

H1N1 FLU

Slow the spread!

H1N1 Vaccine:

Technical Questions & Answers

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October 14, 2009

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In what format will the vaccine be packaged/shipped?

Each pack contains:

1 carton of 50 vials of antigen

2 cartons of 25 vials of adjuvant

Each vial contains 10 doses

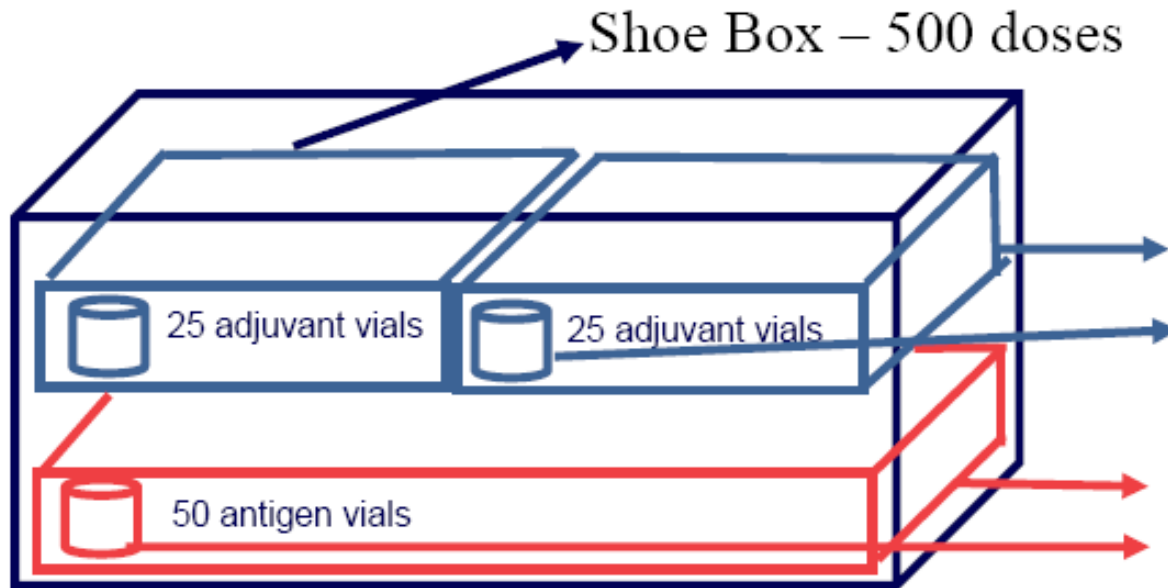
1 shipping box contains:

8 packs

4000 injectable doses

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Flip cap colours:

Unadjuvanted antigen - Avocado

Adjuvanted antigen - Purple

Adjuvant - Peach

Fluviral - Red



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What supplies are required to make up the vaccine?

- 1 syringe (5mL) + needle 20G (1" or 1 ½") to transfer adjuvant into antigen vial
- 10 syringes (1 mL) + 1 needle 20G (1" or 1 ½") to withdraw 0.5mL dose
- 10 needles 25G (1") for vaccine injection in patients.

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The adjuvanted H1N1 vaccine is a **2 component vaccine in separate glass vials, consisting of:**

-One multi-dose vial containing the antigen suspension: a colourless light opalescent liquid.

-A second vial containing the adjuvant emulsion: a whitish homogenous liquid.



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Instructions for mixing and administration of the vaccine:

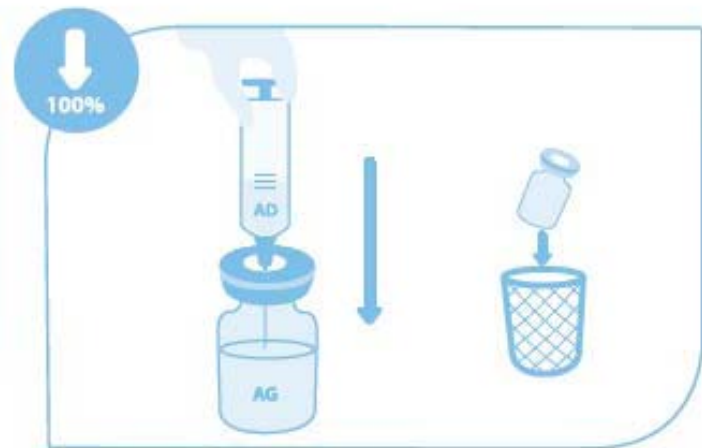
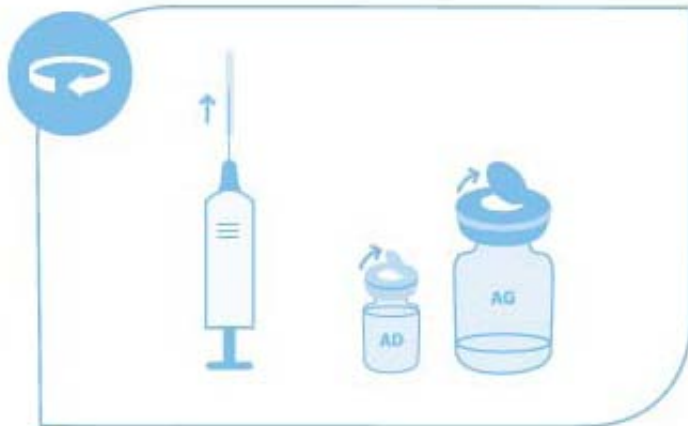
1. Before mixing the two components, the emulsion and suspension should be shaken and inspected visually for any foreign particulate matter and/or abnormal physical appearance.



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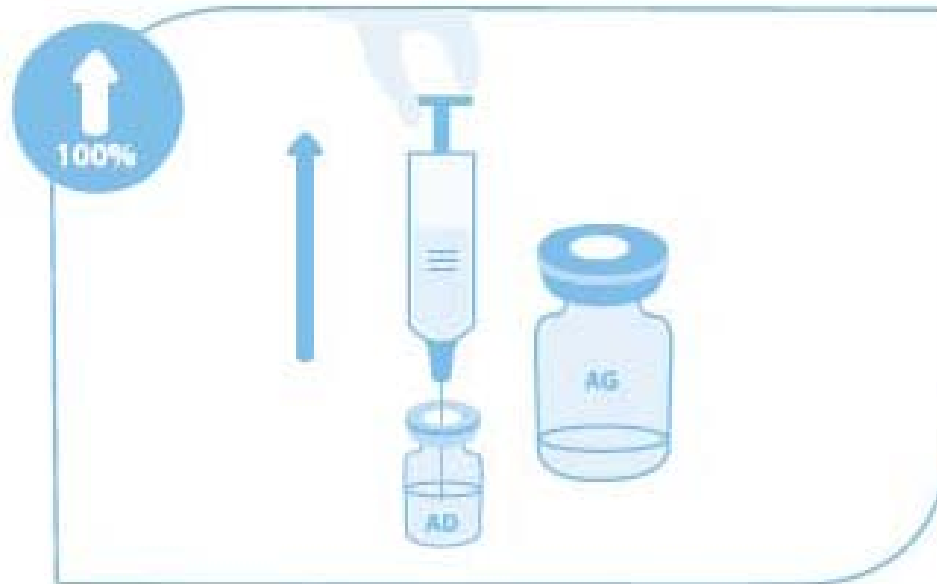
2. The vaccine is mixed by vertically withdrawing the entire contents of the vial containing the adjuvant emulsion by means of a syringe and by injecting it into the vial containing the antigen suspension.



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NOTE: Vertical withdrawal is recommended than inverting the vial to withdraw its contents.



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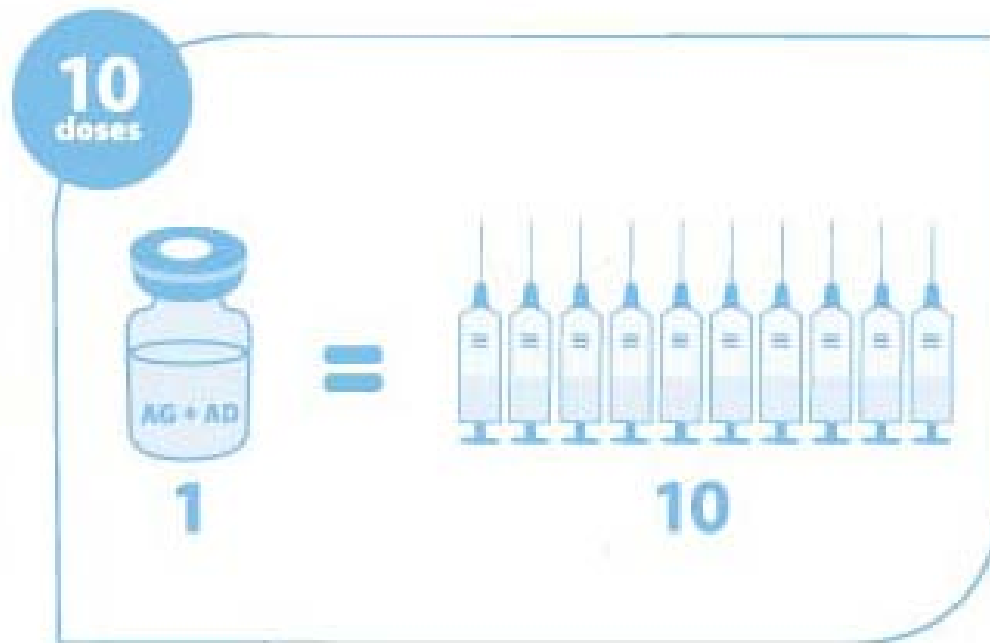
3. The mixture should be well shaken. The mixed vaccine is a whitish emulsion. In the event that discoloration or foreign particles are observed after mixing, discard the vaccine.



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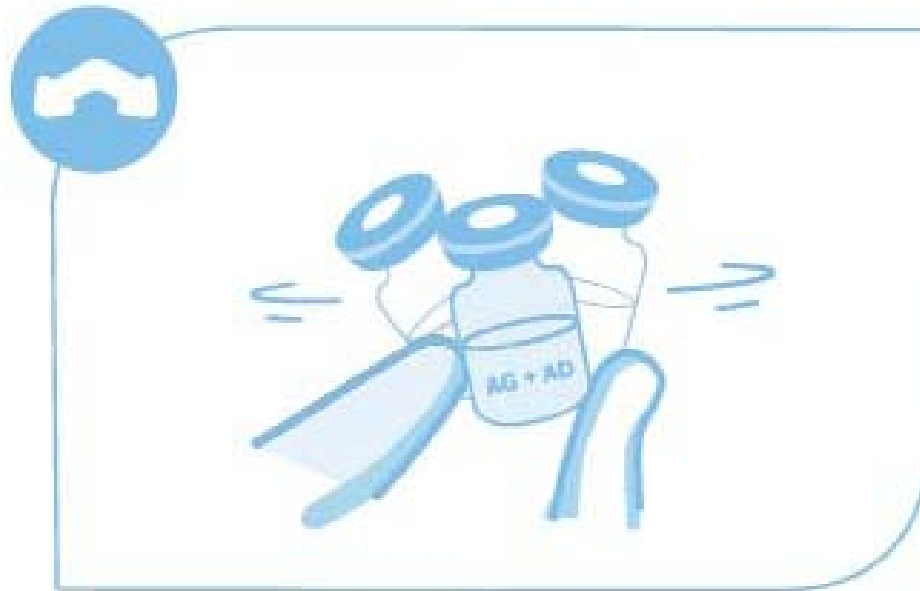
4. The volume of AS03-adjuvanted H1N1 Influenza Vaccine (5 mL) after mixing is sufficient to provide 10 doses of vaccine.



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5. The vial should be shaken prior to each administration.



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6. Each vaccine dose of 0.5 mL is withdrawn into a 1mL syringe for injection.



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7. The needle used for withdrawal must be replaced by a needle suitable for intramuscular injection.

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Dosing & Schedule

- 6 months to 9 years (2 doses of .25 mgs adjuvanted)
- 10 years and over (one dose of .5 mgs Adjuvanted)
- Over 65 years (one dose of .5 mgs adjuvanted)
- Pregnant women (one dose of adjuvanted)
 - If H1N1 activity is high offer all pregnant women over 20 weeks gestation adjuvanted vaccine.

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Consent:

Informed Verbal

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Adverse Events - Adults 18+* H5N1 AS03 Vaccine

Uncommon ($\geq 1/1000$ to $< 1/100$)	Common ($\geq 1/100$ to $< 1/10$)	Very Common ($\geq 1/10$)
Insomnia	Lymphadenopathy	Headache
Paresthesia	Bruising at site	Arthralgia
Somnolence	Sweating increased	Myalgia
Dizziness	Shivering	Induration
G.I. symptoms	ILI	Swelling
Pruritus, rash		Pain
Malaise		Redness
		Fever
		Fatigue

*n= ~5,000. Source: GSK Summary of Product Characteristics (Dresden vaccine)

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Surveillance

- We will have an active surveillance system for adverse events.
- It is very important that we report all adverse events.
- Written reminders.
- Flu-line will capture reports real-time.

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FREQUENTLY ASKED QUESTIONS

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How long is the vaccine stable when mixed?

-After mixing, the vaccine should be used within 24 hours.

-It is recommended to maintain the mixed product between 2°C and 8°C.

What are the storage temperatures?

-Store the product between 2°C and 8°C. Do not freeze. Keep protected from light.

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Does the vaccine contain the preservative, thimerosal?

-Yes. Thimerosal, a mercury derivative (5 μ g per dose), is used as a preservative.

-Thiomersal remains the most effective preservative.

-A thimerosal-free vaccine will NOT be available.

Note: WHO's Global Advisory Committee on Vaccine Safety concluded that there is currently no evidence of mercury toxicity in infants, children, or adults exposed to thiomersal in vaccines.

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What is the rubber stopper made of?

Butyl rubber, Latex free

Is the vaccine inactivated?

Yes

Interval between doses?

Wait 4 weeks before administering the seasonal flu vaccine. Other vaccines i.e. Pneumovax can be given simultaneously.

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Why is there an adjuvant included the pandemic 2009 H1N1 vaccine?

- The need for antigen-sparing in order to maximize number of doses to meet the global demand for vaccine, based on a limited amount of antigen.
- The need for rapid initiation of protection.
- The need to induce immunity to other variants of influenza A(H1N1). (Cross-clade protection)

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Adjuvants, from the Latin word *adjuvare* meaning 'to help', are *compounds used to enhance a vaccine's ability to elicit a strong, durable, protective immune response making them more effective.*

- Conventional vaccine adjuvants were aluminium salts.
- However, aluminium adjuvants were limited in their immunogenic strength.
- The new adjuvants are more powerful.
- AS03 adjuvant, tocopherol oil-in-water based emulsion, is used to induce high antibody titres with a very low antigen dosage.
- It has been used to develop H5N1 (Avian Vaccine) & a more effective Influenza Vaccine for the elderly (UK).
- An AS04 is used in Hepatitis B & Cervarix.

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Will there be a non adjuvanted vaccine available?

-A small quantity of un-adjuvanted vaccine will be available mid-November for pregnant women (1 dose).