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Summary Public Assessment Report

non-generics

Vaxigrip Tetra
Quadrivalent Influenza Vaccine
(split virion, inactivated)

DE/H/1949/001/DC

Date: January 2019

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Non-generics

Vaxigrip Tetra

Influenza vaccine (split virion, inactivated); suspension for injection, pre-filled syringe
This is a summary of the public assessment report (PAR) for Vaxigrip Tetra. It explains how Vaxigrip Tetra was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Vaxigrip Tetra.

For practical information about using Vaxigrip Tetra, patients should read the package leaflet or contact their doctor or pharmacist.

What is Vaxigrip Tetra and what is it used for?

Vaxigrip Tetra is a vaccine which is available as a suspension for injection in prefilled syringe. The vaccine contains the inactivated virion from two influenza A strains (H1N1 and H3N2) and two influenza B strains. Vaxigrip Tetra is used to vaccinate adults and children from 6 months of age against influenza. The use of the vaccine should be based on official recommendations.

How does Vaxigrip Tetra work?

Vaxigrip Tetra is a vaccine. Vaccines work by "teaching" the immune system (the body`s natural defence) how to defend itself against a disease. Vaxigrip Tetra contains small amounts of haemagglutinin (proteins from the surface) of four different strains of influenza virus. The virus has first been inactivated (killed) so that it does not cause any disease. When a person is given the vaccine, the immune system recognises the virus as "foreign" and makes antibodies against it. The immune system will then be able to produce antibodies more quickly when it is exposed to the virus strain. This will help to protect against the disease caused by the virus.

Each year, the World Health Organisation (WHO) makes recommendations on which influenza strains should be included in vaccines for the upcoming influenza season, and these strains need to be included before the vaccine can be used. Vaxigrip Tetra currently contains small amounts of the inactivated virus that is expected to cause influenza in the 2018/2019 season, according to the recommendations from the WHO for the northern hemisphere and from the European Union (EU). The virus strains in Vaxigrip Tetra will need to be replaced before the vaccine can be used in subsequent seasons.

How is Vaxigrip Tetra used?

Vaxigrip Tetra is given as one injection of 0.5 ml into the muscle or deep under the skin.
Please read section 3 of the PL for detailed information on dosing recommendations, the route of administration, and the duration of treatment.
Vaxigrip Tetra is subject to medical prescription in all European Members States, except in France where it is not subject to medical prescription.

What benefits of Vaxigrip Tetra have been shown in studies?

The company provided 5 clinical trials, which compared Vaxigrip Tetra with the licensed Vaxigrip that contains three of the four vaccine strains included in Vaxigrip Tetra. In these clinical trials, more than 7200 individuals including children from 3 years onwards, adults and

elderly more than 60 years of age, received either at least one dose of Vaxigrip Tetra or were vaccinated with at least one dose of two trivalent Vaxigrip vaccines containing one of the two influenza B-strains included in the Vaxigrip Tetra vaccine. The efficacy of the vaccine to prevent influenza infection was shown in one placebo controlled trial, which enrolled 5.806 children aged 6 to 35 months. The immunogenicity of Vaxigrip Tetra is inferred from the demonstration of non-inferior immune response of Vaxigrip compared with the trivalent Vaxigrip vaccine. The clinical trial data show that in the studies, the immune response of Vaxigrip Tetra against each of the influenza vaccine strains was comparable to that against Vaxigrip. Moreover, a higher immune response of Vaxigrip Tetra compared to the comparator vaccines for the additional B-strain not contained in the trivalent comparator formulation was observed. Despite the lack of a confirmed immunological correlate of protection, demonstration of immunological non-inferiority of Vaxigrip Tetra versus comparator vaccine is considered to reflect at least comparable protective efficacy.

What are the possible side effects from Vaxigrip Tetra?
The most common side effects with Vaxigrip Tetra which may affect more than 1 in 10 people depending on the age of vaccination are injection site pain, headache, myalgia, and malaise.

The most common side effects with Vaxigrip Tetra which may affect up to 1 in 10 people are shivering, fever, injection site erythema, injection site swelling, and injection site induration.

Malaise and fever were less frequently reported in elderly individuals more than 60 years of age compared with the younger age groups.

Shivering, injection site erythema and injection site induration are more frequently reported in 3-8 years of age compared as in adults. The most common side effects with Vaxigrip Tetra which may affect up to 1 in 10 children from 6 to 35 months were appetite loss, crying abnormal and fever.

For the full list of all side effects reported with Vaxigrip Tetra, see section 4 of the package leaflet.

Vaccination should be postponed in case of moderate or severe febrile disease or acute disease.

For the full list of restrictions, see the package leaflet.

Why is Vaxigrip Tetra approved?
The member states of the EEA decided that Vaxigrip Tetra`s benefits are greater than its risks and recommended that it be approved for use.

This medicinal product is authorised in the Member states of the EEA under the name Vaxigrip Tetra (CZ, DE, ES, HU, IT, SK), VaxigripTetra suspension injectable en seringue préremplie (BE), VaxigripTetra (BG, EE, EL, FI, FR, IS, HR, LV, LU, MT, NL, PL, PT, RO, SE, SI, CY), Vaxigriptetra (DK, NO), Quadrivalent influenza vaccine (split virion, inactivated) (IE, UK), VaxigripTetra injekcinė suspensija užpildytame švirkšte (LT), or VaxigripTetra Injektionssuspension in einer Fertigspritze (AT).

What measures are being taken to ensure the safe and effective use of Vaxigrip Tetra?
A risk management plan has been developed to ensure that Vaxigrip Tetra is used as safely as possible. Based on this plan, safety information has been included in the summary of product

characteristics and the package leaflet for Vaxigrip Tetra, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore new safety signals reported by patients/healthcare professionals will be monitored / reviewed continuously as well.

Other information about Vaxigrip Tetra

The marketing authorisation application procedure was positively closed on 21.06.2016.

The full PAR for Vaxigrip Tetra can be found on the website http://mri.medagencies.org/Human/. For more information about treatment with Vaxigrip Tetra, read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in January 2019.