

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.

1. Why am I using Ondansetron-AFT?

Ondansetron-AFT contains the active ingredient ondansetron. Ondansetron-AFT is used to help stop nausea (feeling sick) and vomiting which can occur after medical treatments and operations.

For more information, see Section [1. Why am I using Ondansetron-AFT?](#) in the full CMI.

2. What should I know before I use Ondansetron-AFT?

Do not use if you have ever had an allergic reaction to Ondansetron-AFT or 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, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use Ondansetron-AFT?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Ondansetron-AFT 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 is Ondansetron-AFT given?

- Your doctor will decide how much Ondansetron-AFT you should receive and for how long you should receive it.

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

5. What should I know while receiving Ondansetron-AFT?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are receiving Ondansetron-AFT.Keep all of your doctor's appointments, so that your progress can be checked.
Things you should not do	<ul style="list-style-type: none">Do not take any other medicines whether they require a prescription or not without first telling your doctor.
Driving or using machines	<ul style="list-style-type: none">Be careful before you drive or use any machines or tools until you know how Ondansetron-AFT affects you.Ondansetron-AFT may cause dizziness or drowsiness in some people.
Looking after your medicine	<ul style="list-style-type: none">Ondansetron-AFT is stored by hospital staff in the pharmacy or in the ward.This medicine is kept below 30 °C and protected from light.

For more information, see Section [5. What should I know while receiving Ondansetron-AFT?](#) in the full CMI.

6. Are there any side effects?

Less serious side effects: related to nervous system (headache), gastrointestinal (constipation, dry mouth, mild stomach cramps, diarrhoea), respiratory (hiccups), eye (prolonged upward deviation of the eyes), injection site (pain, itching, swelling, redness around the site of injection) and other (sensation of warmth or flushing). **Speak to your doctor if you have any of these less serious effects and they worry you.**

Serious side effects: related to heart (chest pain, tightness in chest, changes in your heart beat, severe dizziness/fainting), blood vessel (low blood pressure), nervous system (seizures), serotonin syndrome (confusion, fever, sweating, fast heart beat, agitation/confusion, involuntary or loss of muscle coordination or shaking, possible loss of consciousness), skin (severe skin reaction where the top layer of the skin detaches from the lower layers), allergic reaction (swelling of eyelids/face/lips/mouth/throat, wheezing or difficulty in swallowing/breathing, skin rash/lumps/hives) and other (blurred vision). **Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

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.

Ondansetron-AFT

Active ingredient: *ondansetron (as hydrochloride dihydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Ondansetron-AFT. **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 Ondansetron-AFT.**

Where to find information in this leaflet:

- [1. Why am I using Ondansetron-AFT?](#)
- [2. What should I know before I use Ondansetron-AFT?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is Ondansetron-AFT given?](#)
- [5. What should I know while receiving Ondansetron-AFT?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using Ondansetron-AFT?

Ondansetron-AFT contains the active ingredient **ondansetron**. Ondansetron-AFT belongs to a group of medicines called serotonin receptor-3 antagonists.

Ondansetron-AFT is used to help stop nausea (feeling sick) and vomiting which can occur after medical treatments and operations.

Your doctor may have prescribed Ondansetron-AFT for another reason. Ask your doctor if you have any question about why Ondansetron-AFT has been prescribed for you.

Ondansetron-AFT is not addictive.

2. What should I know before I use Ondansetron-AFT?

Warnings

Do not use Ondansetron-AFT if:

- you are allergic to ondansetron, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face/lips/tongue or other parts of the body, rash, itching or hives on the skin.
- you are taking apomorphine (a medicine used to treat Parkinson's disease).

Check with your doctor if you:

- have any other medical conditions
 - a heart condition related to changes in the rhythm or rate of your heart beat

- take any medicines for any other condition
- have allergies to any other medicines, foods, dyes or preservatives
- have had an allergic reaction with other medicines used to prevent nausea and vomiting; you may have an allergic reaction to Ondansetron-AFT as well
- have or used to have liver problems
- have severe constipation.

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 doctor if you are pregnant or intend to become pregnant. Ondansetron-AFT is not recommended for use while you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. Ondansetron-AFT is not recommended for use while you are breastfeeding.

Serotonin syndrome

- Serotonin syndrome occurs when the level of serotonin gets too high.
- Symptoms may vary from mild (shivering, diarrhoea) to severe (muscle rigidity, fever, seizures). **Check with your doctor if you experience these symptoms while on Ondansetron-AFT treatment.**

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 Ondansetron-AFT and affect how it works:

- medicines used to treat conditions of abnormal heart beat
- certain medicines used to treat Parkinson's disease (apomorphine), since this may cause low blood pressure and loss of consciousness
- certain type of antidepressant medicines (known as SSRIs and SNRIs), since this may cause serotonin syndrome
- tramadol, since the pain-relieving effect thereof might be reduced.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affects Ondansetron-AFT.

4. How is Ondansetron-AFT given?

How much is given

- Your doctor will decide how much Ondansetron-AFT you will receive and for how long you will receive it; this depends on your condition and other factors such as your weight.

When Ondansetron-AFT is given

- Ondansetron-AFT will be administered to you before starting with your chemotherapy or radiotherapy or at the start of, or after, your anaesthesia.

How Ondansetron-AFT is given to you

- Ondansetron-AFT will only be given to you by a doctor or a nurse
- Ondansetron-AFT will be injected into a muscle (intramuscular), or diluted with a suitable infusion before it is administered to you as a slow single dose injection/infusion into a vein (intravenous 'drip').

If you are given too much Ondansetron-AFT

Since Ondansetron-AFT is given to you in hospital by a doctor or a nurse, it is very unlikely that you will be given too large a dose.

However, if you think that you have received too much Ondansetron-AFT and you experience severe side effects, tell your doctor immediately.

Symptoms of an overdose may include the side effects listed below in the 'Side effects' section, but are usually of a more severe nature. Ask your doctor or pharmacist if you have any concerns.

5. What should I know while receiving Ondansetron-AFT?

Things you should do

Keep all of your doctor's appointments, so that your progress can be checked.

Call your doctor straight away if you:

- become pregnant while being given Ondansetron-AFT.

Remind any doctor, dentist or pharmacist you visit that you are receiving Ondansetron-AFT.

Things you should not do

- Do not take any other medicines whether they require a prescription or not without first telling your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Ondansetron-AFT affects you.

Ondansetron-AFT may cause dizziness in some people.

Looking after your medicine

Ondansetron-AFT is stored by hospital staff in the pharmacy or in the ward.

This medicine is kept below 30 °C and protected from light.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, hospital staff will take it to the pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Nervous system-related:</p> <ul style="list-style-type: none"> headache <p>Gastrointestinal-related:</p> <ul style="list-style-type: none"> constipation dry mouth mild stomach cramps diarrhoea <p>Respiratory system-related:</p> <ul style="list-style-type: none"> hiccups <p>Eye-related:</p> <ul style="list-style-type: none"> prolonged involuntary upward deviation of the eyes <p>Injection site-related:</p> <ul style="list-style-type: none"> pain, itching, swelling, redness around the site of injection <p>Other:</p> <ul style="list-style-type: none"> sensation of warmth or flushing 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Heart-related:</p> <ul style="list-style-type: none"> chest pain tightness in chest changes in your heart beat, e.g. beating faster or slower than normal, or if it beats irregularly or if it 'throbs' severe dizziness or fainting 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</p>

Serious side effects	What to do
<p>Blood vessel system-related:</p> <ul style="list-style-type: none"> • low blood pressure <p>Nervous system-related:</p> <ul style="list-style-type: none"> • seizures <p>Serotonin syndrome-related:</p> <ul style="list-style-type: none"> • confusion • fever • sweating • fast heart beat • agitation or confusion • involuntary or loss of muscle coordination or shaking • possible loss of consciousness <p>Skin-related:</p> <ul style="list-style-type: none"> • severe skin reaction where the top layer of the skin detaches from the lower layers <p>Allergic reaction-related:</p> <ul style="list-style-type: none"> • swelling of the eyelids, face, lips, mouth or throat • wheezing, or difficulty in swallowing or breathing • skin rash, skin lumps or hives <p>Other:</p> <ul style="list-style-type: none"> • blurred vision 	<p>these serious side effects.</p>

If your nausea (feeling sick) or vomiting does not go away, ask your doctor what to do.

In certain illnesses and treatments where ondansetron has been used, blood vessel blockage has occurred. However, it is important to note that blood vessel blockage has also occurred in these illnesses and treatments when ondansetron injection has NOT been used. Discuss with your doctor if you have any concerns.

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 (Australia) or <https://nzphvc.otago.ac.nz/reporting> (New Zealand). 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 Ondansetron-AFT contains

Active ingredient (main ingredient)	Ondansetron (as hydrochloride dihydrate)
Other ingredients (inactive ingredients)	Citric acid Sodium citrate Sodium chloride Water for injections

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

What Ondansetron-AFT looks like

Ondansetron-AFT injection ampoule 4 mg/2 mL:

2 mL clear, colourless, aqueous solution is supplied in clear 2 mL glass ampoules.

Pack size: 1, 5 or 10 ampoules per carton.

AUST R 300688

Ondansetron-AFT injection ampoule 8 mg/4 mL:

4 mL clear, colourless, aqueous solution is supplied in clear 5 mL glass ampoules.

Pack size: 1, 5 or 10 ampoules per carton.

AUST R 300687

Who distributes Ondansetron-AFT

NEW ZEALAND:

AFT Pharmaceuticals Ltd
Level 1, 129 Hurstmere Road
Takapuna
Auckland, 0622
NEW ZEALAND

Phone: 0800 423 823

Email: customer.service@aftp pharm.com

AUSTRALIA:

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113 Wicks Road
North Ryde
NSW 2113
AUSTRALIA

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