Fluenz™
nasal spray suspension
influenza vaccine
(live attenuated, nasal)

Nasal Spray Flu Vaccine Implementation Guide for Pharmacists

Fluenz nasal spray suspension Influenza vaccine (live, nasal) is indicated for active immunisation for the prevention of influenza disease in individuals 2 years to less than 18 years of age. Fluenz should be used in accordance with official recommendations.[1]

Prescribing information and adverse event reporting information can be found at the end of this booklet.

The information provided in this document is not complete and should not be relied upon as the sole source of guidance. You must refer to the Fluenz Summary of Product Characteristics (SmPC) before administering the vaccine.

October 2025 I GB-69512

This booklet has been developed and funded by AstraZeneca UK Ltd. for UK healthcare professionals only.

AstraZeneca

Contents

Seasonal influenza has a significant impact on children

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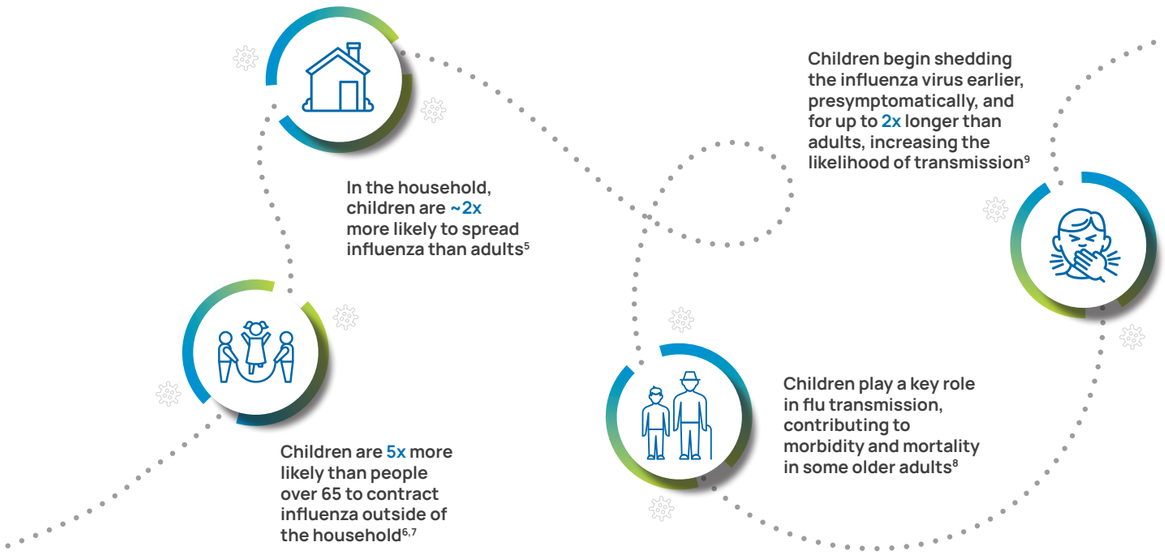
Seasonal influenza vaccination plays a crucial role in protecting children and supporting NHS service resilience by reducing hospital admissions and easing pressure on urgent care. Vaccinating children helps protect the individual child and can also reduce wider transmission within the community[2].

Children are commonly in need of medical care because of influenza, especially children under the age of 5 years old who may be more likely to become sick with influenza.[3]

Almost a fifth of total UK hospitalisations for flu in 2024-2025 season were for children between the ages of 0-14. During the peak week, that accounted for 1,600[4].

Flu can lead to serious complications in children. In 2024-2025 season there were 53 deaths among children associated with influenza[4].

Helping protect children from influenza can have a significant impact on their family & community



The childhood flu vaccination programme reduces primary care burden for ILI in both children and adults

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56%

Reduction in child ILI primary care consultations

During the 2024-2025 flu season, children who received the nasal spray flu vaccine were **~56% less likely to present to their GP with ILI symptoms** than children who had not received a flu vaccine.[4]

80%

Reduction in adult ILI primary care consultations

Studies have shown an **~80% reduction in number of primary care consultations** for ILI in adults aged 50–70 years, in areas where both primary and secondary school children had been vaccinated.[10]

ILI consultation rate per 100,000: 3.4 1° and 2° school programme; 17.4 no school-based vaccination (absolute risk reduction of 14).

ILI; Influenza-like-illness

The Childhood Flu National Immunisation Programme (NIP) was introduced in 2013[11]

The JCVI therefore recommend childhood influenza immunisation to:

Prevent **influenza** and its complications in **children**

Reduce **infection** and **mortality** in **older adults** and at-risk clinical groups

In 2013, the NIP included influenza vaccination for children 2-4 years of age. Annual expansion achieved today's coverage of children 2 to <17 years of age.

Decrease the **spread** of influenza among **children** and **adults**

Be **cost-effective** compared with expansion to:
1. at-risk children only
2. healthy 50–65-year-olds

JCVI: Joint Committee on Vaccines & Immunisation

Today in England all children aged 2 to year 11 should be offered a flu vaccine

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Children eligible for the flu vaccine this year[12]:

All children **aged 2 or 3 years** on 31 August 2025
Including clinically at risk, unless otherwise contraindicated

Primary school aged children
(from Reception to Year 6)

Secondary school aged children
(from Year 7 to Year 11)

As part of a new advanced service, children aged 2 and 3 can now receive their flu vaccine at their local community pharmacy[2]

GP surgeries[12]

Children aged **2-3 years old** begins **on 1st September**.

GPs reach out proactively to parents to book in slot for flu vaccine.

Pharmacies[2]

Children aged **2-3 years old** begins on **1st October**.

Offered by appointment through the National Booking Service (NBS) and via advertised walk-in clinics.

Schools[12]

Children aged **4 to <17 years old** begins on **1st September**.

School Age Immunisation Services (SAIS) proactively go to schools and run immunisation days.

You can find the full Advanced Service Specification for Community Pharmacy here. The Requirements for Service Provision can be found in section 4 (p5).

Flu vaccination in pharmacies provides an essential route of access for young children who may be most at risk

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Pharmacies[2]

Children aged 2-3 years old

On or before the 31st August, including clinically at risk 2 or 3 year olds unless contraindicated.

Any children that are announced and authorised by the Commissioner as eligible for vaccination by the pharmacy contractor

- Increase vaccine access and uptake by strengthening community delivery
- Protect vulnerable patients from serious illness by vaccinating eligible cohorts against prevalent flu strains
- Improve access and convenience for eligible patients to receive the flu vaccine

Flu vaccine uptake for children in 2024-2025 season remained lower than that for adults[13,14]

Overall uptake in **school-age** children was **51%**

Combined uptake for **2- and 3-year-old** children was **43%**

Uptake for adults **aged 65 years** and over was **75%**

Vaccine delivery in schools means School Aged Immunisation Teams can vaccinate whole classes at once and reach larger numbers of children.

In contrast, GP-based delivery depends on busy parents booking GP appointments, so fewer children are reached. This leaves many of the most vulnerable children without protection.[3,4]

Children remain far less protected than adults with adult flu vaccine coverage roughly **1.5x** higher than children's flu vaccination.[4]

Flu vaccination in pharmacies provides an essential route to support who may be most at risk.[2,3]

Recommended vaccines for children[2,12]

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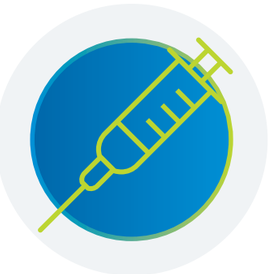
First line: LAIV

(live attenuated influenza vaccine)

Has been recommended first-line since the inception of the programme in 2013 due to **higher efficacy** and potential for **longer term immunity vs. inactivated vaccines** and, **needle free** route of administration[11]



Second line: IIVc

(cell-culture inactivated influenza vaccine)

is recommended where LAIV is **contraindicated or otherwise unsuitable** (for example, parents object to LAIV on the grounds of its porcine gelatine content)

The Live Attenuated Influenza Vaccine (LAIV) for all eligible patients is centrally supplied and administered as a nasal spray for children. The LAIV should be ordered via FDP. More information on stock provision can be found in Service Specification (section 6.7-6.27) of the Community Pharmacy Advanced Service Specification.[2]

Fluenz Live Attenuated Influenza Vaccine (LAIV)

Fluenz is indicated for active immunisation for the prevention of influenza disease in children and adolescents from 2 years to less than 18 years of age. Fluenz should be used in accordance with official recommendations.[1]

- More effective than inactivated vaccines[11]
- Potential for longer term immunity than inactivated vaccines[11]
- Needle-free route of administration[11]

LAIV replicates in the nose to induce a broad immune response that closely resembles natural immunity.[15,16]

Fluenz
nasal spray suspension influenza vaccine (live attenuated, nasal)

Attenuated[1,16]

The properties of the vaccine virus strains are modified and do not produce influenza-like illness.

As LAIV contains live attenuated viruses, it mimics natural infection, which induces more durable immune memory (thereby offering better long-term protection to children than non-live influenza vaccines.[15])

Cold-adapted[1,16]

The vaccine virus strains replicate efficiently in the cooler areas of the nasopharynx at 25°C to initiate an immune response in the nose.

Temperature-sensitive[1,16]

Replication of the vaccine virus strains in the respiratory tract are restricted at 37°C to 39°C temperatures.

LAIV; Live Attenuated Influenza Vaccine

Storage information[1]

Fluenz needs to be **stored in a fridge (between 2–8°C)** and protected from light; it must not be frozen. Keep the vaccine in the outer carton in order to protect from light.

Before ordering vaccine, it may be wise to calculate how much fridge space is needed. Each pack of 10 vaccine applicators is 106 mm by 176 mm by 29 mm (length by width by depth).

Before use, the vaccine may be taken out of the refrigerator once for a **maximum period of 12 hours** at a temperature not above 25°C.

Stability data indicate that the **vaccine components are stable for 12 hours** when stored at temperatures from 8°C to 25°C. At the end of this period, Fluenz should be used immediately or discarded.

There is no stability data available if the vaccine is stored below 2°C. Any Fluenz remaining at the end of the current flu season should be discarded to avoid use of out of date product.

The shelf life of the vaccine is 15 weeks.

Pre-administration checklist[1]

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The information provided in this document is not complete and should not be relied upon as the sole source of guidance. You must refer to the Fluenz Summary of Product Characteristics (SmPC) before administering the vaccine.

1 Is the recipient allergic to any of the following:

- Eggs or egg proteins (e.g. ovalbumin)
- Gentamicin
- Gelatine
- Sucrose
- Water for injection
- Potassium dihydrogen phosphate
- Arginine hydrochloride
- Monosodium glutamate monohydrate
- Dipotassium phosphate

Fluenz must not be given to children or adolescents who are hypersensitive (allergic) to any of the above, as they are present in the vaccine either as an ingredient or a trace residue.

Hypersensitivity reactions (including facial oedema and urticaria) with Fluenz are uncommon (≥1/1,000 to <1/100). As with all vaccines, appropriate medical treatment and supervision should be at hand in case of anaphylactic reaction: these have been reported as very rare (<1/10,000) and not known.

Eggs:
Influenza strains are grown in hens' eggs, so this vaccine may contain traces of egg proteins, e.g. ovalbumin.

Gentamicin:
Gentamicin may be present in this vaccine as a trace residue; it is an antibiotic in the aminoglycoside class, it is not in the same antibiotic class as penicillin.[2,3]

Pre-administration checklist[1]

2 Is the recipient clinically immunodeficient?

Children and adolescents who are clinically immunodeficient or receiving immunosuppressive therapy must not be given Fluenz, this includes:*

- Acute and chronic leukaemias
- Lymphoma
- Symptomatic HIV infection
- Cellular immune deficiencies
- High-dose corticosteroids

Fluenz is not contraindicated for use in individuals with asymptomatic HIV infection; or those who are receiving topical / inhaled corticosteroids, or low-dose systemic corticosteroids, or those receiving corticosteroids as replacement therapy, e.g. for adrenal insufficiency.

* This is not an exhaustive list and clinical judgement should be used. The use of Fluenz should be based on official recommendations.

Pre-administration checklist[1]

Fluenz
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3 Is the recipient in close contact with people who are severely immunodeficient?[1]

Vaccine recipients should be informed that Fluenz is an attenuated live virus vaccine and has the potential for transmission to immunocompromised contacts.

Vaccine recipients should attempt to avoid, whenever possible, close association with severely immunocompromised individuals (e.g. bone marrow transplant recipients requiring isolation) for 1–2 weeks following vaccination. Peak incidence of vaccine virus recovery occurred 2–3 days post-vaccination in Fluenz clinical studies. In circumstances where contact with severely immunocompromised individuals is unavoidable, the potential risk of transmission of the influenza vaccine virus should be weighed against the risk of acquiring and transmitting wild-type influenza virus.

Pre-administration checklist[1]

4 Does the recipient have severe asthma or currently wheezing?[1]

Fluenz should not be administered to children and adolescents with severe asthma or currently wheezing because these individuals have not been adequately studied in clinical studies.

Data in children and adolescents with chronic conditions other than mild-to-moderate asthma is limited.

Chapter 19 of the Green Book has the latest national guidance on administering Fluenz to asthmatic children.[4]

5 Is the recipient on salicylate therapy (e.g. aspirin)?[1]

Children and adolescents receiving salicylate therapy (e.g. aspirin) must not be given this vaccine, as there is an association between the use of salicylates during influenza infection and Reye's syndrome.

For the same reason, salicylates must not be given for 4 weeks following vaccination unless medically indicated.

Pre-administration checklist[1]

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6 Is the recipient pregnant or breastfeeding?[1]

Fluenz is not recommended during pregnancy (for further information, refer to the SmPC).

Limited available evidence suggests that Fluenz is not excreted in breastmilk. However, because there are limited data to assess the effects on the breast-fed infant and, as some viruses are excreted in human milk, Fluenz should not be used during breast-feeding.

7 Is the recipient receiving influenza antivirals?[1]

Influenza antivirals may potentially reduce the efficacy of this vaccine. Therefore, this vaccine should not be administered until at least 48 hours after influenza antivirals are stopped.

Influenza antivirals may also affect the response to this vaccine if taken in the 2 weeks following vaccination.

If this vaccine and influenza antivirals are administered after together it may be worth considering revaccination based on clinical judgement.

Pre-administration checklist[1]

8 Is the individual suffering from severe acute febrile illness or acute infection?

Administration of Fluenz should be postponed in individuals suffering from severe acute febrile illness or acute infection. The presence of a minor infection and/or low-grade fever should not result in the deferral of vaccination.[1]

9 Does the individual have nasal blockage?

Vaccination should be postponed in individuals with nasal blockage, due to the potential for reduced vaccine uptake and the absence of efficacy data in this population. The presence of mild symptoms of a common cold without nasal blockage should not result in the deferral of vaccination.[1]

How to administer Fluenz[1]

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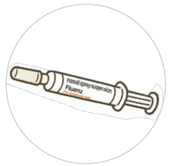
Fluenz is administered as a nasal spray; it must not be injected[1].

The recommended dose is 0.2 ml, administered as 0.1 ml in each nostril. For children 2 to 8 years of age who have not previously been vaccinated against seasonal influenza, a second dose should be given after an interval of at least 4 weeks.[1]

Scan to watch a step-by-step administration video on AstraZeneca's website.

The information provided in this document is not complete and should not be relied upon as the sole source of guidance. You must refer to the Fluenz Summary of Product Characteristics (SmPC) before administering the vaccine.

1



Check the appearance

This can vary, but should fit the following description: colourless to pale yellow, clear to opalescent suspension, with or without small white particles. Do not use Fluenz if the sprayer appears damaged, for example, if the plunger is loose or displaced from the sprayer or if thns of leakage.

2

Check the expiry date

Please remember Fluenz has a maximum shelf life of 15 weeks. Always check the expiry date (day, month, year) on individual sprayers before administration and the vaccine can be administered up to and including on the day of expiry.

3

Prepare the applicator

Prepare the applicator by removing the nozzle tip protector. Do not remove the dose-divider clip at the other end of the applicator. This splits the 0.2 ml dose so that an equal 0.1 ml quantity can be delivered to each nostril.

4

Position the applicator

With the recipient in an upright position, place the tip just inside the first nostril, to ensure vaccine is delivered into the nose.

5

Depress the plunger

With a single motion, depress the plunger as quickly as possible until the dose-divider clip stops it going any further. The recipient can breathe normally when they are receiving vaccine, they do not have to actively inhale or sniff. Please note: the vaccine does not need to be re-administered if the patient sneezes, or blows their nose following administration.

6

Remove the dose-divider clip

To administer the vaccine to the second nostril, pinch the dose-divider clip to remove it from the applicator.

7

Spray into the other nostril

Place the tip just inside the second nostril and, with a single motion, depress the plunger as quickly as possible to deliver the remaining dose. Make sure any used product or waste material is disposed of in accordance with local requirements for medical waste.

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Side effects and safety profile[1]

As with most vaccines, medical treatment and supervision should be readily available in case of a serious adverse event. Please refer to the Fluenz Summary of Product Characteristics (SmPC) for full list of adverse reactions.

Adverse reactions associated with Fluenz are:

Very common (≥1/10)

Nasal congestion/rhinorrhoea, decreased appetite, malaise

Common (≥1/100 to <1/10)

Pyrexia, myalgia, headache

Uncommon (≥1/1,000 to <1/1,100)

Epistaxis, rash and hypersensitivity reactions (including facial oedema, urticaria)

Very rare (<1/10,000)

Anaphylactic reactions, Guillain-Barré syndrome, exacerbation of symptoms of Leigh's syndrome (mitochondrial encephalomyopathy)

Raising awareness of child flu vaccination

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AstraZeneca are pleased to offer other supportive resources to help pharmacies raise awareness of child eligibility, pharmacy access, and support conversations with parents about flu vaccination. These materials have been produced and funded by AstraZeneca.

Parent information leaflet that includes; why child flu vaccination is important, information about the nasal spray flu vaccine

Poster to raise awareness that your pharmacy is offering vaccination to children aged 2 and 3

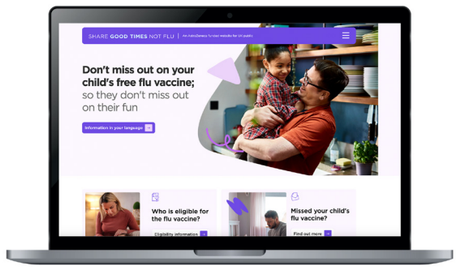
Stickers to give to children after they have had their flu vaccine

Post-administration leaflet to give to parents after their child has received the nasal spray flu vaccine

Order hardcopy materials today free of charge on AstraZeneca's promotional website

Supportive websites

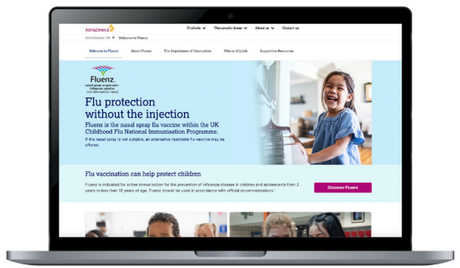
For parents



AstraZeneca offer an information website for parents & carers to help them understand the importance of child flu vaccination and the nasal spray flu vaccine

Visit: www.sharegoodtimesnotflu.co.uk

For healthcare professionals



AstraZeneca also offer an information website for healthcare professionals with further information about the nasal spray flu vaccine. You can also access & order more resources here!

Visit: https://www.myastrazeneca.co.uk/fluenz.html

Please refer to the Fluenz Summary of Product Characteristics (SmPC) for full list of adverse reactions

References

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Prescribing & Adverse Event Reporting Information

FLUENZ® nasal spray suspension Influenza vaccine (live, nasal) Consult Summary of Product Characteristics (SmPC) before prescribing.

Indication: Fluenz is indicated for active immunisation for the prevention of influenza disease in individuals 2 years to less than 18 years of age. Fluenz should be used in accordance with official recommendations. Presentation: Nasal spray, suspension.

Dosage and Administration: 0.2ml (administered as 0.1ml in each nostril). Children 2 to 8 years of age not previously vaccinated against seasonal influenza should be given a second dose after an interval of at least 4 weeks. Should not be used in individuals below 2 years of age because of safety concerns regarding increased rates of hospitalisation and wheezing in this population. Nasal administration only. **Do not inject Fluenz.**

Contraindications: Hypersensitivity to the active substances, any of the excipients, gentamicin (a possible trace residue). Severe allergic reaction (e.g. anaphylaxis) to eggs or to egg proteins (e.g. ovalbumin). Individuals who are clinically immunodeficient due to conditions or immunosuppressive therapy: (such as acute and chronic leukaemias; lymphoma; symptomatic HIV infection; cellular immune deficiencies; and high-dose corticosteroids). Not contraindicated for use in individuals with asymptomatic HIV infection; or individuals who are receiving topical/inhaled corticosteroids or low-dose systemic corticosteroids or those receiving corticosteroids as replacement therapy, e.g. for adrenal insufficiency. Contraindicated in individuals younger than 18 years of age receiving salicylate therapy because of the association of Reye's syndrome with salicylates and wildtype influenza infection.

Warnings and Precautions: Clearly record name and batch number of administered product to improve traceability. Medical treatment and supervision should always be readily available in case of an anaphylactic or serious hypersensitivity event following administration. Not to be used in individuals with severe asthma or active wheezing because these individuals have not been adequately studied in clinical studies. Administration of Fluenz should be postponed in individuals suffering from severe acute febrile illness, acute infection or nasal blockage. The presence of a minor infection and/or low-grade fever, or mild symptoms of a common cold without nasal blockage should not result in the deferral of vaccination. Vaccine recipients should be informed that Fluenz is an attenuated live virus vaccine and has the potential for transmission to immunocompromised contacts. Vaccine recipients should attempt to avoid close association with severely immunocompromised individuals (e.g. bone marrow transplant recipients requiring isolation) for 1-2 weeks following vaccination. Where contact is unavoidable, the potential risk of transmission of the influenza vaccine virus should be weighed against the risk of acquiring and transmitting wild-type influenza virus. The effectiveness of Fluenz preventing influenza disease in immunocompromised individuals has not been evaluated. No data exists regarding the safety in children with unrepaired craniofacial malformations.

Drug Interactions: Fluenz must not be administered to individuals receiving salicylate therapy. Salicylates must not be used for 4 weeks following vaccination unless medically indicated. Fluenz can be administered concomitantly with live attenuated vaccines: measles, mumps, rubella, varicella and orally-administered poliovirus. Co-administration of Fluenz with inactivated vaccines has not been studied. Concurrent use with antiviral agents active against influenza A and/or B viruses has not been evaluated. Based upon the potential for influenza antiviral agents to reduce the effectiveness of Fluenz, it is recommended not to administer the vaccine until 48 hours after the cessation of influenza antiviral therapy. Administration of influenza antiviral agents within two weeks of vaccination may affect the response of the vaccine. Revaccination should be considered if influenza antiviral agents and Fluenz are administered concomitantly.

Pregnancy and Lactation: Not recommended during pregnancy. Should not be used during breast-feeding. No data on the effects of Fluenz on male and female fertility.

Undesirable Events: Consult SmPC for full list of side effects. Very common: decreased appetite, nasal congestion/rhinorrhoea, malaise. Common: headache, myalgia, pyrexia. Uncommon: hypersensitivity reactions (including facial oedema, urticaria), epistaxis, rash. Very rare reports of anaphylactic reactions, Guillain-Barré syndrome, exacerbation of symptoms of Leigh syndrome (mitochondrial encephalomyopathy) have also been observed in the post-marketing setting.

Legal Category: POM. Marketing Authorisation Number: PLGB 17901/0378 Presentation & Basic NHS cost: Fluenz nasal spray suspension pack of 10: £180.00

Business Responsible for Sale and Supply / Further information: AstraZeneca UK Limited, 2 Pancras Square, 8th Floor, London, N1C 4AG, UK.

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Date of preparation: 06/2025 INF 25 0010

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to AstraZeneca by visiting https://contactazmedical.astrazeneca.com or by calling 0800 783 0033.

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