

	Company	Janssen Pharmaceutica NV
	Vaccine Brand Name	No name yet
Vaccine form	Nb of doses/vial	Current thinking based on regimen: 5 doses / vial
	Quantity of antigen/dose	Final dosing to be established on the basis of results of (ongoing) Phase III trials. Current assumption: Either (i) two separate injections of up to 1x10 <sup>11</sup> viral particles (two doses, given with a time interval of a few weeks) or (ii) one single injection of up to 1x10 <sup>11</sup> viral particles (one dose)
	Vial size	2R vial
	Form	Liquid
	Volume/dose	0.5 ml
	Adjuvant	No
	Diluent component	N/A since no diluent for reconstitution needed
Storage conditions	<i>Active ingr:</i> Vaccine product; temp. during transportation	2-8C
	<i>Active ingr:</i> - Vaccine product; temp. during storage	2-8C
	<i>Active ingr:</i> Vaccine product; duration of storage	3 months; option to extend as more real time stability data will become available.
	<i>Diluent:</i> Temp. during transportation	N/A
	<i>Diluent:</i> Temp. during storage	N/A
	<i>Diluent:</i> Duration of storage	N/A
Administration	Storage conditions after reconstitution	Liquid, no reconstitution
	Administration route	IM
	Stability after reconstitution	N/A; Liquid, no reconstitution
	Additional comments on administration	Vaccine to be used within four (4) to six (6) hours after administration of the first dose of the vial; provided the Vaccine Regimens are kept refrigerated during the administration of doses in accordance with Specifications.
Logistics	Units / Collector boxes	5.1.1c
	Boxes / Shippers	
	Palette	