two weeks injection, the frequency of administration can be changed to once every four weeks with a initial dose set to be two-fold of the dose in the once every two weeks injection. In this case, the usual dose in adult patients is 60-180 μg administered as a single injection once every four weeks subcutaneously or intravenously.* *In all cases, the dose should be adjusted in view of the degree of anemic symptoms and the patient's age, and should not exceed 180 μg as a single injection.*	

2.	2.1 **MULTIHANCE INJECTION SOLUTION** [Gadobenate dimeglumine 0.529 g/ml (equivalent to gadobenic acid 0.334 g/ml + meglumine 0.195 g/ml)]	➢ Posology: *MRI of the brain and spine: the recommended dose of MultiHance injection in adult <u>and in paediatric patients greater than 2 years of age</u> is 0.1 mmol/kg body weight. This corresponds to 0.2 mL/kg of the 0.5 M solution.* *The following statements were removed:* *The safety and efficacy of MultiHance have not been established in patients under 18 years old. Therefore, use of MultiHance in this patient group cannot be recommended.* *The following statements were included:* *Paediatric population* *No dosage adjustment is considered necessary.* *Use for MRI of the brain and spine is not recommended in children less that 2 years of age.* *Use of MRI of the liver and MRA is not recommended in children less than 18 years of age.*	**SALVO HEALTHCARE SDN BHD** 11-4, Jalan USJ 9/5Q, Subang Business Centre 47620 Subang Jaya, Selangor.
3.	3.1 **Exjade 125 mg Dispersible Tablet** [Deferasirox 125 mg] 3.2 **Exjade 250 mg Dispersible Tablet** [Deferasirox 250 mg] 3.3 **Exjade 500 mg Dispersible Tablet** [Deferasirox 500 mg]	➢ Indication: *Exjade is also indicated for the treatment of chronic iron overload in patients with non-transfusion-dependent thalassemia syndromes aged 10 years and over.* ➢ Posology: *Non-transfusion-dependent thalassemia syndromes* *Dosage* *Chelation therapy should only be initiated when there is evidence of iron overload (liver iron concentration [LIC]) > 5 mg Fe/g dry weight (dw) or serum ferritin consistently > 800 microgram/L). In patients with no LIC assessment, caution should be taken during chelation therapy to minimize the risk of over chelation*	**NOVARTIS CORPORATION (MALAYSIA) SDN. BHD.** Level 15, CREST, 3 Two Square, No. 2, Jalan 19/1, 46300 Petaling Jaya, Selangor.

		Starting dose *The recommended initial daily dose of Exjade is 10 mg/kg body weight.* *Dose adjustment* *It is recommended that serum ferritin be monitored every month. Every 3 to 6 months of treatment, consider a dose increase in increments of 5 to 10 mg/kg if the patient's LIC is > 7mg Fe/g dw, or serum ferritin is consistently > 2000 micrograms/L and not showing a downward trend. and the patient is tolerating the drug well. Doses above 20 mg/kg are not recommended with non-transfusion-dependent thalassemia syndromes.* *In patients in whom LIC was not assessed and serum ferritin is < 2000 microgram/L, dosing should not exceed 10 mg/kg.* *For patients in whom the dose was increased to > 10 mg/kg, dose reduction is recommended to 10 mg/kg or less when LIC is < 7 mg Fe/g dw or serum ferritin is < 2000 micrograms/L.* *Once a satisfactory body iron level has been achieved (LIC < 3 mg Fe/g dw or serum ferritin < 300 microgram/L), treatment should be interrupted. Treatment should be re-initiated when there is evidence from clinical monitoring that chronic iron overload is present.*	
4.	4.1 **TELFAST 30MG/5ML ORAL SUSPENSION** [Fexofenadine Hydrochloride 30mg equivalent to Fexofenadine 28mg]	➢ Indication: *Seasonal Allergic Rhinitis* *TELFAST Oral Suspension is indicated for the relief of symptoms associated with seasonal allergic rhinitis in children 2 to 11 years of age.*	**SANOFI-AVENTIS (MALAYSIA) SDN. BHD.** 8th Floor, PNB Damansara, No. 19, Lorong Dungun, Damansara Heights, 50490 Kuala Lumpur.

		Chronic Idiopathic Urticaria *TELFAST Oral Suspension is indicated for treatment of uncomplicated skin manifestations of chronic idiopathic urticaria in children 6 months to 11 years of age.* ➢ Posology: *Seasonal Allergic Rhinitis* *Children 2 to 11 years: The recommended dose of TELFAST Oral Suspension is 30 mg (5mL) twice daily. A dose of 30 mg (5mL) once daily is recommended as the starting dose in pediatric patients with decreased renal function.* *Chronic Idiopathic Urticaria* *Children 6 months to less than 2 years: The recommended dose of TELFAST Oral Suspension is 15 mg (2.5 mL) twice daily. For pediatric patients with decreased renal function, the recommended starting dose is 15 mg (2.5 mL) once daily.* *Children 2 to 11 Years: The recommended dose of Telfast Oral Suspension is 30 mg (5mL) twice daily. For pediatric patients with decreased renal function, the recommended starting dose is 30 mg (5mL) once daily.*	