

Can the Flu Vaccine Cause Cancer or Fertility Problems, Harm Your Unborn Child, or Show Up In Your Milk?

Flu Vaccine -- Carcinogenesis, Mutagenesis, Impairment of Fertility, Ability to Cause Fetal Harm, Excretion in Human Milk



None of the influenza vaccines have been evaluated for **carcinogenic or mutagenic potential**, or for **impairment of fertility**. No animal reproduction studies have been conducted with any of them. **It is not known whether any flu vaccine can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity.** It is not known whether any flu vaccine is excreted in human milk.

Yet, pregnant women are routinely given influenza vaccines.

The following information is taken from the *U.S. Food and Drug Administration Center For Biologics Evaluation and Research*, found at <http://www.fda.gov/CbER/appr2008/2008Lsup.htm>.

Influenza Vaccine 1. FLUARIX

<http://www.fda.gov/CbER/label/fluarixLB.pdf>

Proper Name: Influenza Virus Vaccine

Tradename: Fluarix

Manufacturer: GlaxoSmithKline Biologicals, License #1617

2008-2009 United States Formulation

Carcinogenesis, Mutagenesis, Impairment of Fertility: FLUARIX has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.

Pregnancy: Pregnancy Category C. Animal reproduction studies have not been conducted with FLUARIX. It is not known whether FLUARIX can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. FLUARIX should be given to a pregnant woman only if clearly needed. The ACIP has issued recommendations regarding the use of the influenza virus vaccine in pregnant women.³

Nursing Mothers: It is not known whether FLUARIX is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when FLUARIX is administered to a nursing woman. The ACIP has issued recommendations regarding the use of the influenza virus vaccine in nursing mothers.³

Pediatric Use: FLUARIX IS NOT INDICATED FOR USE IN CHILDREN.

Geriatric Use: FLUARIX was administered to 246 subjects ≥65 years of age in 3 European studies (see CLINICAL PHARMACOLOGY). Solicited adverse events were similar in type and frequency to those reported in younger subjects (see ADVERSE REACTIONS).

Footnote 3. Centers for Disease Control and Prevention. Prevention and control of influenza: Recommendations of the Advisory Committee on Immunization Practices (ACIP). *MMWR* 2004;53(RR-6):1-44.

Influenza Vaccine 2. FLUVIRIN

<http://www.fda.gov/CbER/label/fluvirinLB.pdf>

Proper Name: Influenza Virus Vaccine

Tradename: Fluvirin

Manufacturer: Novartis Vaccines and Diagnostics Limited, License #1750

2008-2009 United States Formulation

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

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

8.3 Nursing Mothers

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

8.4 Pediatric Use

The safety and immunogenicity of FLUVIRIN® have not been established in children under 4 years of age. The safety and immunogenicity of FLUVIRIN® have been established in the age group 4 years to 16 years. The use of FLUVIRIN® in these age groups is supported by evidence from adequate and well controlled studies of FLUVIRIN® in adults that demonstrate the immunogenicity of FLUVIRIN® [see ADVERSE REACTIONS (6) and CLINICAL STUDIES (14)].

8.5 Geriatric Use

Since 1997, of the total number of geriatric subjects (n = 397) in clinical studies of FLUVIRIN®, 29% were 65 years and over, while 2.1% were 75 years and over. Antibody responses were lower in the geriatric population than in younger subjects. Adverse events occurred less frequently in geriatric subjects (≥65 years) than in younger adults. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. [See ADVERSE REACTION (6) and CLINICAL STUDIES (14)].

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

FLUVIRIN® has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.

Influenza Vaccine 3. FLUZONE

<http://www.fda.gov/CbER/label/fluzoneLB.pdf>

Proper Name: Influenza Virus Vaccine

Tradename: Fluzone

Manufacturer: Sanofi Pasteur, Inc, License #1725

2008-2009 United States Formulation

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

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

8.2 Nursing Mothers It is not known whether Fluzone vaccine is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Fluzone vaccine is administered to a nursing woman.

8.3 Pediatric Use Safety and effectiveness of Fluzone vaccine in children below the age of 6 months have not been established. The immune response and safety of Fluzone vaccine was evaluated in 31 children between the ages of 6-26 months. [See *Adverse Reactions (6.1), Clinical Studies (14)*.]

8.4 Geriatric Use Immune response to Fluzone vaccine in subjects older than 65 years of age may be lower when compared to immune responses in younger subjects. [See *Clinical Studies (14)*.]

13. NON-CLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility Fluzone vaccine has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.

Influenza Vaccine 4. AFLURIA

<http://www.fda.gov/CbER/label/afluriaLB.pdf>

Proper Name: Influenza Virus Vaccine

Tradename: AFLURIA

Manufacturer: CSL Limited, License No. 1764

2008-2009 United States Formulation

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]*).

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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

Influenza Vaccine 5. FLULAVAL

<http://www.fda.gov/CbER/label/flulavalLB.pdf>

Proper Name: Influenza Virus Vaccine
Tradename: FluLaval
Manufacturer: ID Biomedical Corporation of Quebec, License #1739

2008-2009 United States Formulation

8 USE IN SPECIFIC POPULATIONS

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

8.3 Nursing Mothers It is not known whether FLULAVAL is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when FLULAVAL is administered to a nursing woman.

8.4 Pediatric Use Safety and effectiveness of FLULAVAL in pediatric patients have not been established.

8.5 Geriatric Use In the 2 clinical trials, there were 157 subjects who were ≥ 65 years of age and received FLULAVAL; 21 of these subjects were ≥ 75 years of age. Hemagglutination-inhibiting (HI) antibody responses were lower in geriatric subjects than younger subjects after administration of FLULAVAL. Solicited adverse events were similar in frequency to those reported in younger subjects [see *Adverse Reactions (6.1)*].

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility FLULAVAL has not been evaluated for carcinogenic or mutagenic potential, or for impairment of fertility.

Influenza Vaccine 6. FLUMIST

<http://www.fda.gov/CbER/label/flumistLB.pdf>

Proper Name: Influenza Virus Vaccine Live, Intranasal
Tradename: FluMist
Manufacturer: MedImmune Vaccines, Inc, License #1652

2008-2009 United States Formulation

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category C Animal reproduction studies have not been conducted with FluMist. It is not known whether FluMist can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. FluMist should be given to a pregnant woman only if clearly needed. The effect of the vaccine on embryo-fetal and pre-weaning development was evaluated in a developmental toxicity study using pregnant rats receiving the frozen formulation. Groups of animals were administered the vaccine either once (during the period of organogenesis on

gestation day 6) or twice (prior to gestation and during the period of organogenesis on gestation day 6), 250 microliter/rat/occasion (approximately 110-140 human dose equivalents), by intranasal instillation. No adverse effects on pregnancy, parturition, lactation, embryo-fetal or pre-weaning development were observed. There were no vaccine related fetal malformations or other evidence of teratogenesis noted in this study.

8.3 Nursing Mothers It is not known whether FluMist is excreted in human milk. Therefore, as some viruses are excreted in human milk and additionally, because of the possibility of shedding of vaccine virus and the close proximity of a nursing infant and mother, caution should be exercised if FluMist is administered to nursing mothers.

8.4 Pediatric Use Safety and effectiveness of the vaccine has been demonstrated for children 2 years of age and older with reduction in culture-confirmed influenza rates compared to active control (injectable influenza vaccine made by Sanofi Pasteur Inc.) and placebo [see *Clinical Studies (14.1)*]. FluMist is not indicated for use in children <24 months of age. FluMist use in children <24 months has been associated with increased risk of hospitalization and wheezing in clinical trials [see *Warnings and Precautions (5.1)* and *Adverse Reactions (6.1)*].

8.5 Geriatric Use FluMist is not indicated for use in individuals ≥ 65 years of age. Subjects with underlying high-risk medical conditions (n=200) were studied for safety. Compared to controls, FluMist recipients had a higher rate of sore throat.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

FluMist has not been evaluated for its carcinogenic or mutagenic potential or its potential to impair fertility.

Disclaimer

*Any information contained herein is for educational purposes only. It is not to be construed as legal or medical advice. **Wyoming Vaccine Information Network** does not necessarily agree with all of the statements made in this material. The decision to vaccinate is one that must be made by you in consultation with a trusted health care provider of your choice.*

Please be aware that all information that you read needs to be read carefully, keeping in mind that some of it may not be backed by facts. It is necessary to check on the sources to be certain that a statement is true. This applies to both sides of the vaccination debate.

For more information, contact:

Wyoming Vaccine Information Network, state chapter of *Vaccination Liberation*
<http://www.vaclib.org/chapter/wyhome.htm>

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