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EPAR summary for the public

IDflu

influenza vaccine (split virion, inactivated)

This is a summary of the European public assessment report (EPAR) for IDflu. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for IDflu.

What is IDflu?

IDflu is a vaccine, which is available as a suspension for injection in a pre-filled syringe. The vaccine contains fragments of influenza (flu) viruses that have been inactivated (treated to prevent them causing infection). IDflu contains 15 micrograms of each of three different strains (varieties) of influenza virus (an H1N1 subtype, A/California/7/2009, NYMC X-179A; an H3N2 subtype, A/Hong Kong/4801/2014, NYMC X-263B; and a type B, B/Brisbane/60/2008, wild type).

What is IDflu used for?

IDflu is used to vaccinate adults aged 60 years and over against flu, especially those who are at an increased risk of developing complications from the disease. The use of the vaccine should be based on official recommendations.

The vaccine can only be obtained with a prescription.

How is IDflu used?

IDflu is given as one 'intradermal' injection into the upper layer of the skin, using a special micro-injection system. The shoulder is the recommended site of injection.

How does IDflu work?

IDflu is a vaccine. Vaccines work by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. IDflu contains fragments from three different strains of flu virus.

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When a person is given the vaccine, the immune system recognises the virus fragments as 'foreign' and makes antibodies against them. In the future, the immune system will be able to produce antibodies more quickly when it is exposed to any of these virus strains. The antibodies will then help to protect against the disease caused by these strains of flu virus.

Each year, the World Health Organization (WHO) makes recommendations on which flu strains should be included in vaccines for the upcoming flu season. Fragments of the virus strains that are expected to cause flu in the upcoming season, according to the recommendations from the WHO for the northern hemisphere and from the European Union (EU), need to be included in IDflu before the vaccine can be used.

How has IDflu been studied?

The ability of IDflu to trigger the production of antibodies (immunogenicity) was first assessed in five main studies involving almost 9,000 people. Three studies looked at people aged 60 years and over, who were vaccinated with the 15-microgram strength. The other two studies looked at use of a lower strength in people under the age of 60.

In all studies, IDflu was compared with another flu vaccine given by injection into a muscle. In one study in people aged 60 years and over, IDflu was compared with a flu vaccine containing an adjuvant (a compound added to enhance the immune response). The studies compared the ability of the vaccines to trigger the production of antibodies (immunogenicity) by comparing antibody levels before injection and three weeks afterwards.

The immunogenicity and safety of subsequent formulations of the vaccine have also been examined in studies.

What benefit has IDflu shown during the studies?

In the five original studies, both IDflu and the comparator vaccine brought about adequate levels of antibodies for protection against all three flu strains. In people aged 60 years and over, the 15-microgram strength provided as good a level of protection as the comparator vaccines.

Later seasonal formulations of IDflu have been shown to bring about similar antibody responses against the three flu strains included in the vaccine to those seen in the main studies.

What is the risk associated with IDflu?

The most common side effects with IDflu (seen in more than 1 patient in 10) are headache, muscle pain and local reactions at the site of the vaccination (redness, swelling, hardening of the skin, pain and itching). For the full list of all side effects reported with IDflu, see the package leaflet.

IDflu must not be used in people who are hypersensitive (allergic) to the active substances, to any of the other ingredients, or to any component that may be present in very small amounts such as egg (ovalbumin, chicken proteins), neomycin, formaldehyde or octoxinol 9. People who have fever or an acute (short-lived) infection should not receive the vaccine until they have recovered.

Why has IDflu been approved?

The CHMP decided that IDflu's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe and effective use of IDflu?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of IDflu have been included in the summary of product characteristics and the package leaflet.

Other information about IDflu

The European Commission granted a marketing authorisation valid throughout the EU for IDflu on 2[illegible] February 2009.

The full EPAR for IDflu can be found on the Agency's website ema.europa.eu/Find medicine/Human medicines/European Public Assessment Reports. For more information about treatment with IDflu, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2016.