

Date: 10 Dec 2019

Title	Inner Label REKOVELLE 12 mcg/0.36ml Solution for injection in pre-filled pen MY (NDA)		
Item N°	N/A	Perigord N°	360021
Proof N°	02	Barcode N°	N/A
Approving Country	MY	Dimensions	56 X 63 mm
Colours	P Pro Black, P 270, P Pro Blue		

Proposed packaging material	
Code	REKO12-L-MY-01.02
Size	56x63 mm
Submission	☒ NDA ☐ Renewal ☐ Variation change detail no.:
Code of previous version	REKO12-L-MY-01.02
Changes	NDA 2 nd 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	JWJO, 17-Dec-2019

Rekovelle® 12 mcg/0.36 mL Solution for injection in a pre-filled pen follitropin delta Subcutaneous use After first use: Use within 28 days. Store at or below 30°C. FEERING Formulation Batch No: Exp. Date: Mfg. Date: PH-X-XXX	
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