Wegovy® FlexTouch®

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. Why am I using Wegovy® ?

Wegovy® contains the active ingredient semaglutide. Wegovy® is used for weight loss and weight maintenance in addition to diet and physical activity in adults and adolescents ages 12 years and above, and to reduce the risk of a heart disease related event if you are an adult with a history of heart disease and have a BMI ≥27 kg/m2. It also has **provisional approval** for the treatment of Metabolic Dysfunction Associated Steatohepatitis (MASH) in adults with moderate to advanced liver scarring (fibrosis) without cirrhosis. For more information, see Section 1. Why am I using Wegovy® ? in the full CMI.

2. What should I know before I use Wegovy® ?

Do not use if you have ever had an allergic reaction to semaglutide 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 Wegovy® ? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Wegovy® 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 do I use Wegovy® ?

- When you first start using Wegovy® , the starting dose is 0.25 mg once weekly.
- Your doctor will instruct you to gradually increase your dose every 4 weeks until you reach the dose of 2.4 mg once weekly. If needed, for weight management (BMI ≥ 30 kg/m^2), your doctor can increase dose to 7.2 mg once weekly in adults.
- Wegovy® is given as an injection under the skin (subcutaneous injection). Do not inject it into a vein or muscle.

More instructions can be found in Section 4. How do I use Wegovy® ? in the full CMI.

5. What should I know while using Wegovy® ?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using Wegovy® .
Things you should not do	• Do not stop using this medicine without talking to your doctor. • Do not use this medicine if you think it has been frozen or exposed to excessive heat.
Driving or using machines	• Be careful before you drive or use any machines or tools until you know how Wegovy® affects you. • If you use this medicine in combination with a sulfonylurea (such as gliclazide or glimepiride) or insulin, low blood sugar (hypoglycaemia) may occur which may reduce your ability to concentrate.
Looking after your medicine	• Store in a refrigerator (2°C – 8°C). Do not freeze. Keep away from the cooling element. • Wegovy® FlexTouch® can be taken out of the refrigerator for up 6 weeks at a temperature below 30°C.

For more information, see Section 5. What should I know while using Wegovy® ? in the full CMI.

6. Are there any side effects?

During treatment with Wegovy® , you may feel sick (nausea), or be sick (vomiting), or have diarrhoea. These side effects can cause dehydration (loss of fluids). It is important that you drink enough fluids to prevent dehydration. Inflamed pancreas (acute pancreatitis) which could cause severe pain in the stomach and back which does not go away, allergic reaction (skin rashes over a large part of the body, shortness of breath, wheezing, swelling of the face, lips or tongue, fast pulse, sweating), loss of vision and bowel obstruction are very serious side effects for which you may need 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. This 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.

Wegovy® FlexTouch®

Active ingredient(s): *semaglutide*

0.25 mg, 0.5 mg, 1 mg, 1.7 mg and 2.4 mg, solution for injection pre-filled pen

This medicine has **provisional approval** in Australia for the treatment of MASH in adults with moderate to advanced liver scarring (fibrosis) without cirrhosis. The decision to approve this indication has been made on the basis of promising results from preliminary data. More evidence is required to be submitted when available to fully confirm the benefit and safety of the medicine for this use.

Consumer Medicine Information (CMI)

This leaflet provides important information about using Wegovy® FlexTouch®. **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 Wegovy® FlexTouch®.**

Keep this leaflet. You may need to read it again.

This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

Where to find information in this leaflet

1. Why am I using Wegovy® ?
2. What should I know before I use Wegovy® ?
3. What if I am taking other medicines?
4. How do I use Wegovy® ?
5. What should I know while using Wegovy® ?
6. Are there any side effects?
7. Product details

1. Why am I using Wegovy® ?

Wegovy® contains the active ingredient semaglutide. Wegovy® is similar to a natural hormone called glucagon-like peptide-1 (GLP-1) that is released from the intestine after a meal. Wegovy® works by acting on receptors in the brain that control your appetite, causing you to feel fuller and less hungry and experience less craving for food. This will help you eat less food and reduce your body weight. In the liver, Wegovy® works by slowing down or stopping further liver damage caused by fat build-up and inflammation, and by supporting a reduction of liver scarring.

Wegovy® is used for weight loss and weight maintenance in addition to diet and physical activity in adults, who have

- a BMI of 30 kg/m² or greater (obesity), or
- a BMI of 27 kg/m² and less than 30 kg/m² (overweight) and weight-related health problems.

Wegovy® is used to reduce the risk of a heart disease related event in adults with a history heart disease who do not have Type 1 or Type 2 diabetes and have a BMI of 27 kg/m² or greater.

BMI (Body Mass Index) is a measure of your weight in relation to your height.

Wegovy® is used together with diet and physical activity for weight management in adolescents aged 12 years and above, who have

- obesity

and

- body weight >60 kg.

As an adolescent patient, you should only continue using Wegovy if you have lost at least 5% of your BMI after 12 weeks on the 2.4 mg dose or maximum tolerated dose (see Section 4. How do I use Wegovy® ?). Consult your doctor before you continue.

Wegovy® also has provisional approval for the treatment of Metabolic Dysfunction Associated Steatohepatitis (MASH) in adults with moderate to advanced liver scarring (fibrosis) without cirrhosis. MASH is a condition where fat builds up in the liver creating inflammation, liver damage and scar tissue.

Wegovy® is an injection that is used once a week.

2. What should I know before I use Wegovy® ?

Warnings

Do not use Wegovy® if:

- You are allergic to semaglutide, or any of the ingredients listed at the end of this leaflet.
  Some of the symptoms of an allergic reaction may include:
  - redness, swelling, rash and itching at the injection site
  - rash, itching or hives on the skin
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body.
- Always check the ingredients to make sure you can use this medicine.
- Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

- It is after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.
- It has expired or is damaged, return it to your pharmacist for disposal. The expiry date refers to the last day of that month.

The use of Wegovy is not recommended if you:

- use other products for weight loss
- have type 1 diabetes
- have severe heart failure

There is little experience with Wegovy in patients:

- of 85 years and older
- with an inflammatory bowel disease.
- MASH and BMI<25 kg/m² (or BMI<23 kg/m² for Asian population).

Please consult your doctor if one of the above applies to you.

Check with your doctor if you:

- have any other medical conditions
- have or have had depression, suicidal thoughts or any other major mental illness
- take any medicines for any other condition.

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.

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

This medicine should not be used during pregnancy, and for at least two months before a planned pregnancy because Wegovy® may harm your unborn child. Therefore, it is recommended to use contraception while using this medicine. If you wish to become pregnant, you should stop using this medicine at least two months in advance. If you become or are pregnant, think you may be pregnant or are planning to have a baby when using this medicine, talk to your doctor straight away, as your treatment will need to be stopped.

Do not use this medicine if you are breast-feeding, as it is unknown if it passes into breast milk.

Food or liquid getting into lungs during anaesthesia

- Some patients taking medicines like Wegovy® have had problems with food or liquid from their stomach getting into their lungs while under general anaesthesia or deep sedation.
- **Tell your healthcare professional that you are taking Wegovy® before you have a procedure that requires general anaesthesia or deep sedation.**

Effects on the digestive system

During treatment with Wegovy®, you may feel sick (nausea), or be sick (vomiting), or have diarrhoea. These side effects can cause dehydration (loss of fluids). It is important that you drink enough fluids to prevent dehydration. This is especially important if you have kidney problems. Talk to your doctor if you have any questions or concerns.

Patients with delayed stomach emptying (gastroparesis)

If you have slow (delayed) stomach emptying (called gastroparesis), use of Wegovy® may lead to serious or severe gastrointestinal adverse events. talk to your doctor before using Wegovy®.

Inflammation of the pancreas

If you have severe and on-going pain in the stomach area (see Section 6. Are there any side effects?) – see a doctor straight away as this could be a sign of an inflamed pancreas (acute pancreatitis).

People with diabetes

Do not use Wegovy® as a substitute for insulin.

Low Blood Sugar (Hypoglycaemia)

Taking a sulfonylurea (such as gliclazide or glimepiride) or an insulin with Wegovy® might increase the risk of getting low blood sugar levels (hypoglycaemia). Please see section 6 for the warning signs of low blood sugar levels.

Your doctor may ask you to test your blood sugar levels. This will help your doctor decide if the dose of the sulfonylurea or insulin needs to be changed to reduce the risk of low blood sugar.

Diabetic eye disease (retinopathy)

Fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disease. If you have diabetic eye disease and experience eye problems while taking this medicine, talk to your doctor.

Sudden changes to your eyesight

If you notice a sudden loss of vision or rapidly worsening eyesight during treatment with this medicine, immediately contact your doctor for advice. This may be caused by a very rare side effect called non-arteritic anterior ischaemic optic neuropathy (NAION). Your doctor may refer you for an eye examination and you may have to stop treatment with this medicine. See additional information under Section 6. Are there any side effects?

Children and adolescents

This medicine is not recommended in children and adolescents with overweight or obesity under 12 years as the safety and efficacy in this age group have not been established.

The safety and efficacy of Wegovy® in children and adolescents with MASH have not been studied and Wegovy® is not recommended for use in these populations.

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.

In particular, tell your doctor, pharmacist or nurse if you are using medicines containing the following:

- Warfarin or other similar medicines taken by mouth to reduce blood clotting (oral anti-coagulants). When you start treatment with e.g., warfarin or similar medicines, frequent blood testing to determine the ability of your blood to clot may be required.

People with diabetes

Your doctor may adjust the dose of your diabetes medicines to prevent you from getting low blood sugar.

Do not mix Wegovy® up with other medicines that you inject (e.g., insulins).

Do not use Wegovy® in combination with other medicines that contain GLP-1 receptor agonists (such as liraglutide, dulaglutide, exenatide or lixisenatide).

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

4. How do I use Wegovy®?

How much to use

- Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Adults

- Your treatment will start at a low dose which will be gradually increased over 16 weeks of treatment.
- When you first start using Wegovy®, the starting dose is 0.25 mg once weekly.
- Your doctor will instruct you to gradually increase your dose every 4 weeks until you reach the dose of 2.4 mg once weekly.
- **For weight management only:** in adults with a BMI ≥30 kg/m² at treatment initiation, if needed, your doctor may increase the dose to a maximum of 7.2 mg once weekly (3 injections of 2.4 mg) following a minimum of 4 weeks on 2.4 mg. The maximum dose is 7.2 mg once weekly.
- In case you are feeling very bothered by sickness (nausea) or by being sick (vomiting) talk with your doctor about delaying dose escalation or lowering to the previous dose until symptoms have improved. You will be told to follow the table below.

Dose escalation	Weekly dose
Week 1-4	0.25 mg
Week 5-8	0.5 mg
Week 9-12	1 mg
Week 13-16	1.7 mg
From week 17-20	2.4 mg
From week 21	2.4 mg or 7.2 mg*

*the 7.2 mg maintenance dose is applicable for weight management only, in adult patients with a BMI≥30 kg/m² at treatment initiation, if needed.

- Your doctor will assess your treatment on a regular basis.

Adolescents (above 12 years of age)

- For adolescents, the same dose escalation schedule as for adults should be applied (see above). The dose should be increased until 2.4 mg (maintenance dose) or maximum tolerated dose has been reached. Weekly doses higher than 2.4 mg are not recommended.
- As an adolescent patient, you should regularly review your treatment goals with your doctor.

Follow the instructions provided and use Wegovy® until your doctor tells you to stop.

When to use Wegovy®

- You should use this medicine once a week and if possible, on the same day each week
- You can give yourself the injection at any time of the day – regardless of meals.
- If necessary, you can change the day of your weekly injection of this medicine as long as it has been at least 3 days since your last injection. After selecting a new dosing day, continue with once a week dosing.

How Wegovy® is given

- Wegovy® is given as an injection under the skin (subcutaneous injection). Do not inject it into a vein or muscle.
- The best places to give the injection are the fronts of your upper arm, upper legs or stomach.
- Before you use the pen for the first time, ask your doctor, pharmacist or nurse how to use it.

For Wegovy 7.2 mg inject three doses of 2.4 mg one after each other. The injections can be given in the same body area but should be at least 5 cm apart.Follow the detailed instructions on how to inject Wegovy® FlexTouch® in the instructions for use supplied with the product. These instructions are also available via the following hyperlink https://medsinfo.com.au/media/noiwegof

If you forget to use Wegovy®

If you forgot to inject a dose and:

- it is 5 days or less since you should have used Wegovy®, use it as soon as you remember. Then inject your next dose as usual on your scheduled day.
- it is more than 5 days since you should have used Wegovy®, skip the missed dose. Then inject your next dose as usual on your next scheduled day. Do not take a double dose to make up for a forgotten dose.

If you use too much Wegovy®

Talk to your doctor straight away. You may get side effects such as feeling sick (nausea), being sick (vomiting) or have diarrhoea, which may cause dehydration (loss of fluids).

If you think that you have used too much Wegovy®, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26 in Australia or 0800 764766 in New Zealand**), 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 while using Wegovy®?

Things you should do

- Tell your doctor or pharmacist if you are travelling.
- Ask them for a letter explaining why you are taking injecting devices with you. Each country you visit will need to see this letter, so you should take several copies.
- You may not be able to get Wegovy® FlexTouch® in the country you are visiting.
- Remind any doctor, dentist or pharmacist you visit that you are using Wegovy®.

Things you should not do

- Do not stop using this medicine without talking to your doctor.
- Do not use this medicine if you think it has been frozen or exposed to excessive heat.
- Do not use this medicine to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not share your pen with anyone else.
- Do not use this medicine after the expiry date which is stated on the pen label and carton after 'EXP'. The expiry date refers to the last day of that month.

Driving or using machines

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

Wegovy® is unlikely to affect your ability to drive and use machines. Some patients may feel dizzy when taking Wegovy® mainly during the first 4 months of treatment (see section 6). If you feel dizzy be extra careful while driving or using machines. If you need any further information, talk to your doctor, pharmacist or nurse.

<u>People with diabetes</u>

If you use this medicine in combination with a sulfonylurea or insulin, low blood sugar (hypoglycaemia) may occur which may reduce your ability to concentrate. Avoid driving or using machines if you get any signs of low blood sugar. See section 2 for information on increased risk of low blood sugar and section 6 for the warning signs of low blood sugar.

Looking after your medicine

- Store in a refrigerator (2°C – 8°C). Do not freeze. Keep away from the cooling element.
- Wegovy® can be taken out of the refrigerator for up to 6 weeks at a temperature below 30°C.
- Always store the pen in the original carton in order to protect from light.
- Do not use this medicine if you notice that the solution is not clear and colourless.

Keep it where young children cannot reach it.

When to discard your medicine

Discard the Wegovy® FlexTouch® pen you are using after 6 weeks even if there is still some medicine left in it.

After having injected the 4 doses, there might still be solution left in the pen despite having administered correctly. Any solution left is insufficient for a dose and the pen should be disposed of.

Dispose of used needles safely into a yellow plastic sharps container.

Getting rid of any unwanted medicine

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

Do not use this medicine after the expiry date. The expiry date refers to the last day of that month.

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
Very common: may affect more than 1 in 10 people: • headache* • feeling sick (nausea) • being sick (vomiting) • diarrhoea • constipation • stomach pain. • feeling weak or tired – these usually go away over time. **Common:** may affect up to 1 in 10 people: • headache** • feeling dizzy	Speak to your doctor if you have any of these less serious side effects and they worry you.

Less serious side effects	What to do
• upset stomach or indigestion • burping • gas (flatulence) • bloating of the stomach • inflamed stomach ('gastritis') – the signs include stomach ache, feeling sick (nausea) or being sick (vomiting) • reflux or heartburn – also called 'gastro-oesophageal reflux disease' • dry mouth • gallstones • hair loss – may occur more frequently with semaglutide 7.2 mg • injection site reactions • unpleasant, abnormal or altered taste sensation* • change in skin sensation– this usually goes away over time and may happen more frequently with semaglutide 7.2 mg. • low blood sugar (hypoglycaemia) in patients with diabetes. • low blood pressure** • a delay in the emptying of the stomach** • increase in pancreas blood test results (lipase)** **Uncommon:** may affect up to 1 in 100 people: • fast heartbeat • increase in pancreas blood test results (lipase)* • increase in pancreas blood test results (amylase) • a delay in the emptying of the stomach • low blood pressure* • feeling dizzy or lightheaded on standing or sitting up because of a drop in blood pressure • unpleasant, abnormal or altered taste sensation** • inflamed gallbladder	

*Frequency based on weight management trials.

**Frequency based on MASH trials

Hypoglycaemia

The warning signs of low blood sugar may come on suddenly. They can include: cold sweat, cool pale skin, headache, fast heartbeat, feeling sick (nausea) or very hungry, changes in vision, feeling sleepy or weak, feeling nervous, anxious or confused, difficulty concentrating or shaking.

Your doctor will tell you how to treat low blood sugar and what to do if you notice these warning signs.

Low blood sugar is more likely to happen if you also take a sulfonylurea or insulin. Your doctor may reduce your dose of these medicines before you start using this medicine.

Serious side effects

Serious side effects	What to do
Complications of diabetic eye disease (diabetic retinopathy). If you have diabetes you should inform your doctor if you experience eye problems, such as changes in vision, during treatment with this medicine. **Common:** may affect up to 1 in 10 people **Inflamed pancreas (acute pancreatitis).** Signs of inflamed pancreas may include severe and long-lasting pain in your stomach, with or without vomiting. You may feel the pain from your abdomen to your back. You should see your doctor immediately if you experience such symptoms. **Uncommon:** may affect up to 1 in 100 people **Severe allergic reactions (anaphylactic reactions).** You should seek immediate medical help and inform your doctor straight away if you get symptoms such as breathing problems, swelling of face and throat, wheezing, fast heartbeat, pale and cold skin, feeling dizzy or weak. **Rare:** may affect up to 1 in 1,000 people **Bowel obstruction** A severe form of constipation with additional symptoms such as stomach ache, bloating, vomiting etc. **Not known:** frequency cannot be estimated from the available data. **Loss of vision** A medical condition of the eye called non-arteritic anterior ischaemic optic neuropathy (NAION), which may cause loss of vision to one of your eyes without any pain. You should immediately contact your doctor if you notice sudden or gradually	**Call your doctor straight away, or go straight to the Accident and Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
worsening eyesight **Very rare:** may affect up to 1 in 10, 000 people)	

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. If you are in New Zealand, you can report side effects at https://pophealth.my.site.com/carmreportnz/s/. 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 Wegovy® FlexTouch® contains

Active ingredient (main ingredient)	semaglutide
Other ingredients (inactive ingredients)	• dibasic sodium phosphate dihydrate • propylene glycol • phenol • water for injections • sodium hydroxide/hydrochloric acid (for pH adjustment)
Potential allergens	Nil

Wegovy® FlexTouch® contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

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

What Wegovy® FlexTouch® looks like

Wegovy® FlexTouch® is a clear and colourless solution for injection in a pre-filled disposable pen.

Each pen contains four doses. The pack size of each strength of Wegovy® FlexTouch® contains 1 pre-filled pen and 4 disposable NovoFine® Plus® needles.

Wegovy® FlexTouch® 0.25 mg solution for injection (Aust R 424390)

One mL of solution contains 0.68 mg of semaglutide. One pre-filled pen contains 1.0 mg semaglutide in 1.5 mL solution.

Wegovy® FlexTouch® 0.5 mg solution for injection (Aust R 424391)

One mL of solution contains 1.34 mg of semaglutide. One pre-filled pen contains 2.0 mg semaglutide in 1.5 mL solution.

Wegovy® FlexTouch® 1 mg solution for injection (Aust R 424392)

One mL of solution contains 1.34 mg of semaglutide. One pre-filled pen contains 4.0 mg semaglutide in 3 mL solution.

Wegovy® FlexTouch® 1.7 mg solution for injection (Aust R 424393)

One mL of solution contains 2.27 mg of semaglutide. One pre-filled pen contains 6.8 mg semaglutide in 3 mL solution.

Wegovy® FlexTouch® 2.4 mg solution for injection (Aust R 424394)

One mL of solution contains 3.2 mg of semaglutide. One pre-filled pen contains 9.6 mg of semaglutide in 3 mL solution.

Who distributes Wegovy®

Wegovy® is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty. Ltd.

Level 10

118 Mount Street

North Sydney NSW 2060

Wegovy® is supplied in New Zealand by:

Novo Nordisk Pharmaceuticals Ltd.

PO Box 51-268

Pakuranga

Auckland

New Zealand.

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Further information

For further information call Novo Nordisk Medical Information on 1800 668 626 (Australia) or 0800 733 737 (New Zealand).

www.novonordisk.com.au

www.novonordisk.co.nz

wegovycare® is a free support program. To find out more go to:

wegovycare.com.au

The Patient Support Program is not authorised or approved by the Australian regulator of medicines, the TGA.

Always check the following websites to ensure you are reading the most recent version of the Wegovy® FlexTouch® medicine information:

www.novonordisk.com.au (AU)

https://www.ebs.tga.gov.au/ (AU)

www.novonordisk.co.nz (NZ)

https://www.medsafe.govt.nz/medicines/infosearch.asp (NZ)

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