Maklumat tambahan indikasi
Year 2019
Products Approved For Additional Indication (DCA 330 – 3 January 2019)

<table>
<tr><th>NO</th><th>PRODUCT
(ACTIVE INGREDIENT)</th><th>ADDITIONAL INDICATION</th><th>MARKETING AUTHORIZATION HOLDER</th></tr>
<tr>
<td>1.</td>
<td>1.1 Zepatier 100mg/50mg Film-coated Tablet
[Grazoprevir 100mg/Elbasvir 50mg]</td>
<td>
➢ Indication:

ZEPATIER® (elbasvir/grazoprevir) is indicated for the treatment of chronic hepatitis C (CHC) genotypes 3 infection in adults as follows:

With sofosbuvir:
• in GT3 TN patients (12 weeks)

➢ Posology:

Table 11 – Recommended Dosage Regimens and Durations for ZEPATIER® for Treatment of Chronic Hepatitis C Infection in Patients without Cirrhosis or with Compensated Cirrhosis (Child-Pugh A only)

<table>
<tr><th>Treatment</th><th>Duration</th></tr>
<tr><td colspan="2">Genotype 3 TN</td></tr>
<tr><td>ZEPATIER® with sofosbuvir$</td><td>12 weeks</td></tr>
<tr><td colspan="2">$See Severe Renal impairment and end stage renal disease (ESRD).</td></tr>
</table>

Severe Renal Impairment and ESRD
The safety and efficacy of ZEPATIER® in genotype 4 patients as well as ZEPATIER® with sofosbuvir in genotype 3 patients with severe renal impairment (eGFR) <30 mL/min/1.73m^2) or with ESRD, including patients on hemodialysis have not been established.
</td>
<td>MERCK SHARP & DOHME (MALAYSIA) SDN. BHD.
Lot No. B-22-1 & B-22-2, Level 22 , The Ascent, Paradigm No. 1
Jalan SS 7/26A, Kelana Jaya, 47301 Petaling Jaya, Selangor</td>
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2.	2.1 **SIMPONI® IV 12.5mg/1ml Concentrate for Solution for Infusion** [Golimumab 12.5mg/ 1ml]	➢ Indication: *<u>Rheumatoid arthritis (RA):</u>* *SIMPONI®, by intravenous (IV) administration, in combination with MTX, is indicated for:* *The treatment of moderate to severe, active rheumatoid arthritis in adults when the response to disease modifying anti rheumatic drug (DMARD) therapy including MTX has been inadequate.* *SIMPONI®, in combination with MTX, has been shown to reduce the rate of progression of joint damage as measured by X ray and to improve physical function.* *<u>Ankylosing spondylitis (AS):</u>* *SIMPONI® by intravenous (IV) administration is indicated for the treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to conventional therapies.* *<u>Dosage and Administration</u>* *SIMPONI treatment is to be initiated and supervised by qualified physicians experienced in the diagnosis and treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, non radiographic axial spondyloarthritis or ulcerative colitis.* *SIMPONI® is administered by subcutaneous injection or intravenous infusion.* *The efficacy and safety of switching between IV and SC formulations have not been established.* ➢ Posology: *<u>Intravenous infusion</u>* *<u>Rheumatoid arthritis and ankylosing spondylitis:</u>* *2 mg/kg of SIMPONI® given as a 30-minute intravenous infusion at Weeks 0 and 4, then every 8 weeks thereafter.* *There are no existing clinical trial data to support switching between IV and SC formulations.*	**JOHNSON & JOHNSON SDN BHD** Lot 3 & 5, Jalan Tandang, 46050 Petaling Jaya, Selangor

Missed dose
If a patient forgets to inject SIMPONI® on the planned date, the forgotten dose should be injected as soon as the patient remembers. Patients should be instructed not to inject a double dose to make up for the forgotten dose.

The next dose should be administered based on the following guidance:
- *if the dose is less than 2 weeks late, the patient should inject his/her forgotten dose and stay on his/her original schedule.*
- *if the dose is more than 2 weeks late, the patient should inject his/her forgotten dose and a new schedule should be established from the date of this injection.*

Special populations
Elderly (≥ 65 years)
No dosage adjustment is required in the elderly.

Renal and hepatic impairment
SIMPONI®
has not been studied in these patient populations. No dose recommendations can be made.

Paediatric patients
The safety and efficacy of SIMPONI® in patients aged less than 18 have not yet been established. No data are available.

Method of administration
Subcutaneous injection
SIMPONI® Solution for Injection is for subcutaneous use. After proper training in subcutaneous injection technique, patients may self-inject with SIMPONI® Solution for Injection if their physician determines that this is appropriate, with medical follow-up as necessary. Patients should be instructed to inject the full amount of SIMPONI® Solution for Injection according to the comprehensive instructions for administration provided in the package leaflet. If multiple injections are required, the injections should be administered at different sites on the body.

Intravenous infusion
Intravenous infusion of SIMPONI® IV 12.5mg/1ml Concentrate for Solution for Infusion should be administered by qualified

		health care professionals trained to detect any infusion related issues. Comprehensive instructions for the intravenous infusion of SIMPONI® IV 12.5mg/1ml Concentrate for Solution for Infusion are given in "Instructions for use, handling, and disposal."	
3.	3.1 Perjeta 420mg Concentrate for Solution for Infusion [Pertuzumab 30mg/ml]	➢ Indication : *Metastatic Breast Cancer* *Perjeta is indicated in combination with trastuzumab and docetaxel for patients with HER2-positive metastatic or locally recurrent unresectable breast cancer, who have not received previous anti-HER2 therapy or chemotherapy for their metastatic disease.* *Early Breast Cancer* *Perjeta is indicated in combination with trastuzumab and chemotherapy for the:* • *neoadjuvant treatment of patients with HER2-positive, locally advanced, inflammatory, or early stage breast cancer (either >2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer* • *adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence* ➢ Posology: <u>*General*</u> *Patients treated with Perjeta should have HER2-positive tumors status, defined as a score of 3+ by IHC or a ratio of > 2.0 by ISH assessed by a validated test.* *To ensure accurate and reproducible results, the testing must be performed in a specialized laboratory, which can ensure validation of the testing procedures.* *For full instructions on assay performance and interpretation please refer to the package inserts of validated HER2 testing assays.* *Substitution by any other biological medicinal product requires the consent of the prescribing physician. In order to prevent medication errors, it is important to check the vial labels to ensure that the drug being prepared and administered is*	**ROCHE (MALAYSIA) SDN. BHD.** Level 21, The Pinnacle Persiaran Lagoon Bandar Sunway 47500 Subang Jaya, Selangor

Perjeta. Perjeta therapy should only be administered under the supervision of a healthcare professional experienced in the treatment of cancer patients. Perjeta must be diluted by a healthcare professional and administered as an intravenous infusion. Do not administer as an IV push or bolus.

<u>Metastatic and Early Breast Cancer</u>
The recommended initial dose of Perjeta is 840 mg administered as a 60 minutes intravenous infusion, followed every 3 weeks thereafter by a dose of 420 mg administered over a period 30 to 60 minutes. An observation period of 30-60 minutes is recommended after completion of each Perjeta infusion. The observation period should be completed prior to any subsequent dose of trastuzumab or chemotherapy.

Perjeta and Trastuzumab should be administered sequentially and can be given in any order. When administered with Perjeta, the recommendation is to follow a 3-weekly schedule for Trastuzumab administered either as:

- *an IV infusion with an initial dose of 8 mg/kg followed every 3 weeks thereafter by a dose of 6 mg/kg body weight or*
- *a fixed dose of trastuzumab subcutaneous (SC) injection (600mg) for the initial dose and every 3 weeks thereafter irrespective of the patient's body weight.*

In patients receiving a taxane, Perjeta and trastuzumab should be administered prior to the taxane. When administered with Perjeta, the recommended initial dose of docetaxel is 75 mg/m2.

In patients receiving an anthracycline-based regimen, Perjeta and trastuzumab should be administered following completion of the entire anthracycline regimen.

<u>Metastatic Breast Cancer (MBC)</u>
Perjeta should be administered in combination with trastuzumab and docetaxel until disease progression or unmanageable toxicity. Treatment with Perjeta and trastuzumab may continue even if treatment with docetaxel is discontinued.

Early Breast Cancer (EBC)

In the neoadjuvant setting (before surgery), it is recommended that patients are treated with Perjeta for three to six cycles depending on the regimen chosen in combination with trastuzumab and chemotherapy

In the adjuvant setting (after surgery), Perjeta should be administered in combination with trastuzumab for a total of one year (maximum 18 cycles or until disease recurrence, or unmanageable toxicity, whichever occurs first), as part of a complete regimen for early breast cancer, including standard anthracycline and/ or taxane-based chemotherapy. Perjeta and trastuzumab should start on Day 1 of the first taxane-containing cycle and should continue even if chemotherapy is discontinued.

Patients who start Perjeta and trastuzumab in the neoadjuvant setting should continue to receive adjuvant Perjeta and trastuzumab to complete 1 year of treatment.

Delayed or Missed doses

For recommendations on delayed or missed doses, please refer to Table 1 below.

Time between two sequential doses	***Perjeta***	***Trastuzumab IV***
< 6 weeks	*The 420 mg dose of Perjeta IV should be administered as soon as possible. Do not wait until the next planned dose.*	*The 6 mg/kg dose of Trastuzumab IV should be administered as soon as possible. Do not wait until the next planned dose.*
≥ 6 weeks	*The loading dose of 840 mg Perjeta IV should be re-administered as a 60-minute infusion, followed*	*The loading dose of 8 mg/kg of Trastuzumab IV should be re-administered over approximately 90 minutes, followed*

	by a maintenance dose of 420 mg IV administered over a period of 30 to 60 minutes every 3 weeks thereafter.	*by a maintenance dose of 6 mg/kg IV administered over a period of 30 or 90 minutes every 3 weeks thereafter.*

Table 1 Recommendations regarding delayed or missed doses

Dose modifications
Perjeta should be discontinued if trastuzumab treatment is discontinued.
Dose reductions are not recommended for Perjeta and trastuzumab (see trastuzumab prescribing information).
For chemotherapy dose modifications, see relevant prescribing information.

Infusion-related reactions
The infusion rate of Perjeta may be slowed or interrupted if the patient develops an infusion-related reaction.

Hypersensitivity reactions/anaphylaxis
The infusion should be discontinued immediately and permanently if the patient experiences a serious hypersensitivity reaction

Left ventricular dysfunction
See section 2.4 Warnings and Precautions for information on dose recommendations in the event of left ventricular dysfunction.

<u>Special dosage instructions</u>
Geriatric use: No dose adjustment is required in the elderly population (≥65 years of age)
Paediatric use: The safety and efficacy of Perjeta in children and adolescents below 18 years of age have not been established.
Renal impairment: Dose adjustments of Perjeta are not needed in patients with mild or moderate renal impairment.
No dose recommendations can be made for patients with severe renal impairment because of the limited pharmacokinetic data available

		Hepatic impairment: The safety and efficacy of Perjeta have not been studied in patients with hepatic impairment.	