# *This flu season, ask for 4-strain protection. Ask for FLUCELVAX QUADRIVALENT.*

An annual flu shot is the single best way to help protect yourself and those around you against the flu.<sup>11</sup> If you're ready to get vaccinated this flu season, ask for FLUCELVAX QUADRIVALENT, the flu shot that:

- Is made for people aged 4 years and older<sup>1</sup>
- Offers similar immunogenicity and safety as comparable flu shots containing 3 flu strains<sup>1,2</sup>
- Contains the same 4 flu strains as flu shots made in chicken eggs<sup>1</sup>
- Does not contain antibiotics, preservatives, or latex<sup>1</sup>
- Is made in the USA using modern cell culture technology<sup>9</sup>

### To learn more, visit **www.flucelvax.com**.

# INDICATIONS AND USAGE for FLUCELVAX QUADRIVALENT (Influenza Vaccine)

FLUCELVAX QUADRIVALENT is a vaccine that helps protect against influenza (flu). FLUCELVAX QUADRIVALENT is for people aged 4 and older. Vaccination with FLUCELVAX QUADRIVALENT may not protect all people who receive the vaccine.<sup>1</sup>

#### CONTRAINDICATIONS

Do not administer FLUCELVAX QUADRIVALENT to anyone with a history of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine.<sup>1</sup>



# Important Safety Information

#### What is FLUCELVAX QUADRIVALENT?

FLUCELVAX QUADRIVALENT is a vaccine that helps protect against influenza (flu). FLUCELVAX QUADRIVALENT is for people aged 4 and older. Vaccination with FLUCELVAX QUADRIVALENT may not protect all people who receive the vaccine.<sup>1</sup>

#### Who should not get FLUCELVAX QUADRIVALENT?

You should not get FLUCELVAX QUADRIVALENT if you have had a severe allergic reaction to any of the components of the vaccine.<sup>1</sup>

#### Who may not be able to get FLUCELVAX QUADRIVALENT?

#### Tell your healthcare provider if you:

- have ever had Guillain-Barré Syndrome (severe muscle weakness) after getting a flu shot<sup>1</sup>
- have ever fainted after receiving an injection<sup>1</sup>

#### What if I have a weakened immune system?

Tell your healthcare provider if you have problems with your immune system, as your immune response to the vaccine may be less.<sup>1</sup>

# What are the most common side effects of FLUCELVAX QUADRIVALENT?<sup>1</sup>

- pain or redness where you got the shot
- headache
- tiredness
- muscle aches
- feeling unwell (malaise)

These are not all of the possible side effects of FLUCELVAX QUADRIVALENT. You can ask your healthcare provider for a complete list of reported side effects.

Ask your healthcare provider for advice about any side effects that concern you. You may report side effects to the Vaccine Adverse Events Reporting System (VAERS) by calling 1-800-822-7967 or by going to http://vaers.hhs.gov.<sup>15</sup>

To report SUSPECTED ADVERSE REACTIONS, contact Seqirus at 1-855-358-8966 or VAERS at 1-800-822-7967 and http://vaers.hhs.gov.<sup>15</sup>

Please see accompanying US full Prescribing Information for FLUCELVAX QUADRIVALENT.

#### REFERENCES

1. FLUCELVAX QUADRIVALENT (Influenza Vaccine) [package insert]. Holly Springs, NC: Segirus Inc; 2015. 2. FLUCELVAX (Influenza Vaccine) [package insert]. Holly Springs, NC: Segirus Inc; 2016. 3. FDA approves first seasonal influenza vaccine manufactured using cell culture technology. US Food and Drug Administration website. http://www. fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm328982.htm. Updated 2012. Accessed September 9, 2015. 4. Center for Infectious Disease Research & Policy. The compelling need for game-changing influenza vaccines: an analysis of the influenza vaccine enterprise and recommendations for the future. http://www. cidrap.umn.edu/sites/default/files/public/downloads/ccivi\_report.pdf. Updated 2012. Accessed November 24, 2015. 5. Artenstein AW, Opal JM, Opal SM, Tramont EC, Peter G, Russell PK. History of US military contributions to the study of vaccines against infectious diseases. Mil Med. 2005;170(suppl 4):3-11. 6. Perdue ML, Arnold F, Li S, et al. The future of cell culture-based influenza vaccine production. *Expert Rev Vaccines.* 2011;10(8):1183-1194. doi: 10.1586/erv.11.82. **7.** Cell-based flu vaccines. Centers for Disease Control and Prevention website. http://www.cdc.gov/flu/protect/ vaccine/cell-based.htm. Updated 2015. Accessed September 9, 2015. 8. Doroshenko A, Halperin SA. Trivalent MDCK cell culture-derived influenza vaccine Optaflu® (Novartis Vaccines). Expert Rev Vaccines. 2009;8(6):679-688. doi: 10.1586/erv.09.31. 9. A milestone in protection from influenza. US Department of Health and Human Services website. http://www.hhs.gov/news/press/2014pres/06/20140617a.html. Updated 2014. Accessed September 9, 2015. **10.** Influenza (seasonal). World Health Organization website. http://www.who.int/mediacentre/factsheets/fs211/en/. Updated March, 2014. Accessed November 19, 2015. 11. Key facts about influenza (flu) & flu vaccine. Centers for Disease Control and Prevention website, http://www.cdc.gov/flu/kevfacts.htm. Updated August 7, 2015. Accessed November 19, 2015. **12.** Key facts about seasonal flu vaccine. Centers for Disease Control and Prevention website. http://www.cdc.gov/flu/ protect/keyfacts.htm#give-me-flu. Updated October 2, 2015. Accessed November 19, 2015. 13. Centers for Disease Control and Prevention. The Pink Book. 13th ed. Atlanta, GA: Centers for Disease Control and Prevention; 2015. http://www.cdc.gov/vaccines/ pubs/pinkbook/downloads/flu.pdf. Accessed November 23, 2015. 14. How flu spreads. Centers for Disease Control and Prevention website. http://www.cdc.gov/flu/about/ disease/spread.htm. Updated August 15, 2014. Accessed November 19, 2015. 15. US Department of Health and Human Services. Vaccine adverse event reporting system. Vaccine Adverse Event Reporting System website. https://vaers.hhs.gov/index. Updated 2015. Accessed November 19, 2015.

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**INFORMATION FOR PATIENTS** 



# INDICATIONS AND USAGE for FLUCELVAX QUADRIVALENT® (Influenza Vaccine)

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#### CONTRAINDICATIONS

Do not administer FLUCELVAX QUADRIVALENT to anyone with a history of severe allergic reaction (e.g. anaphylaxis) to any component of the vaccine.<sup>1</sup>

Please see Important Safety Information throughout and accompanying US full Prescribing Information for FLUCELVAX QUADRIVALENT.

# Four-strain flu protection for people aged 4+

FLUCELVAX QUADRIVALENT is a new flu shot for **people aged 4** years and older that helps protect against 4 strains of the flu.<sup>1</sup> It's the evolution of FLUCELVAX<sup>®</sup> (influenza vaccine), a flu shot made by cell culture technology that helps protect against 3 strains of the flu.<sup>2</sup>

FLUCELVAX was the first FDA-approved flu vaccine to use cells, instead of chicken eggs, and represented the first major advance in flu vaccine manufacturing technology since flu vaccine production began in the 1930s.<sup>3-5</sup> FLUCELVAX QUADRIVALENT is made the same way.<sup>1</sup>

So what does this mean for you? Well, this modern manufacturing process allows us to make a flu shot that is **antibiotic free**, was shown to generate a strong immune response, and to be well tolerated.<sup>1</sup> FLUCELVAX QUADRIVALENT is also preservative and latex free.<sup>1</sup>



Common side effects of FLUCELVAX QUADRIVALENT are as follows:

#### Children Aged 4 to 17 Years<sup>1</sup>

- Pain, bruising, or redness Tiredness where you got the shot • Muscle aches
- Headache
- Crankiness
- Change in eating habits

#### Adults 18 Years and Older<sup>1</sup>

- Pain or redness where you got the shot
- Headache

Talk to your doctor or pharmacist about any side effects that concern you.

• Loss of appetite

Muscle aches

Muscle aches

• Tiredness

Please see full Important Safety Information on the back and accompanying full Prescribing Information for FLUCELVAX QUADRIVALENT.

FLUCELVAX QUADRIVALENT is a flu vaccine **for people aged 4 years and older** that is made from inactivated (dead) flu viruses. It helps protect against the same 4 strains as traditional egg-based quadrivalent flu vaccines and is antibiotic, latex, and preservative free.<sup>1</sup>



# A process that's transforming flu shot manufacturing

For many decades, conventional flu vaccines have been produced using chicken eggs.<sup>6</sup> FLUCELVAX QUADRIVALENT is made using modern cell culture technology instead.<sup>1</sup> Cell culture technology has been used for many years to make other types of vaccines including polio, smallpox, rubella, and chicken pox vaccines.<sup>7</sup> This innovation in flu manufacturing has the potential to boost production when more flu shots are needed, which could be beneficial during a flu outbreak or pandemic.6,8

FLUCELVAX QUADRIVALENT is made in the USA. With support from the US government, a new flu vaccine manufacturing facility was built in Holly Springs, North Carolina, specifically to make cell culture-based vaccines. This facility can help ensure that flu shots are available when needed.<sup>9</sup>

### Selected Important Safety Information Who may not be able to get FLUCELVAX QUADRIVALENT?

Tell your healthcare provider if you:

- after getting a flu shot<sup>1</sup>
- have ever fainted after receiving an injection<sup>1</sup>





• have ever had Guillain-Barré Syndrome (severe muscle weakness)

# Don't underestimate the consequences of flu

Although many people who get the flu recover within a week without requiring medical attention, some will suffer from a more severe illness or even death, especially if they are considered high risk.<sup>10</sup> People at high risk for complications from the flu are young children, older adults (65+), and people with weakened immune systems. Pregnancy or chronic conditions such as asthma, COPD, diabetes, and heart disease also increase the risk of flu-related complications.<sup>10-12</sup>

# The flu is serious!

In a study of 31 flu seasons in the United States from 1976 to 2007, the number of flu-related deaths ranged from 3000 to 49,000 during each flu season.<sup>11</sup>

#### Selected Important Safety Information What if I have a weakened immune system?

Tell your healthcare provider if you have problems with your immune system, as your immune response to the vaccine may be less.<sup>1</sup>

# Do your part to fight the flu. Get vaccinated."

An annual flu shot is the single best way to help protect yourself against the flu.<sup>11</sup> And even though no vaccine is 100% protective, if you do end up getting the flu after getting a flu shot, it may make your illness milder than if you had not gotten one at all.<sup>12</sup> Need more convincing? Consider this:

- A flu shot cannot give you the flu.<sup>12</sup>
- It's important to get a flu shot every year because the strains circulating in the community may change every year.<sup>11</sup>
- The more people who are vaccinated in a community, the less the flu can spread.<sup>12</sup>
- Children aged 5 through 18 years typically have the highest rates of infection during community outbreaks of the flu.<sup>13</sup>
- The very young and elderly and those with certain medical conditions like asthma, COPD, heart disease, or diabetes have a high risk of developing flu-related complications if they get the flu.<sup>12</sup>
- A flu shot helps protect people with chronic health conditions who are at greater risk of getting seriously ill and being hospitalized.<sup>12</sup>
- It's best to get your flu shot early in the season, but any time during the flu season is better than not at all. Outbreaks can happen as early as October with flu activity peaking in January or later.11

Please see full Important Safety Information on the back and accompanying full Prescribing Information for FLUCELVAX QUADRIVALENT.

<sup>a</sup>FLUCELVAX QUADRIVALENT is not approved for use in children younger than 4 years of age.<sup>1</sup>

### Did vou know?

The flu can be passed on to someone else before you even know you're sick, putting the people around you at risk of getting sick too.<sup>14</sup>

#### Selected Important Safety Information

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- pain or redness where you got the shot
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- tiredness
- muscle aches
- feeling unwell (malaise)

These are not all of the possible side effects of FLUCELVAX QUADRIVALENT. You can ask your healthcare provider for a complete list of reported side effects.

#### The Centers for Disease Control and Prevention recommends a flu shot for everyone aged 6 months and older.<sup>12,a</sup>

