

**AS03- as03 injection, solution**  
**GlaxoSmithKline Biologicals SA**

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**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.**

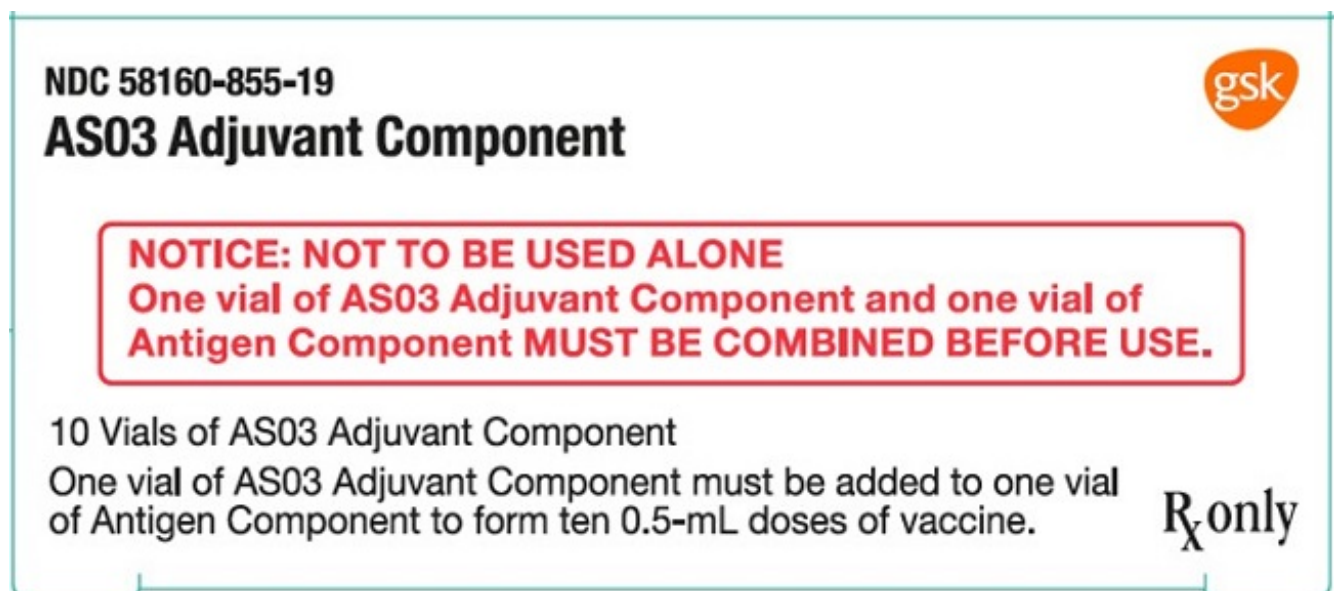
10 Vials of AS03 Adjuvant Component

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

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The image shows a rectangular box representing the principal display panel for the AS03 Adjuvant Component. The box has a light blue border. In the top left corner, it displays "NDC 58160-855-19" and "AS03 Adjuvant Component" in bold black text. In the top right corner, there is the GSK logo, which consists of the letters "gsk" in white inside an orange circle. In the center of the box, there is a red-bordered rectangle containing the text "NOTICE: NOT TO BE USED ALONE" in bold red uppercase letters, followed by "One vial of AS03 Adjuvant Component and one vial of Antigen Component MUST BE COMBINED BEFORE USE." in bold red uppercase letters. Below this red-bordered box, the text "10 Vials of AS03 Adjuvant Component" and "One vial of AS03 Adjuvant Component must be added to one vial of Antigen Component to form ten 0.5-mL doses of vaccine." is written in black. In the bottom right corner of the box, the text "Rx only" is written in a large, black, serif font.

**AS03**

as03 injection, solution

**Product Information**

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

**Ingredients**

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

**Packaging**

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
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**

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

**Labeler** - GlaxoSmithKline Biologicals SA (372748392)

Revised: 1/2024

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