

Proposed packaging material	
Code	16-L-MY-01.01
Size	43 x 85mm
Submission	☐ NDA ☐ Renewal ☒ Variation change detail no.: MES-15-001.
Code of previous version	16-L-(HK,MY)-01.01
Changes	Requested by NPRA align storage condition as per PI.
	☐ CCDS version: ☐ SPC country/version/date:
	☐ Core PIL version: ☐ LAC no.:
Name & Date	JWVO, 24-July-2017

Exp. Date: Batch No.: Mfg. Date:	Manufacturer: FERRING Léeiva, a.s., Czech Republic	1 enema Pentasa® 1 g Mesalazine1g Constit purified water ad100ml Dosage: As directed by physician Shake well before use Store below 30°C. Do not refrigerate or freeze. Store in the original package, as the product is sensitive to light. KEEP OUT OF REACH OF CHILDREN
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