

RA Department

From: Farmakovigilans (Unit Risk Communication (RiMUP)) <rimup@npra.gov.my>
Sent: Thursday, 6 December, 2018 11:32 AM
To: reg@royce-pharma.com
Subject: Erymin -400 Tablet Rimups
Attachments: RiMUP-ErymT400 (ENG) 240918.pdf; RiMUP-ErymT400 (BM) 240918.pdf

Dear Ms Huda,

I have rejected the **Erymin-400 Tablet rimups** today as the approved PI was not updated with the directive issued on 12 Dec 2017. Please refer to Directive Bil. (33) dlm. BPFK/PPP/07/25 Jld 1 in NPRA website.

This is a TOTAL REJECTION for **Erymin-400 Tablet rimups** RiMUP as you need to proceed with variation submission to update the PI and relevant section A as soon as possible. The evaluation will only resume after they are updated accordingly.

For the following submission for this product after the variation is approved, please submit the clean copy of RiMUPs with cover letter hardcopy manually to us.

Do contact me if you have any further queries.

Thank you.

Regards,

Bavahrni

Pharmacovigilance section |

Centre for Post Registration and Cosmetic Control |

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