Maklumat tambahan indikasi
Year 2019
Products Approved For Additional Indication (DCA 337 – 1 Ogos 2019)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Ibrance Capsules 75mg** [Palbociclib 75mg] 1.2 **Ibrance Capsules 100mg** [Palbociclib 100mg] 1.3 **Ibrance Capsules 125mg** [Palbociclib 125mg]	➢ Indication: *Ibrance is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine based therapy in postmenopausal women.* ➢ Posology: *To replace:* *"When co-administered with palbociclib, the recommended dose of letrozole is 2.5 mg taken once daily continuously throughout the 28-day cycle. Please refer to the full prescribing information of letrozole."* *with:* *"Administer the recommended dose of an aromatase inhibitor when given with IBRANCE. Please refer to the full prescribing information for the aromatase inhibitor being used."*	**PFIZER (MALAYSIA) SDN. BHD.** Level 10 & 11, Wisma Averis, Tower 2 Avenue 5, Bangsar South No.8, Jalan Kerinchi 59200 Kuala Lumpur
2.	2.1 **Privigen solution for infusion 10%** [Human Normal Immunoglobulin 100gm/l]	➢ Indication: *1. <u>Replacement therapy in :</u>* *a. Primary immunodeficiency syndromes (PID) such as:* - *Congenital agammaglobulinaemia and hypogammaglobulinaemia* - *Common variable immunodeficiency* - *Severe combined immunodeficiency* - *Wiskott-Aldrich syndrome*	**DKSH MALAYSIA SDN BHD.** B-11-01, The Ascent, Paradigm No. 1, Jalan SS7/26A, Kelana Jaya 47301 Petaling Jaya, Selangor

b. *Myeloma or chronic lymphocytic leukemia with severe secondary hypogammaglobulinaemia and recurrent infections*
c. *Children with congenital AIDS and recurrent infections*

2. *<u>Immunomodulation:</u>*

a. *Immune thrombocytopenic purpura (ITP) in childrens or adults at high risk of bleeding or prior to surgical interventions to correct the platelet count*
b. *Guillain-Barre syndrome*
c. *Kawasaki disease*
d. ***Chronic inflammatory demyelinating polyneuropathy (CIDP)***

3. *Allogeneic bone marrow transplantation*

- Posology:

<u>Dosage</u>
The dosage and dosage regimen is dependent on the indication. In replacement therapy the dosage may need to be individualised for each patient depending on the pharmacokinetic and clinical response. The following dosage regimens are given as a guideline.

<u>Replacement therapy in primary immunodeficiency syndromes</u>
The dosage regimen should achieve a trough IgG level (measured before the next infusion) of at least 5 to 6 g/l. Three to 6 months are required after the initiation of therapy for equilibration to occur. The recommended starting dose is 0.4 to 0.8 g/kg body weight (bw) followed by at least 0.2 g/kg body weight (bw) every 3 to 4 weeks. The dose required to achieve a trough level of 5 to 6 g/l is of the order of 0.2 to 0.8 g/kg bw/month. The dosage interval when steady state has been reached varies from 3 to 4 weeks. Trough levels should be measured in order to adjust the dose and dosage

		interval. *<u>Replacement therapy in myelomas or chronic lymphocytic leukaemia with severe secondary hypogammaglobulinaemia and recurrent infections and in children with congenital AIDS and recurrent infections</u>* *The recommended dosage is 0.2 to 0.4 g/kg bw every 3 to 4 weeks.* *<u>Immune thrombocytopenic purpura</u>* *For the treatment of an acute episode, 0.8 to 1 g/kg bw on day one, which may be repeated once within 3 days, or 0.4 g/kg bw daily for 2 to 5 days. The treatment can be repeated if relapse occurs.* *<u>Guillain-Barré syndrome</u>* *0.4 g/kg bw/day over 5 days. Experience in children is limited.* *<u>Kawasaki disease</u>* *1.6 to 2.0 g/kg bw should be administered in divided doses over 2 to 5 days or 2.0 g/kg bw as a single dose. Patients should receive concomitant treatment with acetylsalicylic acid.* ***<u>Chronic inflammatory demyelinating polyneuropathy (CIDP):</u>*** ***The recommended starting dose is 2 g/kg body weight (bw) divided over 2 to 5 consecutive days followed by maintenance doses of 1 g/kg bw given on one day or divided over 2 consecutive days every 3 weeks. The long-term therapy over 24 weeks depends on the patient`s response to the maintenance therapy. The lowest effective maintenance dose and the dosage regimen are to***	

adjust according to the individual course of the disease.

<u>Allogeneic bone marrow transplantation</u>
Human immunoglobulin therapy can be used as part of the conditioning regimen and after transplantation. To treat infections and prevent graft-versus-host disease, the dosage should be individually adjusted. The starting dosage is usually 0.5 g/kg bw/week, commencing seven days before the transplant. The treatment is continued for up to 3 months after the transplant. If the lack of antibody production persists, a dosage of 0.5 g/kg bw/month is recommended until IgG antibody levels return to normal.

The dosage recommendations are summarised in the following table:

Indication	*Dose*	*Intervals between injections*
<u>Replacement therapy in:</u> *primary immunodeficiency syndromes*	*Starting dose: 0.4-0.8 g/kg bw* *thereafter: 0.2-0.8 g/kg bw*	*every 3-4 weeks to obtain IgG trough levels of at least 5-6 g/l*
secondary immunodeficiency syndromes	*0.2-0.4 g/kg bw*	*every 3-4 weeks to obtain IgG trough levels of at least 5-6 g/l*
children with congenital HIV infection and recurrent infections	*0.2-0.4 g/kg bw*	

		every 3-4 weeks
<u>Immunomodulation:</u>		
Immune thrombocytopenic purpura	*0.8-1 g/kg bw or 0.4 g/kg bw/day*	*on the first day; the therapy may be repeated once within 3 days*
Guillain-Barré syndrome	*0.4 g/kg bw/day*	*over 2-5 days*
Kawasaki disease	*1.6-2 g/kg bw or*	*over 5 days*
	2 g/kg bw	*divided into several doses given over 2-5 days in conjunction with acetylsalicylic acid*
Chronic inflammatory demyelinating polyneuropathy (CIDP)	***starting dose: 2 g/kg bw***	*as a single dose in conjunction with acetylsalicylic acid*
	maintenance dose: 1 g/kg bw	***in divided doses over 2-5 days***
		over 1-2 days every 3

		weeks
<u>Allogeneic bone marrow transplantation</u> • *treatment of infections and prevention of graft-versus-host disease* • *persistent lack of antibody production*	*0.5 g/kg bw* *0.5 g/kg bw*	*weekly, from day 7 before up to 3 months after the transplant* *monthly, until antibody levels return to normal*

<u>Use of the product in paediatric population</u>

In the phase III pivotal study on patients with primary immunodeficiency diseases (n = 80), 19 patients between 3 and 11 years of age and 15 patients from 12 up to and including 18 years of age were treated. In an extension study of patients with primary immunodeficiency diseases (n = 55), 13 patients between 3 and 11 years of age and 11 between 12 and including 18 years of age were treated. In the clinical study on 57 patients with chronic immune thrombocytopenic purpura 2 paediatric patients (15 and 16 years of age) were treated. No dose adjustment for children was required in these three studies. ***Literature reports indicate that intravenous immunoglobulins are effective in children with CIDP. However, no data is available on Privigen in this respect.***