

Core CMI for Oral Vaccines for both Adult And Paediatric use (*text in italics is instructional for the CMI writer only*)

# [Medicine name]<sup>®</sup> *(if phonetic spelling is required, the Second Edition of the Usability Guidelines suggests using the system outlined in the Webster's International Dictionary).*

Generic name

## Consumer Medicine Information

Consumer Name  
Consumer Address  
Consumer Address

*Date of Dispensing*

*Pharmacist Name*  
*Pharmacist Address*  
*Pharmacist Address*

## What is in this leaflet<sup>1</sup>

This leaflet answers some common questions about [Medicine name].

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines, including vaccines, have risks and benefits. Your doctor has weighed the risks of you or your child taking [Medicine name] against the benefits they expect it will have.

**If you have any concerns about this vaccine, ask your doctor, nurse or pharmacist.**

**Keep this leaflet.**

You may need to read it again.

***Note: The statements in this core document are optional. Some may not be appropriate for a given product. In order to achieve consistency, however, CMI writers are encouraged to use these statements and follow the Second Edition of the Usability Guidelines wherever possible.***

## What [Medicine name] is used for

[Medicine name] is a vaccine used to help prevent *x disease*.

*Specify the target population with respect to the indications, then explain the cause of the disease and why it is beneficial to prevent the disease.*

### How it works

[Medicine name] works by causing your body to produce its own protection against *x disease*. It does this/One of the ways it does this is by making substances called antibodies in the blood/gut wall which fight *x organism*. If a vaccinated person comes into contact with *x organism*, the body is usually ready to destroy it.

Your body usually takes several weeks after vaccination to develop protection against *x disease/organism*.

Protection requires *x doses*. *Follow up (booster) doses may also be required.*

Most people will produce enough antibodies against *x organism/disease*. However, as with all vaccines, 100% protection cannot be guaranteed.

The vaccine will not give you or your child *x disease*<sup>2</sup>. The chance of a severe reaction from [Medicine name] is very small, but the risks from not being

vaccinated against *x disease* may be very serious.

## Before you take [Medicine name]

### When you or your child must not take it

*(as per PI):*

**Do not take [Medicine name] if you have an allergy to:**

- [Medicine name] or any of the ingredients listed at the end of this leaflet
- eggs and/or chicken feathers
- some animal proteins (check with your doctor)
- yeast

Symptoms of an allergic reaction may include:

*List symptoms as per your PI. If your PI doesn't state specific hypersensitivity symptoms, you may wish to consider the following:*

- shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- skin rash, itching or hives

**Do not take [Medicine name] if you have, or have had, any of the following medical conditions:**

- any long-standing illness (*chronic illness, unstable chronic disease*)
- blood or bleeding problems (*bleeding disorders, blood dyscrasias*)

<sup>1</sup> Depending on the length of your CMI, consider using a table of contents (see Second Edition of the Usability Guidelines).

<sup>2</sup> This sentence may not be applicable if your vaccine is manufactured from live, attenuated virus.

- leukaemia or any other cancers of the blood, bone marrow or lymph system (*leukaemia, lymphoma of any type, other malignant neoplasms affecting the bone marrow or lymphatic systems*)
- lowered immunity due to diseases including HIV / AIDS or cancer (*primary or acquired immunodeficiency, immunocompromised patients*)
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy) (*immunocompromised patients*)
- lung infections (*respiratory infections*)
- high temperature (*high temperature*)
- skin allergies, including rash and eczema (*atopic dermatitis, eczema, inflammatory dermatologic conditions*)
- (other) skin problems, including recurring boils (*furunculosis, exudative dermatologic conditions*)
- brain disease (*encephalopathy*)
- kidney problems (*renal damage*)
- prolonged diarrhoea or vomiting (*persistent diarrhoea, vomiting*)
- tuberculosis (TB) (*tuberculosis, active untreated tuberculosis*)
- *list any other contraindicated medical conditions, as per PI*

Any other contraindications as per PI.

**Do not take [Medicine name] if you are pregnant or intend to become pregnant.**

[Medicine name] is not recommended for use during pregnancy.

**Do not give [Medicine name] to a child under/over x years.**

The safety and effectiveness of [Medicine name] in children under x years have not been established.

or:

There is no/not enough experience with the use of [Medicine name] in children under x years.

or:

[Medicine name] is not recommended for use in children under x years.

**Do not take [Medicine name] after the expiry date (EXP)<sup>3</sup> printed on the pack.**

**Do not take [Medicine name] if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

**If you are not sure whether you or your child should take [Medicine name], talk to your doctor or pharmacist.**

**Before you or your child start to take it**

**Tell your doctor if you have reacted to previous vaccination with any of the following:**

- life-threatening allergic reaction (*anaphylaxis*)
- difficulty breathing (*bronchospasm*)
- swelling of the throat (*laryngeal oedema*)
- fainting or collapse (*generalised collapse*)
- shock-like state or being unresponsive for a long period of time (*hypotonic / hyporesponsive episode*)
- fits or convulsions (*convulsions*)
- high temperature (greater than 40°C) (*or as per PI*)
- crying or screaming lasting for more than 3 hours
- severe skin reaction at the injection site, including severe bruising (*thrombocytopenia*)

**Tell your doctor if you have an infection or high temperature.**

Your doctor may decide to delay vaccination until the illness has passed. A mild illness, such as a cold, is not usually a reason to delay vaccination.

**Tell your doctor if you have had a blood or plasma transfusion in the last x months.**

Your doctor may decide to delay vaccination for a few months.

**Tell your doctor if you have, or have had, any medical conditions, especially the following:**

- lowered immunity due to diseases such as some blood disorders, malaria, kidney disease requiring dialysis, HIV/AIDS or cancer (*agammaglobulinaemia, hypogammaglobulinaemia, malaria, renal dialysis, HIV infection, combined immunodeficiency, immunosuppressed patients, generalised malignancy*)
- lowered immunity due to treatment with medicines such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy) (*immunocompromised patients*)
- leukaemia or any other cancers of the blood, bone marrow or lymph system (*leukaemia, lymphoid tumours, lymphoma*)
- lung infections or asthma (*respiratory infection, asthma*)
- brain disease (*brain injury, family history of stable neurological disease*)
- epilepsy (*epilepsy*)
- fits or convulsions (*convulsions*)
- allergies or allergic reactions, including: runny, blocked or itchy nose; itchy rash or hives; swelling of the face, lips, mouth or tongue (*allergy, allergic reactions, rhinitis, urticaria, angioedema*)
- a low blood platelet count (*thrombocytopenia*)
- vomiting or diarrhoea
- *list any other medical conditions which are precautions, as per PI*

**Tell your doctor if you have allergies to:**

- any other medicines
- any other substances, such as foods, preservatives or dyes

<sup>3</sup> Only include 'EXP' if that is the abbreviation used on your packaging.

**Tell your doctor if you are pregnant or intend to become pregnant.**

Your doctor will discuss the possible risks and benefits of having [Medicine name] during pregnancy.

*or:*

[Medicine name] is not recommended for use during pregnancy. If there is a need to consider [Medicine name] during your pregnancy, your doctor will discuss with you the benefits and risks of having it.

*or:*

[Medicine name] may affect your developing baby. If it is necessary for you to have [Medicine name], your doctor will discuss the risks and benefits of taking/having it during pregnancy.

**Tell your doctor if you are breast-feeding.**

Your doctor will discuss the possible risks and benefits of having [Medicine name] during breastfeeding.

*or:*

[Medicine name] passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected.

*or:*

It is not known whether [Medicine name] passes into breast milk.

*or:*

[Medicine name] is not expected to cause any problems for breast-fed babies.

Before you are given [Medicine name], your doctor may give you a skin test and/or a blood test to see if you have ever had *x disease*.

**Taking other medicines**

**Tell your doctor or pharmacist if you are taking any other medicines, including any that**

[Medicine name]

**you buy without a prescription from your pharmacy, supermarket or health food shop.**

Some medicines and [Medicine name] may interfere with each other. These include:

- phenytoin, a medicine used to control epilepsy or convulsions
- theophylline, a medicine used to control asthma
- warfarin, a medicine used to prevent blood clots
- immunoglobulins, blood products used to prevent some infections
- medicines which lower the immune system, such as corticosteroids, cyclosporin or other medicines used to treat cancer (including radiation therapy)
- alcohol
- *list any other drug interactions, as per PI*

These medicines may be affected by [Medicine name], or may affect how well it works. (You may need different amounts of these medicines, or you may need to take different medicines.) Your doctor or pharmacist will advise you and decide whether or not to give the vaccine.

**Having other vaccines**

**Tell your doctor if you have had any vaccines in the last 4 weeks.**

Your doctor will advise you if [Medicine name] is to be given with another vaccine.

Your doctor and pharmacist may have more information on medicines and vaccines to be careful with or avoid during vaccination with [Medicine name].

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**How to take [Medicine name]**

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**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

Your doctor or pharmacist will tell you how many capsules / how much syrup to take and when to take them / it.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

**How much to take**

*Include dosage ranges, usual doses for each indication or patient group.*

**How to take it**

*Including taking with water or any other special precautions, if appropriate.*

**Swallow [Medicine name] whole with a full glass of water. Do not chew the capsules.**

The capsules have a special coating to stop them dissolving until they have passed through the stomach into the intestines where they work. Chewing them destroys the coating.

**Swallow [Medicine name] either alone, mixed with syrup or on a lump of sugar.**

**When to take it**

*Include time with respect to food, vaccination schedule, how long to take it, etc.*

It does not matter if you take [Medicine name] before or after food.

**Take [Medicine name] on an empty stomach 1 hour before food.**

Food can interfere with the absorption of [Medicine name].

**If you forget to take it**

*Include information on missed dosage.*

**If you are not sure what to do, ask your doctor or pharmacist.**

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**After taking [Medicine name]**

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## **Things you or your child must do**

*Precautions or warnings as per PI.*

### **Keep an updated record of your vaccinations.**

### **Keep follow-up appointments with your doctor or clinic.**

It is important to take your follow-up doses of [Medicine name] at the appropriate times to make sure the vaccine has the best chance of providing protection against x *organism*.

### **Have any blood tests when your doctor says to.**

Your doctor may wish to test your body's response to [Medicine name] to make sure that you have developed protection against x *disease*.

## **Things to be careful of**

### **Be careful driving or operating machinery until you know how [Medicine name] affects you.**

[Medicine name] should not normally interfere with your ability to drive or operate machinery. However, it may cause dizziness, light-headedness, tiredness, drowsiness (*as per PI*) in some people.

### **Be careful when drinking alcohol for 2 days after vaccination with [Medicine name].**

Your sensitivity to [Medicine name] may be increased.

*Any other precautions as per PI.*

*Any other precautions as per PI.*

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## **Side effects**

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*The side effects for a particular product will depend on the Product Information and the company's disclosure policy.*

*The following side effects have been listed according to severity. Select those side effects applicable to your product.*

### **Tell your doctor or pharmacist as soon as possible if you or your child do not feel well after having [Medicine name].**

[Medicine name] may have unwanted side effects in a few people. All medicines, including vaccines, can have side effects. Sometimes they are serious, most of the time they are not. You or your child may need medical treatment if you get some of the side effects.

### **Ask your doctor or pharmacist to answer any questions you may have.**

### **Tell your doctor or pharmacist if you notice any of the following and they worry you:**

- flushing or redness of the skin (*erythema, flushing*)
- headaches (*headaches*)
- tiredness, weakness or fatigue (*fatigue, asthenia*)
- dizziness or light-headedness (*hypotension*)
- high blood pressure (*hypertension*)
- generally feeling unwell (*malaise*)
- mild flu-like symptoms, such as high temperature, sore throat, runny nose, cough and chills (*mild influenza-like symptoms, high temperature, chills, rhinitis, coryza*)
- increased sweating (*minor sweating*)
- soreness, aching muscles, muscle tenderness or weakness (not caused by exercise) (*soreness, myalgia*)
- sleepiness (*sleepiness, somnolence*)
- disturbed sleep, insomnia (*disturbed sleep, insomnia*)
- nervousness and irritability (*nervousness, irritability*)
- unusual screaming or crying (*persistent screaming, crying*)
- eating and drinking less than usual, loss of appetite (*fussing, diminished appetite, anorexia*)
- regurgitating milk (*possetting*)
- nausea or vomiting (*nausea, vomiting*)
- constipation (*constipation*)
- diarrhoea (*diarrhoea*)
- stomach cramps or pain (*abdominal cramps, abdominal pain*)

- *any other side effects, as per PI<sup>4</sup>*

These side effects are usually mild.

or:

These are the more common side effects of [Medicine name]. Mostly these are mild and short-lived.

### **Tell your doctor immediately if you notice any of the following:**

- unusual bleeding, bruising or purple spots on the skin (*thrombocytopaenia, purpura, haematoma, ecchymoses*)
- skin rash, itchy spots or red lumps on the skin (*erythema nodosum, erythema multiforme, serum sickness*)
- painful, swollen joints (*arthralgia, serum sickness*)
- swelling of the glands in the neck, armpit or groin (*parotitis, regional lymphadenopathy*)
- itchiness, hives or rash over the body (*generalised itchiness, rash, pruritis*)
- earache or temporary hearing loss (*otitis media*)
- increased sensitivity to light (*photophobia*)
- severe dizziness, unsteadiness when walking or spinning sensation, (*vertigo, cerebellar ataxia*)
- fits or convulsions (*convulsions*)
- weak and stiff neck (*cranial nerve paresis*)
- difficulty passing urine (*difficulty passing urine*)
- ringing or buzzing in the ears (*tinnitus*)
- drooping eyelid and sagging muscles on one side of the face (Bell's Palsy) (*Bell's palsy*)
- sore throat, difficulty swallowing (*bronchitis, pharyngitis, and other upper respiratory tract infections*)
- fast heart beat (*tachycardia*)
- tingling of the hands or feet, or sudden numbness or weakness in the legs or arms (*paraesthesia*)

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<sup>4</sup> List medical terms in brackets after the consumer terminology. The medical terms are not to go into the CMI; rather, they are there to help the CMI writer choose applicable wording for adverse events listed in their PI.

- unusual tiredness or weakness that is sudden and severe (*transverse myelitis*)
- Any other side effects, as per PI

These may be serious side effects. You or your child may need urgent medical attention. Serious side effects are rare.

**If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:**

- 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, (*anaphylactoid reactions, anaphylaxis, angioedema*)
- pinkish, itchy swellings on the skin, also called hives or nettle rash (*urticaria*)
- shortness of breath, wheezing or trouble breathing (*respiratory distress, respiratory failure, wheezing*)
- chest pain (*fatal myocarditis*)
- unusual stiffness causing loss of movement (*hypertonic episode*)
- a seizure or convulsion, which may be accompanied by a very high temperature (*febrile convulsions*)
- feeling weak or paralysed, or generally feeling sore or tender (*polyneuritis, Guillain-Barré Syndrome*)
- yellowing of the skin and/or eyes (*hepatitis*)
- dark coloured urine or pale stools (*hepatitis*)
- passing little or no urine, which may be associated with nausea, loss of appetite and weakness (*renal failure*)
- rapid, shallow breathing, cold, clammy skin, a rapid, weak pulse, dizziness, weakness and fainting (shock) (*shock, syncope*)
- sudden dimming or loss of vision (*optic neuritis*)
- 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 (*disseminated encephalomyelitis, encephalitis, encephalopathy, neurological*

*disorders, transient neurological reactions, meningitis)*

- any other side effects, as per PI

These are very serious side effects. You or your child may need urgent medical attention or hospitalisation.

All of these side effects are rare.

**Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you or your child feel unwell.**

**Do not be alarmed by this list of possible side effects.**

You or your child may not experience any of them.<sup>5</sup>

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## Storing [Medicine name]

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**Keep your tablets in the pack until it is time to take them.**

If you take the tablets out of the pack they will not keep well.

**Keep your tablets in the refrigerator, between 4°C and 8°C. Do not freeze [Medicine name].**

Freezing destroys the vaccine.

**Do not store [Medicine name] or any other medicine in the bathroom or near a sink.**

**Do not leave it on a window sill or in the car on hot days.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

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## Product description

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*This information will be product specific. The Second Edition of the*

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<sup>5</sup> Consider placing this statement at the beginning of this section.

*Usability Guidelines suggest the following order:*

### **What it looks like**

### **Ingredients**

Active ingredients:

- *list actives*

Other ingredients

- *list excipients*

[Medicine name] does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

*Where Australian Food Standard codes exist, these could follow each Australian Approved name.*

### **Manufacturer/Distributor/Supplier**

*Include:*

- *Name and address of sponsor*
- *AUST R number*
- *Date of preparation*