

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use AFLURIA® safely and effectively. See full prescribing information for AFLURIA®.

AFLURIA®, Influenza Virus Vaccine
Suspension for Intramuscular Injection
2008-2009 Formula
Initial U.S. Approval: 2007

INDICATIONS AND USAGE

- AFLURIA® is an inactivated influenza virus vaccine indicated for active immunization of persons ages 18 years and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine. (1)
- This indication is based on the immune response elicited by AFLURIA®; there have been no controlled clinical studies demonstrating a decrease in influenza disease after vaccination with AFLURIA®. (14)

DOSAGE AND ADMINISTRATION

- A single 0.5 mL dose for intramuscular injection. (2)

DOSAGE FORMS AND STRENGTHS

AFLURIA®, a sterile suspension for intramuscular injection, is supplied in two presentations:

- 0.5 mL preservative-free, single-dose, pre-filled syringe. (3)
- 5 mL multi-dose vial containing ten doses. Thimerosal, a mercury derivative, is added as a preservative; each 0.5 mL dose contains 24.5 micrograms (mcg) of mercury. (3)

Each 0.5 mL dose contains 15 mcg of influenza virus hemagglutinin (HA) from each of the three strains: A/Brisbane/59/2007 (H1N1), A/Uruguay/716/2007 (H3N2), and B/Florida/4/2006. (3, 11)

CONTRAINDICATIONS

- Hypersensitivity to eggs or chicken protein, neomycin, or polymyxin, or life-threatening reaction to previous influenza vaccination. (4)

WARNINGS AND PRECAUTIONS

- If Guillain-Barré Syndrome (GBS) has occurred within 6 weeks of previous influenza vaccination, the decision to give AFLURIA® should be based on careful consideration of the potential benefits and risks. (5.1)
- Immunocompromised persons may have a diminished immune response to AFLURIA®. (5.2)

ADVERSE REACTIONS

The most common (≥ 10%) local (injection-site) adverse reactions were tenderness, pain, redness, and swelling. The most common (≥ 10%) systemic adverse reactions were headache, malaise, and muscle aches. (6)

To report SUSPECTED ADVERSE REACTIONS, contact CSL Biotherapies at 1-888-435-8633 or VAERS at 1-800-822-7967 and www.vaers.hhs.gov.

DRUG INTERACTIONS

- Do not mix with any other vaccine in the same syringe or vial. (7.1)
- Immunosuppressive therapies may diminish the immune response to AFLURIA®. (7.2)

USE IN SPECIFIC POPULATIONS

- Safety and effectiveness of AFLURIA® have not been established in pregnant women or nursing mothers and in the pediatric population. (8.1, 8.3, 8.4)
- Antibody responses were lower in geriatric subjects than in younger subjects. (8.5)

See 17 for PATIENT COUNSELING INFORMATION.

Revised: XX/2008

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1 FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

AFLURIA® is an inactivated influenza virus vaccine indicated for active immunization of persons ages 18 years and older against influenza disease caused by influenza virus subtypes A and type B present in the vaccine.

This indication is based on the immune response elicited by AFLURIA®; there have been no controlled clinical studies demonstrating a decrease in influenza disease after vaccination with AFLURIA® (*see Clinical Studies [14]*).

2 DOSAGE AND ADMINISTRATION

2.1 Prior to Administration

AFLURIA® should be inspected visually for particulate matter and discoloration prior to administration (*see Description [11]*), whenever suspension and container permit. If either of these conditions exists, the vaccine should not be administered. Any vaccine that has been frozen or is suspected of being frozen must not be used.

2.2 Administration

When using the preservative-free, single-dose syringe, shake the syringe thoroughly and administer the dose immediately.

When using the multi-dose vial, shake the vial thoroughly before withdrawing each dose, and administer the dose immediately. Between uses, store the vial at 2–8°C (36–46°F) (*see How Supplied/Storage and Handling [16]*). Once the stopper has been pierced, the vial must be discarded within 28 days.

AFLURIA® should be administered as a single 0.5 mL intramuscular injection, preferably in the deltoid muscle of the upper arm.

3 DOSAGE FORMS AND STRENGTHS

AFLURIA® is a sterile suspension for intramuscular injection. Each 0.5 mL dose contains 15 micrograms (mcg) of influenza virus hemagglutinin (HA) from each of the three influenza virus strains included in the vaccine (*see Description [11]*).

AFLURIA® is supplied in two presentations:

- 0.5 mL preservative-free, single-dose, pre-filled syringe.
- 5 mL multi-dose vial containing ten doses. Thimerosal, a mercury derivative, is added as a preservative; each 0.5 mL dose contains 24.5 mcg of mercury.

4 CONTRAINDICATIONS

AFLURIA® is contraindicated in individuals with known hypersensitivity to eggs or chicken protein, neomycin, or polymyxin, or in anyone who has had a life-threatening reaction to previous influenza vaccination.

5 WARNINGS AND PRECAUTIONS

5.1 Guillain-Barré Syndrome (GBS)

If GBS has occurred within 6 weeks of previous influenza vaccination, the decision to give AFLURIA® should be based on careful consideration of the potential benefits and risks.

5.2 Altered Immunocompetence

If AFLURIA® is administered to immunocompromised persons, including those receiving immunosuppressive therapy, the immune response may be diminished.

5.3 Preventing and Managing Allergic Reactions

Appropriate medical treatment and supervision must be available to manage possible anaphylactic reactions following administration of the vaccine.

5.4 Limitations of Vaccine Effectiveness

Vaccination with AFLURIA® may not protect all individuals.

6 ADVERSE REACTIONS

6.1 Overall Adverse Reactions

Serious allergic reactions, including anaphylactic shock, have been observed during postmarketing surveillance in individuals receiving AFLURIA®.

80 The most common local (injection-site) adverse reactions observed in clinical studies
81 with AFLURIA® were tenderness, pain, redness, and swelling. The most common systemic
82 adverse reactions observed were headache, malaise, and muscle aches.

83 84 **6.2 Safety Experience from Clinical Studies**

85 Because clinical studies are conducted under widely varying conditions, adverse reaction
86 rates observed in the clinical studies of a vaccine cannot be directly compared to rates in the
87 clinical studies of another vaccine and may not reflect the rates observed in clinical practice.

88
89 Clinical safety data for AFLURIA® have been obtained in two clinical studies (*see*
90 *Clinical Studies [14]*).

91
92 A US study (Study 1) included 1,357 subjects for safety analysis, ages 18 to less than 65
93 years, randomized to receive AFLURIA® (1,089 subjects) or placebo (268 subjects) (*see*
94 *Clinical Studies [14] for study demographics*). There were no deaths or serious adverse events
95 reported in this study.

96
97 A UK study (Study 2) included 275 subjects, ages 65 years and older, randomized to
98 receive preservative-free AFLURIA® (206 subjects) or a European-licensed trivalent
99 inactivated influenza vaccine as an active control (69 subjects) (*see Clinical Studies [14]*).
100 There were no deaths or serious adverse events reported in this study.

101
102 The safety assessment was identical for the two studies. Local (injection-site) and
103 systemic adverse events were solicited by completion of a symptom diary card for 5 days post-
104 vaccination (Table 1). Unsolicited local and systemic adverse events were collected for 21
105 days post-vaccination (Table 2). These unsolicited adverse events were reported either
106 spontaneously or when subjects were questioned about any changes in their health post-
107 vaccination. All adverse events are presented regardless of any treatment causality assigned by
108 study investigators.
109

110 **Table 1: Proportion of Subjects With Solicited Local or Systemic Adverse Events* Within**
 111 **5 Days After Administration of AFLURIA® or Placebo, Irrespective of**
 112 **Causality†**
 113

Solicited Adverse event	Study 1 Subjects ≥ 18 to < 65 years		Study 2 Subjects ≥ 65 years
	AFLURIA®‡ n=1089	Placebo§ n=268	AFLURIA® n=206
Local			
Tenderness¶	60%	18%	34%
Pain¶	40%	9%	9%
Redness	16%	8%	23%
Swelling	9%	1%	11%
Bruising	5%	1%	4%
Systemic			
Headache	26%	26%	15%
Malaise	20%	19%	10%
Muscle aches	13%	9%	14%
Nausea	6%	9%	3%
Chills/ Shivering	3%	2%	7%
Fever ≥ 37.7°C (99.86°F)	1%	1%	1%
Vomiting	1%	1%	0%

114 * In Study 1, 87% of solicited local and systemic adverse events were mild, 12% were moderate, and 1% were severe. In
 115 Study 2, 76.5% were mild, 20.5% were moderate, and 3% were severe. In both studies, most solicited local and systemic
 116 adverse events lasted no longer than 2 days.

117 † Values rounded to the nearest whole percent.

118 ‡ Includes subjects who received either the single-dose (preservative-free) or multi-dose formulation of AFLURIA®.

119 § Thimerosal-containing placebo.

120 ¶ Tenderness defined as pain on touching.

121 ¶ Pain defined as spontaneously painful without touch.

122

123 **Table 2: Adverse Events* Reported Spontaneously by ≥ 1% of Subjects Within 21 Days**
 124 **After Administration of AFLURIA® or Placebo, Irrespective of Causality†**
 125

Adverse Event	Study 1 Subjects ≥ 18 to < 65 years		Study 2 Subjects ≥ 65 years
	AFLURIA®‡ n=1089	Placebo§ n=268	AFLURIA® n=206
Headache	8%	6%	8%
Nasal Congestion	1%	1%	7%
Cough	1%	0.4%	5%
Rhinorrhea	1%	1%	5%
Pharyngolaryngeal Pain	3%	1%	5%
Reactogenicity Event	3%	3%	0%
Diarrhea	2%	3%	1%
Back Pain	2%	0.4%	2%
Upper Respiratory Tract Infection	2%	1%	0.5%
Viral Infection	0.4%	1%	0%
Lower Respiratory Tract Infection	0%	0%	1%
Myalgia	1%	1%	1%
Muscle Spasms	0.4%	1%	0%

126 * In Study 1, 63% of unsolicited adverse events were mild, 35% were moderate, and 2% were severe. In Study 2, 47% were
 127 mild, 51% were moderate, and 3% were severe. In both studies, most unsolicited adverse events lasted no longer than 5 days.

128 † Values greater than 0.5% rounded to the nearest whole percent.

129 ‡ Includes subjects who received either the single-dose (preservative-free) or multi-dose formulation of AFLURIA®.

130 § Thimerosal-containing placebo.

131

132 **6.3 Postmarketing Experience**

133 Because postmarketing reporting of adverse reactions is voluntary and from a population
 134 of uncertain size, it is not always possible to reliably estimate their frequency or establish a
 135 causal relationship to vaccine exposure. The adverse reactions described have been included in
 136 this section because they: 1) represent reactions that are known to occur following
 137 immunizations generally or influenza immunizations specifically; 2) are potentially serious; or
 138 3) have been reported frequently. The following adverse reactions also include those identified
 139 during postapproval use of AFLURIA® outside the US since 1985.

140

141 **Blood and lymphatic system disorders**

142 Transient thrombocytopenia

143

144 **Immune system disorders**

145 Allergic reactions including anaphylactic shock and serum sickness

146

147 Nervous system disorders

148 Neuralgia, paresthesia, and convulsions; encephalopathy, neuritis or neuropathy, transverse
149 myelitis, and GBS

150

151 Vascular disorders

152 Vasculitis with transient renal involvement

153

154 Skin and subcutaneous tissue disorders

155 Pruritus, urticaria, and rash

156

157 General disorders and administration site conditions

158 Influenza-like illness (e.g., pyrexia, chills, headache, malaise, myalgia), injection-site
159 inflammation (e.g., pain, erythema, swelling, warmth), and induration

160

161 6.4 Other Adverse Reactions Associated With Influenza Vaccination

162 Anaphylaxis has been reported after administration of AFLURIA®. Although
163 AFLURIA® contains only a limited quantity of egg protein, this protein can induce immediate
164 hypersensitivity reactions among persons who have severe egg allergy. Allergic reactions
165 include hives, angioedema, allergic asthma, and systemic anaphylaxis (*see Contraindications*
166 *[4]*).

167

168 The 1976 swine influenza vaccine was associated with an increased frequency of GBS.
169 Evidence for a causal relation of GBS with subsequent vaccines prepared from other influenza
170 viruses is unclear. If influenza vaccine does pose a risk, it is probably slightly more than one
171 additional case per 1 million persons vaccinated.

172

173 Neurological disorders temporally associated with influenza vaccination, such as
174 encephalopathy, optic neuritis/neuropathy, partial facial paralysis, and brachial plexus
175 neuropathy, have been reported.

176

177 Microscopic polyangiitis (vasculitis) has been reported temporally associated with
178 influenza vaccination.

179

180

181 7 DRUG INTERACTIONS

182

183 7.1 Concurrent Use With Other Vaccines

184 There are no data to assess the concomitant administration of AFLURIA® with other
185 vaccines. If AFLURIA® is to be given at the same time as another injectable vaccine(s), the
186 vaccine(s) should be administered at different injection sites.

187

AFLURIA® should not be mixed with any other vaccine in the same syringe or vial.

7.2 Concurrent Use With Immunosuppressive Therapies

The immunological response to AFLURIA® may be diminished in individuals receiving corticosteroid or immunosuppressive therapies.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C: Animal reproduction studies have not been conducted with AFLURIA®. It is also not known whether AFLURIA® can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. AFLURIA® should be given to a pregnant woman only if clearly needed.

8.3 Nursing Mothers

AFLURIA® has not been evaluated in nursing mothers. It is not known whether AFLURIA® is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when AFLURIA® is administered to a nursing woman.

8.4 Pediatric Use

Safety and effectiveness in the pediatric population have not been established.

8.5 Geriatric Use

In four clinical studies, 343 subjects ages 65 years and older received AFLURIA®. Hemagglutination-inhibiting (HI) antibody responses in geriatric subjects were lower after administration of AFLURIA® in comparison to younger adult subjects (*see Clinical Studies [14]*). Adverse event rates were generally similar in frequency to those reported in subjects ages 18 to less than 65 years, although some differences were observed (*see Adverse Reactions [6.2]*).

11 DESCRIPTION

AFLURIA®, Influenza Virus Vaccine for intramuscular injection, is a sterile, clear, colorless to slightly opalescent suspension with some sediment that resuspends upon shaking to form a homogeneous suspension. AFLURIA® is prepared from influenza virus propagated in the allantoic fluid of embryonated chicken eggs. Following harvest, the virus is purified in a sucrose density gradient using a continuous flow zonal centrifuge. The purified virus is inactivated with beta-propiolactone, and the virus particles are disrupted using sodium

228 taurodeoxycholate to produce a “split virion”. The disrupted virus is further purified and
229 suspended in a phosphate buffered isotonic solution.

230

231 AFLURIA® is standardized according to USPHS requirements for the 2008-2009
232 influenza season and is formulated to contain 45 mcg HA per 0.5 mL dose in the recommended
233 ratio of 15 mcg HA for each of the three influenza strains recommended for the 2008-2009
234 Northern Hemisphere influenza season: A/H1N1 (A/Brisbane/59/2007), A/H3N2
235 (A/Uruguay/716/2007), and influenza B (B/Florida/4/2006).

236

237 The single-dose formulation is preservative-free; thimerosal, a mercury derivative, is not
238 used in the manufacturing process for this formulation. The multi-dose formulation contains
239 thimerosal, added as a preservative; each 0.5 mL dose contains 24.5 mcg of mercury.

240

241 A single 0.5 mL dose of AFLURIA® contains sodium chloride (4.1 mg), monobasic
242 sodium phosphate (80 mcg), dibasic sodium phosphate (300 mcg), monobasic potassium
243 phosphate (20 mcg), potassium chloride (20 mcg), and calcium chloride (1.5 mcg). From the
244 manufacturing process, each dose may also contain residual amounts of sodium
245 taurodeoxycholate (≤ 10 ppm), ovalbumin (≤ 1 mcg), neomycin sulfate (≤ 0.2 picograms [pg]),
246 polymyxin B (≤ 0.03 pg), and beta-propiolactone (< 25 nanograms).

247

248 The rubber tip cap and plunger used for the preservative-free, single-dose syringes and
249 the rubber stoppers used for the multi-dose vial contain no latex.

250

251

252 **12 CLINICAL PHARMACOLOGY**

253

254 **12.1 Mechanism of Action**

255 Influenza illness and its complications follow infection with influenza viruses. Global
256 surveillance of influenza identifies yearly antigenic variants. For example, since 1977
257 antigenic variants of influenza A (H1N1 and H3N2) and influenza B viruses have been in
258 global circulation. Specific levels of HI antibody titers post-vaccination with inactivated
259 influenza virus vaccine have not been correlated with protection from influenza virus. In some
260 human studies, antibody titers of 1:40 or greater have been associated with protection from
261 influenza illness in up to 50% of subjects.^{1,2}

262

263 Antibody against one influenza virus type or subtype confers limited or no protection
264 against another. Furthermore, antibody to one antigenic variant of influenza virus might not
265 protect against a new antigenic variant of the same type or subtype. Frequent development of
266 antigenic variants through antigenic drift is the virologic basis for seasonal epidemics and the
267 reason for the usual change to one or more new strains in each year’s influenza vaccine.
268 Therefore, inactivated influenza vaccines are standardized to contain the HA of three strains

269 (i.e., typically two type A and one type B) representing the influenza viruses likely to be
270 circulating in the US during the upcoming winter.

271
272 Annual revaccination with the current vaccine is recommended because immunity
273 declines during the year after vaccination and circulating strains of influenza virus change from
274 year to year.³

275

276

277 **13 NONCLINICAL TOXICOLOGY**

278

279 **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

280 AFLURIA® has not been evaluated for carcinogenic or mutagenic potential or for
281 impairment of fertility.

282

283

284 **14 CLINICAL STUDIES**

285

286 Three randomized, controlled clinical studies of AFLURIA® have evaluated the immune
287 responses (specifically, HI antibody titers) to each virus strain in the vaccine. In these studies,
288 post-vaccination immunogenicity was evaluated on sera obtained 21 days after administration
289 of AFLURIA®. No controlled clinical studies demonstrating a decrease in influenza disease
290 after vaccination with AFLURIA® have been performed.

291

292 The US study (Study 1) was a randomized, double-blinded, placebo-controlled,
293 multicenter study in healthy subjects ages 18 to less than 65 years. A total of 1,357 subjects
294 were vaccinated (1,089 subjects with AFLURIA® and 268 with a thimerosal-containing
295 placebo). Subjects receiving AFLURIA® were vaccinated using either a single-dose
296 (preservative-free) or multi-dose (one of three lots) formulation. The evaluable efficacy
297 population consisted of 1,341 subjects (1,077 in the AFLURIA® group and 264 in the placebo
298 group) with complete serological data who had not received any contraindicated medications
299 before the post-vaccination immunogenicity assessment. Among the evaluable efficacy
300 population receiving AFLURIA®, 37.5% were men and 62.5% were women. The mean age of
301 the entire evaluable population receiving AFLURIA® was 38 years; 73% were ages 18 to less
302 than 50 years and 27% were ages 50 to less than 65 years. Additionally, 81% of AFLURIA®
303 recipients were White, 12% Black, and 6% Asian.

304

305 In Study 1, the following co-primary immunogenicity endpoints were assessed: 1) the
306 lower bounds of the 2-sided 95% confidence intervals (CI) for the proportion of subjects with
307 HI antibody titers of 1:40 or greater after vaccination, which should exceed 70% for each
308 vaccine antigen strain; and 2) the lower bounds of the 2-sided 95% CI for rates of
309 seroconversion (defined as a 4-fold increase in post-vaccination HI antibody titers from pre-

310 vaccination titers of 1:10 or greater, or an increase in titers from less than 1:10 to 1:40 or
311 greater), which should exceed 40% for each vaccine antigen strain.

312
313 In subjects ages 18 to less than 65 years, serum HI antibody responses to AFLURIA® met
314 the pre-specified co-primary endpoint criteria for all three virus strains (Table 3). Clinical lot-
315 to-lot consistency was demonstrated for the single-dose (preservative-free) and multi-dose
316 formulations of AFLURIA®, showing that these formulations elicited similar immune
317 responses.

318
319 **Table 3: Study 1 – Serum HI Antibody Responses in Subjects ≥ 18 to < 65 Years**
320 **Receiving AFLURIA®**

321

Treatment Arm	Number Enrolled/ Evaluable	Vaccine Strain	Seroconversion Rate* (95% CI)	HI Titer ≥ 1:40† (95% CI)
All active AFLURIA® influenza vaccine formulations‡	1089/1077	H1N1	48.7% (45.6, 51.7)	97.8% (96.7, 98.6)
		H3N2	71.5% (68.7, 74.2)	99.9% (99.5, 100.0)
		B	69.7% (66.9, 72.5)	94.2% (92.7, 95.6)
Placebo	270/264	H1N1	2.3% (0.8, 4.9)	74.6% (68.9, 79.8)
		H3N2	0.0% (N/A)	72.0% (66.1, 77.3)
		B	0.4% (< 0.1, 2.1)	47.0% (40.8, 53.2)

322 * Seroconversion rate is defined as a 4-fold increase in post-vaccination HI antibody titer from pre-vaccination titer ≥ 1:10, or
323 an increase in titer from < 1:10 to ≥ 1:40. Lower bound of 95% CI for seroconversion should be > 40% for the study
324 population.

325 † HI titer ≥ 1:40 is defined as the proportion of subjects with a minimum post-vaccination HI antibody titer of 1:40. Lower
326 bound of 95% CI for HI antibody titer ≥ 1:40 should be > 70% for the study population.

327 ‡ Active formulations include aggregated results for the single-dose (preservative-free) and multi-dose formulations of
328 AFLURIA®.

329
330 The UK study (Study 2) was a randomized, controlled study that enrolled 275 healthy
331 subjects ages 65 years and older. This study compared AFLURIA® with a European-licensed
332 trivalent inactivated influenza vaccine as an active control. The evaluable efficacy population
333 consisted of 274 subjects (206 in the AFLURIA® group and 68 in the control group). Among
334 these subjects, 50% were men and 50% were women, with a mean age of 72 years (range: 65
335 to 93 years).

336 The co-primary immunogenicity endpoints for the seroconversion rate and the proportion
337 of subjects with a minimum post-vaccination HI antibody titer of 1:40 are presented in Table 4.
338

339
340 **Table 4: Study 2 – Serum HI Antibody Responses in Subjects ≥ 65 Years Receiving**
341 **AFLURIA®**
342

Number of Subjects	Vaccine Strain	Seroconversion Rate* (95% CI)	HI Titer ≥ 1:40† (95% CI)
206	H1N1	34.0% (27.5, 40.9)	85.0% (79.3, 89.5)
	H3N2	44.2% (37.3, 51.2)	99.5% (97.3, 100.0)
	B	45.6% (38.7, 52.7)	77.7% (71.4, 83.2)

343 * Seroconversion rate is defined as a 4-fold increase in post-vaccination HI antibody titer from pre-vaccination titer ≥ 1:10, or
344 an increase in titer from < 1:10 to ≥ 1:40. Lower bound of 95% CI for seroconversion should be > 30% for the study
345 population.

346 † HI titer ≥ 1:40 is defined as the proportion of subjects with a minimum post-vaccination HI antibody titer of 1:40. Lower
347 bound of 95% CI for HI antibody titer ≥ 1:40 should be > 60% for the study population.

348
349 A second UK study (Study 3) was a randomized, controlled study that enrolled 406
350 healthy subjects ages 18 years and older (stratified by age from 18 to less than 60 years and 60
351 years and older). This study compared AFLURIA® with a European-licensed trivalent
352 inactivated influenza vaccine as an active control. In a post-hoc analysis of different age
353 ranges, among subjects ages 18 to less than 65 years receiving AFLURIA® (146 subjects), 47%
354 were men and 53% were women, with a mean age of 48 years for all subjects. Among subjects
355 ages 65 years and older receiving AFLURIA® (60 subjects), 53% were men and 47% were
356 women, with a mean age of 71 years.

357
358 The post-hoc analysis of serum HI antibody responses showed that the lower bound of the
359 95% CI for subjects with HI antibody titers of 1:40 or greater after vaccination exceeded 70%
360 for each strain. HI antibody responses were lower in subjects ages 65 years and older after
361 administration of AFLURIA®. Serum HI antibody responses to the active control were similar
362 to those for AFLURIA® in both age groups.

363
364

365 **15 REFERENCES**

- 366
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- 370 antibody in protection against challenge infection with influenza A2 and B viruses.
- 371 *J Hyg Camb* 1972;70:767-777.
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- 373 Recommendations of the Advisory Committee on Immunization Practices (ACIP).
- 374 *MMWR Recomm Rep* 2007;56 (RR-6):1-53.
- 375

376

377 **16 HOW SUPPLIED/STORAGE AND HANDLING**

378

379 AFLURIA® is supplied as a 0.5 mL preservative-free, single-dose, pre-filled syringe

380 (packaged without needles) and as a 5 mL multi-dose vial containing ten 0.5 mL doses, with

381 thimerosal, a mercury derivative, added as a preservative; each 0.5 mL dose contains 24.5 mcg

382 of mercury.

383

Product Description

NDC Number

Package of ten 0.5 mL preservative-free, prefilled syringes

5 mL multi-dose vial

33332-008-01

33332-108-10

384

385 Store refrigerated at 2–8°C (36–46°F). Do not freeze. Protect from light. Do not use

386 AFLURIA® beyond the expiration date printed on the label.

387

388

389 **17 PATIENT COUNSELING INFORMATION**

- 390
- 391 • Inform the patient that AFLURIA® is an inactivated vaccine that cannot cause
 - 392 influenza but stimulates the immune system to produce antibodies that protect against
 - 393 influenza. The full effect of the vaccine is generally achieved approximately 3 weeks
 - 394 after vaccination. Annual revaccination is recommended.
 - 395 • Instruct the patient to report any severe or unusual adverse reactions to their healthcare
 - 396 provider.
- 397
- 398
- 399



400 Manufactured by:
401 **CSL Limited**
402 Parkville, Victoria, 3052, Australia
403 US License No. 1764
404
405
406 Distributed by:
407 **CSL Biotherapies Inc.**
408 King of Prussia, PA 19406 USA
409
410
411 AFLURIA is a registered trademark of CSL Limited.
412
413