

Your Ref: n/a  
Our Ref: ORI/RA/0016/22

**National Pharmaceutical Regulatory Agency**  
Lot 36, Jalan Universiti  
46200 Petaling Jaya,  
Selangor Malaysia



**Attn:**  
**Pusat Pasca Pendaftaran Produk & Kawalan Kosmetik (PPPPKK)**  
**Pharmacovigilance Unit**

Date: 08/11/2022  
by hand & Email

Sir/Madam,

**Ref: MANUAL SUBMISSION FOR PATIENT INFORMATION LEAFLET / RISALAH MAKLUMAT UBAT PESAKIT (RiMUP)**  
**Sub:**

- |      |                          |   |                                        |
|------|--------------------------|---|----------------------------------------|
| i)   | Product Name             | : | GIONA EASYHALER®                       |
| ii)  | Product Registration No. | : | MAL04125479AZ & MAL04125480AZ          |
| iii) | Active Ingredient        | : | Budesonide 100 mcg/dose & 200 mcg/dose |

We refer the above and kindly be informed that enclosed herewith are our manual submissions for Patient Information Leaflet (PIL) / Risalah Maklumat Ubat Pesakit (RiMUP) for GIONA EASYHALER.

Person-In-Charge  
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Thank you.

With best regards,

**Deeparkshri Gopal Krishnan**  
Regulatory Affairs Manager

**Orion Pharma (MY) Sdn Bhd**

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