

Date: 10 Dec 2019

Title	Inner label REKOVELLE 36mcg/1.08ml Prefilled pen		
Item N°	N/A	Perigord N°	359489
Proof N°	02	Barcode N°	N/A
Approving Country	MY	Dimensions	56 X 63 mm
Colours	P Pro Black, P Pro Blue, P. 382.		

Proposed packaging material	
Code	REKO36-L-MY-01.02
Size	56 x 63 mm
Submission	☒ NDA ☐ Renewal ☐ Variation change detail no.:
Code of previous version	REKO36-L-MY-01.01
Changes	NDA 2nd Def: align the name of the product on inner label with the proposed name for registration.
	☐ CCDS version: ☐ Core PIL version: ☐ SPC country/version/date: ☐ LAC no.:
Name & Date	JIWO, 17-Dec-2019

Rekovelle® 36 mcg/1.08 mL Solution for injection in a pre-filled pen folitropin delta Subcutaneous use After first use: Use within 28 days. Store at or below 30°C.	Batch No: Exp. Date: Mfg. Date:.  FERRING FOLLITROPIN DELTA PR-XXX