

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
2007-2008 Formula
Initial U.S. Approval: XXXX**

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/Solomon Islands/3/2006 (H1N1), A/Wisconsin /67/2005 (H3N2), and B/Malaysia/2506/2004. (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.

Issued: XX/XXXX

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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.

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6 ADVERSE REACTIONS

6.1 Overall Adverse Reactions

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

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

6.2 Safety Experience from Clinical Studies

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

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

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

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

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

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 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 Causality†**
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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%

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

116 † Values rounded to the nearest whole percent.

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

118 § Thimerosal-containing placebo.

119 ¶ Tenderness defined as pain on touching.

120 ¶ Pain defined as spontaneously painful without touch.

121
 122 **Table 2: Adverse Events* Reported Spontaneously by ≥ 1% of Subjects Within 21 Days**
 123 **After Administration of AFLURIA® or Placebo, Irrespective of Causality†**
 124

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%

125 * In Study 1, 63% of unsolicited adverse events were mild, 35% were moderate, and 2% were severe. In Study 2, 47% were
 126 mild, 51% were moderate, and 3% were severe. In both studies, most unsolicited adverse events lasted no longer than 5 days.
 127 † Values greater than 0.5% rounded to the nearest whole percent.
 128 ‡ Includes subjects who received either the single-dose (preservative-free) or multi-dose formulation of AFLURIA®.
 129 § Thimerosal-containing placebo.

130
 131 **6.3 Postmarketing Experience**

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

139
 140 **Blood and lymphatic system disorders**
 141 Transient thrombocytopenia

142
 143 **Immune system disorders**
 144 Allergic reactions including anaphylactic shock and serum sickness

145
146 **Nervous system disorders**
147 Neuralgia, paresthesia, and convulsions; encephalopathy, neuritis or neuropathy, transverse
148 myelitis, and GBS

149
150 **Vascular disorders**
151 Vasculitis with transient renal involvement

152
153 **Skin and subcutaneous tissue disorders**
154 Pruritus, urticaria, and rash

155
156 **General disorders and administration site conditions**
157 Influenza-like illness (e.g., pyrexia, chills, headache, malaise, myalgia), injection-site
158 inflammation (e.g., pain, erythema, swelling, warmth), and induration

159 **6.4 Other Adverse Reactions Associated With Influenza Vaccination**

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

166
167 The 1976 swine influenza vaccine was associated with an increased frequency of GBS.
168 Evidence for a causal relation of GBS with subsequent vaccines prepared from other influenza
169 viruses is unclear. If influenza vaccine does pose a risk, it is probably slightly more than one
170 additional case per 1 million persons vaccinated.

171
172 Neurological disorders temporally associated with influenza vaccination, such as
173 encephalopathy, optic neuritis/neuropathy, partial facial paralysis, and brachial plexus
174 neuropathy, have been reported.

175
176 Microscopic polyangiitis (vasculitis) has been reported temporally associated with
177 influenza vaccination.

178 **7 DRUG INTERACTIONS**

180 **7.1 Concurrent Use With Other Vaccines**

181
182 There are no data to assess the concomitant administration of AFLURIA® with other
183 vaccines. If AFLURIA® is to be given at the same time as another injectable vaccine(s), the
184 vaccine(s) should be administered at different injection sites.

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

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

230 AFLURIA® is standardized according to USPHS requirements for the 2007-2008
231 influenza season and is formulated to contain 45 mcg HA per 0.5 mL dose in the recommended
232 ratio of 15 mcg HA for each of the three influenza strains recommended for the 2007-2008
233 Northern Hemisphere influenza season: A/H1N1 (A/Solomon Islands/3/2006), A/H3N2
234 (A/Wisconsin/67/2005), and influenza B (B/Malaysia/2506/2004).

235
236 The single-dose formulation is preservative-free; thimerosal, a mercury derivative, is not
237 used in the manufacturing process for this formulation. The multi-dose formulation contains
238 thimerosal, added as a preservative; each 0.5 mL dose contains 24.5 mcg of mercury.

239
240 A single 0.5 mL dose of AFLURIA® contains sodium chloride (4.1 mg), monobasic
241 sodium phosphate (80 mcg), dibasic sodium phosphate (300 mcg), monobasic potassium
242 phosphate (20 mcg), potassium chloride (20 mcg), and calcium chloride (1.5 mcg). From the
243 manufacturing process, each dose may also contain residual amounts of sodium
244 taurodeoxycholate (≤ 10 ppm), ovalbumin (≤ 0.10 mcg), neomycin sulfate (≤ 0.2 picograms
245 [pg]), polymyxin B (≤ 0.03 pg), and beta-propiolactone (< 25 nanograms).

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

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251 **12 CLINICAL PHARMACOLOGY**

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253 **12.1 Mechanism of Action**

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

261

262 Antibody against one influenza virus type or subtype confers limited or no protection
263 against another. Furthermore, antibody to one antigenic variant of influenza virus might not
264 protect against a new antigenic variant of the same type or subtype. Frequent development of
265 antigenic variants through antigenic drift is the virologic basis for seasonal epidemics and the
266 reason for the usual change to one or more new strains in each year's influenza vaccine.
267 Therefore, inactivated influenza vaccines are standardized to contain the HA of three strains
268 (i.e., typically two type A and one type B) representing the influenza viruses likely to be
269 circulating in the US during the upcoming winter.

270

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

274 275 276 **13 NONCLINICAL TOXICOLOGY**

277 278 **13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility**

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

281 282 283 **14 CLINICAL STUDIES**

284
285 Three randomized, controlled clinical studies of AFLURIA[®] have evaluated the immune
286 responses (specifically, HI antibody titers) to each virus strain in the vaccine. In these studies,
287 post-vaccination immunogenicity was evaluated on sera obtained 21 days after administration
288 of AFLURIA[®]. No controlled clinical studies demonstrating a decrease in influenza disease
289 after vaccination with AFLURIA[®] have been performed.

290
291 The US study (Study 1) was a randomized, double-blinded, placebo-controlled,
292 multicenter study in healthy subjects ages 18 to less than 65 years. A total of 1,357 subjects
293 were vaccinated (1,089 subjects with AFLURIA[®] and 268 with a thimerosal-containing
294 placebo). Subjects receiving AFLURIA[®] were vaccinated using either a single-dose
295 (preservative-free) or multi-dose (one of three lots) formulation. The evaluable efficacy
296 population consisted of 1,341 subjects (1,077 in the AFLURIA[®] group and 264 in the placebo
297 group) with complete serological data who had not received any contraindicated medications
298 before the post-vaccination immunogenicity assessment. Among the evaluable efficacy
299 population receiving AFLURIA[®], 37.5% were men and 62.5% were women. The mean age of
300 the entire evaluable population receiving AFLURIA[®] was 38 years; 73% were ages 18 to less
301 than 50 years and 27% were ages 50 to less than 65 years. Additionally, 81% of AFLURIA[®]
302 recipients were White, 12% Black, and 6% Asian.

303
304 In Study 1, the following co-primary immunogenicity endpoints were assessed: 1) the
305 lower bounds of the 2-sided 95% confidence intervals (CI) for the proportion of subjects with
306 HI antibody titers of 1:40 or greater after vaccination, which should exceed 70% for each
307 vaccine antigen strain; and 2) the lower bounds of the 2-sided 95% CI for rates of
308 seroconversion (defined as a 4-fold increase in post-vaccination HI antibody titers from pre-
309 vaccination titers of 1:10 or greater, or an increase in titers from less than 1:10 to 1:40 or
310 greater), which should exceed 40% for each vaccine antigen strain.

311
312 In subjects ages 18 to less than 65 years, serum HI antibody responses to AFLURIA[®] met
313 the pre-specified co-primary endpoint criteria for all three virus strains (Table 3). Clinical lot-

314 to-lot consistency was demonstrated for the single-dose (preservative-free) and multi-dose
 315 formulations of AFLURIA[®], showing that these formulations elicited similar immune
 316 responses.

317

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

320

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)

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

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

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

328

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

335

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

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Number of Subjects	Vaccine Strain	Seroconversion Rate* (95% CI)	HI Titer \geq 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)

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

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

347

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

356

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

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365 15 REFERENCES

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378 16 HOW SUPPLIED/STORAGE AND HANDLING

378 AFLURIA® is supplied as a 0.5 mL preservative-free, single-dose pre-filled syringe
 379 (packaged without needles) and as a 5 mL multi-dose vial containing ten 0.5 mL doses, with
 380 thimerosal, a mercury derivative, added as a preservative; each 0.5 mL dose contains 24.5 mcg
 381 of mercury.
 382

Product Description

Package of ten 0.5 mL preservative-free, prefilled syringes
 5 mL multi-dose vial

NDC Number

33332-007-01
 33332-107-10

383
 384 Store refrigerated at 2–8°C (36–46°F). Do not freeze. Protect from light. Do not use
 385 AFLURIA® beyond the expiration date printed on the label.
 386
 387

17 PATIENT COUNSELING INFORMATION

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

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 398
 399 Manufactured by:
 400 **CSL Limited**
 401 Parkville, Victoria, 3052, Australia
 402 US License No. 1764
 403

404
 405 Distributed by:
 406 **CSL Biotherapies Inc.**
 407 King of Prussia, PA 19406 USA
 408

409
 410 AFLURIA is a registered trademark of CSL Limited.
 411

412 Part number: XXXXX XXX (XXXXXX)