Maklumat tambahan indikasi
Year 2017
Products Approved For Additional Indication (DCA 312 – 5 June 2017)

NO	PRODUCT (ACTIVE INGREDIENT)	ADDITIONAL INDICATION	MARKETING AUTHORIZATION HOLDER
1.	1.1 **Byetta Injection 5mcg** [Exenatide 250 mcg/ml] 1.2 **Byetta Injection 10mcg** [Exenatide 250 mcg/ml]	➢ Indication: *Byetta is also indicated as adjunctive therapy to basal insulin with or without metformin and/or pioglitazone in adults who have not achieved adequate glycaemic control with these agents.* ➢ Posology: *BYETTA is recommended for use in patients with type 2 diabetes mellitus who are already receiving metformin, a sulfonylurea, pioglitazone and/or a basal insulin. One can continue to use BYETTA when a basal insulin is added to existing therapy. When BYETTA is added to existing metformin and/or pioglitazone therapy, the current dose of metformin and/or pioglitazone can be continued as no increased risk of hypoglycaemia is anticipated, compared to metformin or pioglitazone alone. When BYETTA is added to sulphonylurea therapy, a reduction in the dose of sulphonylurea should be considered to reduce the risk of hypoglycaemia (see section 4.4). When BYETTA is used in combination with basal insulin, the dose of basal insulin should be evaluated. In patients at increased risk of hypoglycaemia consider reducing the dose of basal insulin (see section 4.8).* *The dose of BYETTA does not need to be adjusted on a day-to-day basis depending on self-monitored glycaemia. However, blood glucose self-monitoring may become necessary to adjust the dose of sulphonylureas or the dose of basal insulin.* *Method of administration* *BYETTA and basal insulin must be administered as two separate injections.*	**ASTRAZENECA SDN. BHD.** Level 12, Surian Tower 1 Jalan PJU 7/3, Mutiara Damansara 47810 Petaling Jaya, Selangor

<table>
<tr>
<td>2.</td>
<td>2.1 Exviera 250mg Film Coated Tablets
[Dasabuvir sodium monohydrate 270.26 mg (equivalent to dasabuvir 250 mg)]</td>
<td>
➢ Posology:

Table 1. Recommended co-administered medicinal product(s) and treatment duration for Exviera by patient population
<table>
<tr><th>Patient Population</th><th>Treatment*</th><th>Duration</th></tr>
<tr><td>Genotype 1b, without cirrhosis or with compensated cirrhosis</td><td>Exviera + ombitasvir/paritaprevir/ritonavir</td><td>12 weeks</td></tr>
<tr><td>Genotype 1a, without cirrhosis</td><td>Exviera + ombitasvir/paritaprevir/ritonavir + ribavirin*</td><td>12 weeks</td></tr>
<tr><td>Genotype 1a, with compensated cirrhosis</td><td>Exviera + ombitasvir/paritaprevir/ritonavir + ribavirin*</td><td>**12 weeks
(see section Pharmacodynamic Properties.)</td></tr>
<tr><td colspan="3">* Note: Follow the genotype 1a dosing recommendations in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection.
** 24 weeks of Exviera + ombitasvir/paritaprevir/ritonavir + ribavirin therapy is recommended for patients with genotype 1a-infection with cirrhosis who have had a previous null response to interferon (IFN) and ribavirin (see section Pharmacodynamic Properties).</td></tr>
</table>
</td>
<td>ABBVIE SDN BHD
9th Floor Menara Lien Hoe
No.8, Persiaran Tropicana Tropicana Golf & Country Resort
47410 Petaling Jaya, Selangor</td>
</tr>
</table>

3.	3.1 **Viekirax 12.5 mg/75 mg/50 mg Film Coated Tablets** [Ombitasvir 12.5 mg, Ritonavir 50 mg, Paritaprevir 75 mg]	➢ Posology: Table 1. Recommended co-administered medicinal product(s) and treatment duration for Viekirax by patient population	**ABBVIE SDN BHD** 9th Floor Menara Lien Hoe No.8, Persiaran Tropicana Tropicana Golf & Country Resort 47410 Petaling Jaya, Selangor

Patient population	Treatment*	Duration
Genotype 1b, without cirrhosis or with compensated cirrhosis	Viekirax + dasabuvir	12 weeks
Genotype 1a, without cirrhosis	Viekirax + dasabuvir + ribavirin*	12 weeks
Genotype 1a, with compensated cirrhosis	Viekirax + dasabuvir + ribavirin*	**12 weeks (see section Pharmacodynamic Properties.)
Genotype 4, without cirrhosis	Viekirax + ribavirin	12 weeks

* Note: Follow the genotype 1a dosing recommendations in patients with an unknown genotype 1 subtype or with mixed genotype 1 infection.

** 24 weeks of Viekirax + dasabuvir + ribavirin therapy is recommended for patients with genotype 1a-infection with cirrhosis who have had a previous null response to interferon (IFN) and ribavirin (see section Pharmacodynamic Properties).