Public Health England

Protecting and improving the nation's health

Use of live attenuated influenza vaccine (LAIV) FluMist Quadrivalent: Frequently asked questions for healthcare workers

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Introduction

Live attenuated influenza vaccine (LAIV) has been used in the UK since 2013 to protect children against infection with influenza. The vaccine is the preferred product for children in flu 'at-risk' groups aged from two to 17 years (inclusive), and used as part of the routine children's programme delivered in schools and general practices.

The vaccine was chosen for children because of its good safety profile, superior performance compared with inactivated flu vaccines and ease of administration.

LAIV is manufactured by AstraZeneca/Medimmune and has been sold in many countries for over 10 years. Only one LAIV vaccine is available, marketed as Fluenz Tetra for the UK and EU market, and FluMist Quadrivalent for the US market. Fluenz Tetra and FluMist Quadrivalent are the same product but in different packaging.

Frequently asked questions

Why are stocks of FluMist Quadrivalent, as well as Fluenz Tetra, being used this season?

In agreement with the Medicines and Healthcare products Regulatory Agency (MHRA), AstraZeneca is supplying two batches of the US labelled FluMist Quadrivalent to the UK market in addition to the usual UK labelled Fluenz Tetra stock. FluMist Quadrivalent is fully licensed for use in the UK (in accordance with the Fluenz Tetra licence). This action has been taken due to a shortage of Fluenz Tetra supply to meet the timelines for the 2015/2016 vaccination programme in the UK. There will be sufficient FluMist Quadrivalent stock to fulfil the requirements of the vaccination programme. An explanatory letter from AstraZeneca will be available from 23 October.

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Is there any differences between Fluenz Tetra and FluMist Quadrivalent?

Fluenz Tetra and FluMist Quadrivalent are pharmaceutically identical and FluMist Quadrivalent is full licensed for use in the UK (in accordance with the Fluenz Tetra licence).

Some differences exist between the packaging of Fluenz Tetra and FluMist Quadrivalent. In addition, there are differences between the US prescribing information (USPI) and the UK patient information leaflet (PIL) and summary of product characteristics (SmPC). In agreement with the MHRA, all FluMist Quadrivalent packs will therefore be supplied with a UK PIL for Fluenz Tetra, the USPI should not be used. The SmPC and PIL are also available electronically at https://www.medicines.org.uk/emc/medicine/29112

As these are the same vaccine, both are indicated for the prophylaxis of influenza in children and adolescents from 24 months to less than 18 years of age. In the US LAIV is licensed up to the age of 49 years. In the UK LAIV is only licensed for those aged from 24 months to less than 18 years of age.

Why is there a mismatch between the actual expiry date and that printed on the FluMist® Quadrivalent packaging and labelling?

To ensure timely supply, changes in the supply schedule were required. This has resulted in a mismatch between the actual expiry date and that printed on the packaging and labelling. The two batches of FluMist Quadrivalent being supplied (FL2113 and FL2118) must not be used after 24 February 2016. This does not affect the safety, quality or efficacy of the batches.

In agreement with the MHRA, a pre-planned withdrawal of any unused stock of FluMist Quadrivalent will begin on 25 January 2016. This will help ensure that no time-expired vaccine remains in circulation. AstraZeneca's logistics provider, Movianto, will contact you to arrange collection. Please quarantine any unused FluMist Quadrivalent ahead of 24 February 2016. This should avoid accidental administration prior to collection.

Batches of UK labelled Fluenz Tetra will not be subject to the withdrawal and may be used up to the expiry date stated on the carton and nasal applicator.

When can I expect to see deliveries of FluMist Quadrivalent?

FluMist Quadrivalent will be distributed once existing stocks of Fluenz Tetra have been delivered to the NHS.

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How do I order FluMist Quadrivalent?

FluMist Quadrivalent can be ordered in exactly the same way as Fluenz Tetra using the Immform website. You will not be able to choose between the two vaccines and only one option will be available at any one time. In order to preserve stocks of both Fluenz Tetra and FluMist Quadrivalent, it is very important that you only order what you need for your expected usage over the next two weeks. Please DO NOT over-order, or overstock vaccine fridges. Careful management of vaccine stock is essential to avoid vaccine wastage and ensure that we are able to offer vaccine to all eligible children.

I have had a vaccine cold chain failure involving stocks of LAIV (Fluenz Tetra or FluMist Quadrivalent). What should I do?

Quarantine the stock. DO NOT DISCARD IT OR USE IT. You should consult the PHE document 'Responding to cold chain failures involving the live attenuated intra-nasal influenza vaccine (LAIV)'.

Do I need to re-consent children to receive FluMist Quadrivalent instead of Fluenz Tetra?

No, they are pharmaceutically identical live attenuated influenza vaccines (LAIV) and are therefore interchangeable. You DO NOT need to re-consent the child.

The parents of a child will not allow their child to have the FluMist Quadrivalent vaccine instead of Fluenz Tetra – what should I do?

The parents should be reassured that the products are pharmaceutically identical and that any differences are in the packaging and branding only. As stocks of Fluenz Tetra are limited it is not possible to choose to have this instead of FluMist Quadrivalent. In addition, unless a child is in a flu 'at risk' group and is clinically contraindicated to receive LAIV, inactivated intramuscular flu vaccine should NOT be offered in place of Fluenz Tetra.

Can I still use the national PGD written by PHE to administer both Fluenz Tetra and FluMist Quadrivalent?

The initial template PGD written and clinically approved by PHE only mentioned Fluenz Tetra by name. The PGD has now been amended to refer to the live attenuated influenza vaccine and mentions both Fluenz Tetra and FluMist Quadrivalent by name. The PGD is available at: https://www.gov.uk/government/collections/immunisation-patient-group-direction-pgd.

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Before this PGD can be lawfully used, it must be authorised by NHS England and then signed by the individual user and their authorising manager.

How do I administer FluMist Quadrivalent?

FluMist Quadrivalent should be administered in exactly the same way as Fluenz Tetra. A training slide set for influenza immunisation is available at: https://www.gov.uk/government/publications/national-flu-programme-training-slide-set-for-healthcare-professionals

How should I record use of FluMist Quadrivalent on the clinical system?

Where a child has been vaccinated using Fluenz Tetra or FluMist Quadrivalent vaccine there is no change to GP coding requirements. There is no specific Read code for FluMist Quadrivalent, but this vaccine can be recorded using the usual approach on the GP system (either 'Influenza vaccine (Live attenuated)' or 'Fluenz Tetra'). As with all vaccines, it remains important to record the batch number and expiry date.

Will use of FluMist Quadrivalent affect vaccine uptake monitoring and reporting?

No, provided that the use of FluMist Quadrivalent is recorded as set out above, vaccine uptake reporting to child health records departments and/or PHE will be unaffected.

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