

Mepharm (Malaysia) Sdn. Bhd. (349607-D)

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11th June 2020

Senior Principal Assistant Director
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U/P: Dr. Azuana Ramli

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Puan,

Draf Risalah Maklumat untuk Pengguna (RiMUP)

Product: Olfen-100 SR Depocaps

Registration No. MAL 19986450AZ

We would like to submit the draft copy of the Patient Information Leaflet (PIL) or RiMUP for your approval.

We were requested by the Centre of Product & Cosmetic Evaluation (PPPK) to update the product package insert with information on the cardiovascular adverse effects for diclofenac products (Rujukan (30) dlm. BPFK/PPP/07/25) and at the same time we have also included the latest required information regarding the risks of anastomotic leakage and Kounis Syndrome (Rujukan (4) dlm. BPFK/PPP/07/25 Jld.4).

As such please find attached the draft copy of the PIL or RiMUP for English version and Malay version for your approval.

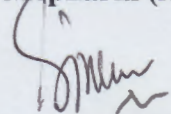
Kindly advise us the BPFK approval numbers for these 2 PIL or RiMUP. Please also inform us if there are any amendments on the PIL or RiMUP.

We look forward to hearing from you on the above matter.

Sekian, terima kasih.

Yours sincerely,

Mepharm (Malaysia) Sdn. Bhd.



Simon Wong
Pharmacist