

AS03- as03 injection, solution
GlaxoSmithKline Biologicals SA

SPL UNCLASSIFIED SECTION

Health Care Professional and Patient Fact Sheets are not available at this time.

PRINCIPAL DISPLAY PANEL

NDC 58160-855-19

AS03 Adjuvant Component

NOTICE: NOT TO BE USED ALONE

**One vial of AS03 Adjuvant Component and one vial of Antigen Component
MUST BE COMBINED BEFORE USE.**

10 Vials of AS03 Adjuvant Component

One vial of AS03 Adjuvant Component must be added to one vial of Antigen Component to form ten 0.5-mL doses of vaccine.

Rx only

Rev. 11/20

504407

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AS03

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Product Information

Product Type	VACCINE	Item Code (Source)	NDC:58160-855
Route of Administration	INTRAMUSCULAR		

Ingredients

Ingredient Kind	Ingredient Name	Quantity
ADJV	SQUALENE (UNII: 7QWM220FJH)	
ADJV	.ALPHA.-TOCOPHEROL, DL- (UNII: 7QWA1RIO01)	
ADJV	POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58160-855-19	10 in 1 CARTON		
1	NDC:58160-855-01	2.5 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		11/10/2020	

Labeler - GlaxoSmithKline Biologicals SA (372748392)

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