

FLUMIST®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this vaccine, speak to your healthcare professional (doctor, nurse or pharmacist).

1. Why am I/my child being given FLUMIST?

FLUMIST contains three different types (strains) of influenza virus – two Type A (H1N1 and H3N2) and one Type B (Victoria lineage) strain. It is a vaccine used to help prevent certain types of influenza (flu).

FLUMIST may be given to a child (including adolescents) aged 24 months (2 years) to under 18 years old.

For more information, see Section [1. Why am I/my child being given FLUMIST?](#) in the full CMI.

2. What should I know before I am/my child is given FLUMIST?

Do not use if you/your child have ever had an allergic reaction to any medicine containing influenza virus, eggs or egg proteins (e.g. ovalbumin), gentamicin (an

antibiotic), or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you/your child have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I am/my child is given FLUMIST?](#) in the full CMI.

3. What if I am/my child is taking other medicines?

Some medicines may interfere with FLUMIST and affect how it works. Tell your healthcare professional if you/your child are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription.

A list of these medicines is in Section [3. What if I am/my child is taking other medicines?](#) in the full CMI.

4. How is FLUMIST given?

- FLUMIST is given by a trained healthcare professional
- FLUMIST is a nasal spray not an injection. **It must not be injected.**

More instructions can be found in Section [4. How is FLUMIST given?](#) in the full CMI.

5. What should I know after having FLUMIST?

Things you should do	• Keep an updated record of you/your child's vaccinations • Keep any follow-up appointments with your doctor or clinic
Looking after your vaccine	FLUMIST is usually stored in the doctor's surgery, clinic or pharmacy. However, if you need to store FLUMIST: • Keep FLUMIST in the original pack until it is time for it to be given. • Keep it in the refrigerator between 2°C and 8°C. Protect from light. Do not freeze – freezing destroys vaccine.

For more information, see Section [5. What should I know after having FLUMIST?](#) in the full CMI.

6. Are there any side effects?

The following side effects may occur after you/your child have FLUMIST.

Common side effects include runny or stuffy nose, loss of appetite, generally feeling unwell, headache, fever, muscle tenderness or weakness/aches not caused by exercise, nose bleeds.

Serious side effects include sudden signs of allergy such as rash, itching or hives on the skin, swelling of face, lips, tongue or other parts of the body, shortness of breath and wheezing or difficulty breathing, feeling weak or paralysed, or generally feeling sore or tender, headache and high temperature associated with hallucinations, confusion, paralysis of part or all of the body, disturbances of behaviour, speech and eye movements, stiff neck and sensitivity to light.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

FLUMIST®

Active ingredient(s): *influenza virus vaccine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using FLUMIST. **You should also speak to your healthcare professional if you would like further information or if you have any concerns or questions about using FLUMIST.**

Where to find information in this leaflet:

- [1. Why am I/my child being given FLUMIST?](#)
- [2. What should I know before I am/my child is given FLUMIST?](#)
- [3. What if I am/my child is taking other medicines?](#)
- [4. How is FLUMIST given?](#)
- [5. What should I know after having FLUMIST?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I/my child being given FLUMIST?

FLUMIST contains three different types (strains) of influenza virus – two Type A (H1N1 and H3N2) and one Type B (Victoria lineage) strain. It is a vaccine used to help prevent certain types of influenza (flu).

FLUMIST may be given to a child (including adolescents) aged 24 months (2 years) to under 18 years old.

Influenza (flu) is an infectious disease caused by different types of influenza viruses. It can spread very rapidly, particularly in homes and at kindergartens/ preschools and schools. The most common symptoms include fever, headache, general aches and pains, sore throat, runny nose, coughing, weakness and tiredness.

Vaccination for the flu helps to prevent infection as well as controlling the spread of flu within the community including to the very young, the elderly and other people at risk.

New types of viruses can appear each year. Every year the World Health Organization (WHO) and the Australian Influenza Vaccine Committee (AIVC) decide which virus types should be in flu vaccines for the next flu season in Australia (typically from May to October). This means that the viruses in the vaccines usually change every year, so previous season flu vaccines are unlikely to give protection from the flu in the next season. It is recommended that flu vaccines be given every year,

particularly for people who are at risk or are in contact with others at risk.

Like all vaccines, FLUMIST may not fully protect all people who are vaccinated. It will only help to prevent flu if it is caused by one of the strains in the vaccine or another strain which is closely related to one in the vaccine.

FLUMIST will not help prevent the flu if it is caused by another strain of virus or if you already have the virus prior to vaccination. It also will not help prevent other diseases that have flu-like symptoms (e.g. the common cold).

FLUMIST will not give you/your child the flu.

How flu vaccines work

Flu vaccines (injections and nasal sprays) work by helping the body to produce its own protection against the flu. They do this by making substances called antibodies to fight flu viruses. If a vaccinated person comes into contact with a flu virus the body usually destroys it.

The body usually takes several weeks after vaccination to develop protection against flu viruses.

Your healthcare professional can recommend the best time for you/your child to be vaccinated for the coming flu season.

2. What should I know before I am/my child is given FLUMIST?

Warnings

Do not use FLUMIST if you/your child:

- are allergic to any vaccines containing influenza virus, eggs or egg proteins (e.g. ovalbumin), gentamicin (an antibiotic), or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this vaccine.
- have a blood disorder or a cancer that affects the immune system; or you/your child have been told by your doctor that you have a weakened immune system as a result of a disease, medicine or other treatment.
- have been taking, or have recently been told to take aspirin (a substance in many medicines used to relieve pain and lower fever).
- are less than 24 months (2 years) old.
- have Guillain-Barre Syndrome-a rare condition where the body's immune system attacks the nerves, causing weakness and tingling in your arms and legs that can get worse over time.

Check with your healthcare professional if you/your child:

- have allergies to any other medicines, foods, preservatives or dyes.

- have or have had asthma/wheezing
- may need to be in contact with anyone who has a weakened immune system (e.g. a parent/grandparent undergoing cancer treatment, or someone in isolation following a bone marrow transplant).

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your/your child's healthcare professional if you/your child are pregnant or intend to become pregnant.

Talk to your/your child's healthcare professional if you/your child are breastfeeding or intend to breastfeed.

Your healthcare professional can discuss with you/your child the risks and benefits involved.

3. What if I am/my child is taking other medicines?

Tell your healthcare professional if you/your child are taking any other medicines or vaccines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

You/your child should not be given aspirin (a substance in many medicines used to relieve pain and lower fever) for at least 4 weeks after vaccination with FLUMIST, unless your healthcare professional tells you otherwise.

Some medicines may interfere with FLUMIST and affect how it works. These include:

- medicines which affect the body's immune response such as corticosteroids (e.g. prednisolone), some cancer treatments (chemotherapy) or radiotherapy.
- flu-specific antiviral medicines such as oseltamivir and zanamivir

These medicines may be affected by FLUMIST or may affect how well it works. Your healthcare professional will advise whether or not you/your child should have the vaccine.

Check with your healthcare professional if you are not sure about what medicines, vitamins or supplements you/your child are taking and if these affect FLUMIST.

Your healthcare professional have more information on medicines to be careful with or avoid while taking this vaccine.

Having other vaccines

FLUMIST may be given at the same time as other vaccines (e.g. for measles, mumps, rubella etc).

4. How is FLUMIST given?

FLUMIST is given by a trained healthcare professional (e.g. doctor or nurse). Unlike other flu vaccines, it is a nasal spray not an injection.

FLUMIST must not be injected.

How much is given and how will it be given

Children (including adolescents) aged 24 months to less than 18 years of age are given one single nasal applicator (200 µL) of FLUMIST.

This is administered by the healthcare professional as one spray (half the applicator; 100 µL) in one nostril. A clip is then removed and the other half of the applicator (100 µL) is sprayed into the other nostril.

You/your child can breathe normally when it is given - there is no need to sniff in.

Some children who have not previously had FLUMIST may need a second vaccination a month later. Please ask your healthcare professional if this includes you/your child and when/how to arrange for another visit if required.

If you have any concerns, ask your healthcare professional.

When will it be given

FLUMIST is usually given annually before the start of each flu season.

If you forget to get FLUMIST

If you forget to get your/your child's annual vaccination or your child's second vaccination (if advised by your doctor), talk to your doctor or nurse to arrange a visit as soon as possible.

If you have trouble remembering to arrange for an annual vaccination, ask your healthcare professional for some hints.

If too much FLUMIST is given

Overdose is unlikely as your healthcare professional gives you/your child the nasal spray and these are supplied as single-use nasal applicators.

If you think that you/your child have been given too much FLUMIST, you/your child may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know after having FLUMIST?

Things you/your child should do

Keep an updated record of you/your child's vaccinations.

Keep any follow-up appointments with your/your child's doctor or clinic.

Things to be careful of

Wherever possible, the person who has been vaccinated should avoid close contact with anyone who has a weakened immune system (e.g. parent/grandparent undergoing cancer treatment, or someone in isolation following a bone marrow transplant) for 1-2 weeks following vaccination.

Looking after your vaccine

FLUMIST is usually stored in the doctor's surgery, clinic or pharmacy. However if you need to store FLUMIST:

- Keep FLUMIST in the original pack until it is time for it to be given.
- Keep it in the refrigerator between 2°C and 8°C. Protect from light. Do not freeze – freezing destroys the vaccine.

- 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. If the vaccine has not been used after this 12 hour period, it should be discarded.

Keep it where young children cannot reach it.

Getting rid of any unwanted vaccine

FLUMIST is usually stored and disposed of at the doctor's surgery, clinic or pharmacy. However if you need to dispose of either full or empty FLUMIST nasal applicators you should return these to the doctor's surgery, clinic or pharmacy for appropriate vaccine disposal. No medicines, including vaccines, should ever be disposed of via wastewater or household waste.

FLUMIST should not be given after the expiry date.

6. Are there any side effects?

All medicines, including vaccines, can have side effects. If you/your child do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

Tell your healthcare professional as soon as possible if you/your child feel unwell after having the vaccine.

See the information below and, if you need to, ask your healthcare professional if you/your child have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
• runny or stuffy nose • loss of appetite • generally feeling unwell • headache • fever, chills, cough, sore throat • muscle tenderness or weakness/aches not caused by exercise • nose bleeds	Speak to your doctor if you/your child have any of these less serious side effects and they worry you. They are the more common side effects and usually mild and short-lived

Serious side effects

Serious side effects	What to do
• sudden signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath and wheezing or difficulty breathing • feeling weak or paralysed, or generally feeling sore or tender	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you/your child notice any of these serious side effects.

Serious side effects	What to do
• headache and high temperature associated with hallucinations, confusion, paralysis of part or all of the body, disturbances of behaviour, speech and eye movements, stiff neck and sensitivity to light	You may need urgent medical attention or hospitalisation. These side effects are rare.

Tell your healthcare professional if you notice anything else that may be making you/your child feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you/your child experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this vaccine.

Always make sure you speak to your healthcare professional before you decide to stop taking any of your medicines.

7. Product details

This vaccine is only available with a doctor's prescription.

What FLUMIST contains

Active ingredients (main ingredients)	Three strains of influenza virus • Type A (H1N1) • Type A (H3N2) • Type B (Victoria lineage)
Other ingredients (inactive ingredients)	• sucrose • dibasic potassium phosphate • monobasic potassium phosphate • hydrolysed gelatin (porcine Type A)** • arginine hydrochloride • monosodium glutamate monohydrate • water for injections
Potential allergens	*Egg products (FLUMIST may contain trace amounts of egg protein [ovalbumin <0.24µg/dose])

	*Antibiotics (gentamicin sulfate <0.015 µg/dose)
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*from the manufacturing process

**derived from pig

Do not take this vaccine if you are allergic to any of these ingredients.

FLUMIST contains no preservatives (e.g. thiomersal), lactose, gluten, tartrazine or any azo dyes.

What FLUMIST looks like

FLUMIST comes in a single-use glass pre-filled nasal applicator (looks like a small syringe). The nozzle, cap and plunger are made of plastic or rubber. The applicators do not contain latex.

Each applicator contains 200 µL of colourless to pale yellow liquid (vaccine) which may contain small white particles. It may come in boxes of 1 or 10 applicators (AUST R 470065).

Who distributes FLUMIST

AstraZeneca Pty Ltd
ABN 54 009 682 311
66 Talavera Road
MACQUARIE PARK NSW 2113
Telephone:- 1800 805 342

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