

Consumer Medicine Information (CMI) summary

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

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. What is ZYTORVI and what is it used for?

ZYTORVI contains the active ingredient toripalimab. ZYTORVI is used to treat a kind of head and neck cancer called nasopharyngeal cancer (NPC).

For more information, see Section [1. What is ZYTORVI and what is it used for?](#) in the full CMI.

2. What should I know before I am given ZYTORVI?

Do not use if you have ever had a severe allergic reaction to toripalimab or to any of the ingredients listed at the end of the CMI.

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

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

Patient Alert Card

Important information from this package leaflet can be found in the Patient Alert Card you have been given by your doctor. It is important that you keep this Patient Alert Card and show it to your partner or caregivers.

3. What if I am taking other medicines?

Some medicines may interfere with ZYTORVI and affect how it works.

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

4. How will ZYTORVI be given to me?

ZYTORVI will be given to you in a hospital or clinic under the supervision of a doctor experienced in cancer treatment. ZYTORVI will be given to you as an infusion into your vein. Your doctor will decide how many treatments you need.

More instructions can be found in Section [4. How will ZYTORVI be given to me?](#) in the full CMI.

5. What should I know during treatment with ZYTORVI?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are receiving treatment with ZYTORVI.• If you miss a dose of ZYTORVI, call your doctor right away to reschedule your appointment.• Tell your doctor if you are pregnant, think you might be pregnant, or are planning to become pregnant.
Driving or using machines	<ul style="list-style-type: none">• ZYTORVI is unlikely to affect your ability to drive and use machines. However, if you have side effects that affect your ability to concentrate and react, you should be careful when driving or operating machines.

For more information, see Section [5. What should I know during treatment ZYTORVI?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, ZYTORVI can cause side effects, although not everybody gets them. Your doctor will discuss potential side effects with you and will explain the risks and benefits of your treatment.

Some side effects can be serious and you may require urgent medical attention.

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.



This medicine is subject to additional monitoring, which will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

ZYTORVI

Active ingredient(s): *toripalimab*

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

- [1. What is ZYTORVI and what is it used for?](#)
- [2. What should I know before I am given ZYTORVI?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will ZYTORVI be given to me?](#)
- [5. What should I know during treatment with ZYTORVI?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. What is ZYTORVI and what is it used for?

ZYTORVI contains the active ingredient toripalimab. ZYTORVI is a type of protein designed to recognise and attach to a specific target substance in the body to help your immune system fight your cancer.

ZYTORVI is used in adults to treat a kind of head and neck cancer called nasopharyngeal cancer (NPC).

ZYTORVI may be given in combination with other anti-cancer medicines. It is important that you also read the package leaflet for these other medicines. If you have any questions about these medicines, please ask your doctor.

2. What should I know before I am given ZYTORVI?

Warnings

Do not use ZYTORVI if:

- you have a severe allergy to toripalimab, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have or have had any other medical conditions, especially the following:
 - immune system problems such as Crohn's disease, ulcerative colitis, or lupus
 - received an organ transplant (like a kidney transplant)

- received or plan to receive a bone marrow (stem cell) transplant with donor stem cells (allogeneic)

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

Talk with your doctor if you are pregnant, think you may be pregnant or are planning to have a baby.

ZYTORVI can cause harmful effects or death to your unborn baby.

If you are a woman who could become pregnant, you must use effective contraception while you are being treated with ZYTORVI and for at least 4 months after your last dose.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not breastfeed during treatment and for at least 4 months after your last dose of ZYTORVI. It is not known if ZYTORVI passes into your breast milk.

Use in children and adolescents

ZYTORVI should not be used in children and adolescents under the age of 18 years because it has not been studied in this age group.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with ZYTORVI and affect how it works. It is especially important to tell your doctor or pharmacist if you take other medicines that make your immune system weak. Examples of these include corticosteroids, such as prednisone.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZYTORVI.

4. How is ZYTORVI given?

How much is given

- Your doctor will work out the correct dose for you and how many treatments you need depending on your condition.

How is it given

- ZYTORVI is given into your vein (intravenous infusion) once every two or three weeks. Your doctor will determine how often to give it. The intravenous infusion will take 60 minutes for your first dose and may be given over 30 minutes for subsequent doses.
- If ZYTORVI is given in combination with other anti-cancer medicines, you will be given ZYTORVI first, followed by the other medicine.

If you miss a dose

- If you miss a dose of ZYTORVI, call your doctor right away to reschedule your appointment.
- It is very important that you do not miss a dose of this medicine.

If you are given too much

As ZYTORVI will be given to you in hospital under the care of a highly trained doctor, it is unlikely that you will be given too much.

However, if you experience any side effects after being given ZYTORVI, tell your doctor immediately.

5. What should I know during treatment with ZYTORVI?

Things you should do

- **Keep all of your doctor's appointments so that your progress can be checked.** Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects. Tell your doctor if you are about to start or have started on any new medicine.
- Remind any other doctors, dentists, and pharmacists who treat you that you are being given ZYTORVI.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZYTORVI affects you.

ZYTORVI is unlikely to affect your ability to drive and use machines. However, if you have side effects that affect your ability to concentrate and react, you should be careful when driving or operating machines.

Looking after your medicine

It is unlikely that you will be asked to store ZYTORVI yourself. Your doctor, pharmacist or nurse is responsible for storing ZYTORVI correctly and disposing of any unused product correctly.

6. Are there any side effects?

Like all medicines, ZYTORVI can cause side effects, although not everybody gets them. Your doctor will discuss the side effects of ZYTORVI with you and will explain the risks and benefits of your treatment. Your doctor may also do blood tests to check for side effects.

If you do experience any side effects, most of them are minor and temporary.

The side effects listed below can sometimes become life-threatening and can rarely lead to death. These side effects may happen anytime during treatment or even after your treatment has ended. You may experience more than one side effect at the same time.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• Inflammation of the lungs, which may include shortness of breath, chest pain or coughing.• Inflammation of the heart muscle, which may include shortness of breath, irregular heartbeat, feeling tired, or chest pain.• Inflammation of the liver, which may include nausea or vomiting, feeling less hungry, pain on the right side of stomach, yellowing of skin or whites of eyes, dark urine or bleeding or bruising more easily than normal.• Inflammation of the intestines, which may include diarrhoea or more movements than usual, black, tarry, sticky stools or stools with blood or mucus, severe stomach pain or tenderness, nausea, vomiting.• Inflammation of the skin, which may include rash, itching, skin blistering, peeling or sores, and/or ulcers in mouth or in lining of nose, throat, or genital area.• Inflammation of the kidneys, which may include changes in the amount or colour of your urine.• Inflammation of hormone glands (especially the thyroid, pituitary and adrenal glands), which may include rapid heartbeat, weight gain or weight loss, increased sweating, hair loss, feeling cold, constipation, deeper voice, severe tiredness, dizziness or fainting, headaches that will not go away or unusual headache.• Type 1 diabetes, including diabetic ketoacidosis (acid in the blood produced from diabetes), symptoms may include feeling more hungry or thirsty than usual, need to urinate more often or weight loss, feeling tired or feeling sick, stomach pain, fast and deep breathing, confusion, unusual	Call or see your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
<p>sleepiness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat.</p> <ul style="list-style-type: none"> Inflammation in the muscles and joints, which may include muscle pain or weakness, joint stiffness or swelling. Inflammation of other organ systems: <ul style="list-style-type: none"> - inflammation of the eyes, which may include changes in eyesight. - inflammation of the pancreas, which may include abdominal pain, nausea and vomiting. - inflammation of the nervous system, which may include numbness, tingling, confusion, fever, memory problems or seizures. - Low number of platelets, which may include bruising or bleeding more easily. - Inflammation of the joints, which may include pain and swelling <p>For patients who have had a solid organ, tissue, or bone marrow transplant that used donor stem cells:</p> <ul style="list-style-type: none"> transplant-related complications or rejection of transplanted organ or tissue. 	

Most common side effects in clinical trials

Most common side effects	What to do
<ul style="list-style-type: none"> Low levels of thyroid hormones Rash Fever Diarrhoea Upper respiratory infection Difficulty getting to sleep or staying asleep Itching Ulcers in mouth Lung infection High blood pressure 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

You may experience a reaction while you are receiving your infusion of ZYTORVI. Infusion reactions can sometimes be severe or life threatening. Common infusion reactions include fever, chills, itching or rash.

Tell your doctor or nurse if you feel unwell while you are receiving the infusion of ZYTORVI.

Tell your doctor or pharmacist if you notice anything else that may be making you 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 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 medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What ZYTORVI contains

Active ingredient (main ingredient)	<ul style="list-style-type: none"> toripalimab
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> Citric acid monohydrate Sodium citrate dihydrate Sodium chloride Mannitol Polysorbate 80 Water for injections.

ZYTORVI does not contain preservatives.

Tell your doctor if you are allergic to any of these ingredients.

What ZYTORVI looks like

ZYTORVI is a concentrated injection that is clear to slightly opalescent, colourless to slightly yellow solution in a glass vial. AUST R 426950.

Who distributes ZYTORVI

Dr Reddy's Laboratories (Australia) Pty Ltd
Suite 3.03, Level 3, 390 St Kilda Road
Melbourne, VIC, 3004, Australia
Telephone: 1800 733 397

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