

Biological Therapies

Folic Acid 15 mg in 1 mL Injection

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 being given this medicine?

This medicine contains the active ingredient folic acid. It is used for the prevention and treatment of folate deficiency. For more information, see Section [1. Why am I being given this medicine?](#) in the full CMI.

2. What should I know before I am given this medicine?

Do not use if you have ever had an allergic reaction to this medicine 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 am given this medicine?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Folic Acid Injection 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 this medicine given to me?

Folic Acid Injection will be injected intramuscularly (into a muscle), intravenously (into a vein) or subcutaneously (under the skin) by your doctor. Your doctor will decide what to do. This medicine must only be given by a doctor or nurse. The amount given depends on many factors including your medical condition.

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

5. What should I know while being given this medicine?

Things you must do	<ul style="list-style-type: none">• Remind or tell any doctor, surgeon, anaesthetist, dentist or pharmacist you visit that you are being treated with Folic Acid Injection.• Tell your doctor if you feel that giving this medicine is not helping your condition.• Keep all of your doctor's appointments so that your progress can be checked.
Things you must not do	<ul style="list-style-type: none">• Do not attempt to inject this medicine yourself.• Do not take any other medicines without first telling your doctor or consulting a pharmacist.• Do not give this medicine to anyone else, even if they have the same condition as you.
Looking after your medicine	<ul style="list-style-type: none">• This medicine is usually stored in the doctor's surgery or clinic, or at the pharmacy.• The medicine should be protected from light and stored refrigerated (store at 2°C to 8°C), do not freeze and where children cannot reach it. Each vial is for SINGLE USE in one patient on one occasion only.

For more information, see Section [5. What should I know while being given this medicine?](#) in the full CMI.

6. Are there any 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.

Biological Therapies

Folic Acid 15 mg in 1 mL Injection

Active ingredient(s): *Folic Acid*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Biological Therapies Folic Acid Injection. **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 Folic Acid Injection.**

Where to find information in this leaflet:

- [1. Why am I being given this medicine?](#)
- [2. What should I know before I am given this medicine?](#)
- [3. What if I am taking other medicines?](#)
- [4. How is this medicine given to me?](#)
- [5. What should I know while being given this medicine?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I being given this medicine?

Folic Acid Injection contains the active ingredient folic acid; (2S)-2-[[4-[[[2-amino-4-oxo-1,4-dihydropteridin-6-yl)methyl]amino]benzoyl]amino] pentanedioic acid (a member of the Vitamin B group). Once administered, folic acid is converted to folate in the body.

Folate Deficiency:

Folic Acid Injection may be prescribed if you have a diagnosed folate deficiency and are unable to absorb sufficient folate through oral intake. Oral intake may be insufficient in; malabsorption disorders, alcoholism, gastrointestinal diseases, pregnancy and lactation, haemolytic anaemia, exfoliative dermatitis and chronic infection.

For use in Pregnancy and Lactation:

Without folate, cells cannot divide normally. This is especially important for all rapidly dividing cells in the body, such as the cells in a developing baby (foetus). Your doctor may prescribe Folic Acid Injection to prevent folate deficiency in pregnancy or lactation, particularly if you have a problem that decreases your folate levels.

Megaloblastic Anaemia:

Anaemia occurs when red blood cells cannot carry enough oxygen to meet the needs of the body's cells. Folate is needed to make red blood cells grow properly, without it the red blood cells become large and less effective. This is a type of anaemia called megaloblastic anaemia. Megaloblastic anaemia may also be caused by a vitamin B12 deficiency, since vitamin B12 is required to use folate properly in the body.

Symptoms of anaemia include tiredness, breathlessness, lack of energy, fast heartbeat and pale colour of the skin.

Folic Acid Injection may be prescribed to help with the symptoms of megaloblastic anaemia if folate deficiency is the diagnosed cause.

Your doctor may have prescribed Folic Acid Injection for another reason.

Ask your doctor if you have any questions about why Folic Acid Injection has been prescribed for you.

Folic Acid Injection is not addictive.

2. What should I know before I am given this medicine?

Warnings

You must not be given this medicine if:

- You have a known allergy to folic acid or its derivatives.** If you have had an allergic reaction to folic acid before, you may be allergic to Folic Acid Injection
- You have megaloblastic anaemia but have not had tests to prove folate deficiency is the cause.** Vitamin B12 deficiency will also cause megaloblastic anaemia. B12 deficiency can also cause damage to the nervous system. Folic Acid Injection might correct the anaemia caused by B12 deficiency but will not stop the nerve damage.
- You must not be given this medicine if the solution in the vial is not clear or contains particles.**
- If you are not sure whether you should be given this medicine, talk to your doctor.**

Check with your doctor if you:

- Have any other medical conditions.
- Take any medicines for any other condition.
- Have had an allergy to any of the ingredients listed at the end of this leaflet.** Your doctor may test if you have an allergy to this medicine by injecting a small amount under your skin.
- Have allergies to any other medicines or any other substances, such as foods, preservatives or dyes.**

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

Folic Acid Injection is used in the prevention of folic acid deficiency in pregnancy and lactation.

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.

If you have not told your doctor about any of the above, tell them before you are given Folic Acid Injection.

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.

Your doctor and pharmacist have more information about medicines to be careful with, or avoid while you are being treated with this medicine.

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

4. How is this medicine given to me?

This medicine must only be given by a doctor or nurse.

Folic Acid Injection will be injected intramuscularly (into a muscle), intravenously (into a vein) or subcutaneously (under the skin) by your doctor. Your doctor will decide what to do.

How much is given

Your doctor will tell you how much Folic Acid Injection will need to be given. This is determined by many factors including your medical condition. The usual amount given is 1 to 5 mg per day.

Follow all directions given to you by your doctor carefully. They may differ from the information contained in this leaflet.

How long is the treatment time with this medicine

Each person will respond differently to Folic Acid Injection.

Your doctor will advise you about the length of treatment with Folic Acid Injection.

If you miss an appointment or need to change an appointment

If you miss an appointment, talk to your doctor and arrange another appointment as soon as possible.

If you are not sure what to do, contact your doctor or pharmacist as soon as possible.

If too much of this medicine is given

Your doctor should be the only person to inject Folic Acid Injection, so an overdose is unlikely to occur.

If you think that you or anyone else may have been given too much Folic Acid Injection you 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 while being given this medicine?

Things you must do

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are being treated with Folic Acid Injection.
- Tell all doctors, dentists and pharmacists who treat you that you are being given this medicine.
- Tell your doctor if you become pregnant while using Folic Acid Injection.
- Tell your doctor if you feel that giving Folic Acid Injection is not helping your condition.
- 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.

Things you must not do

- Do not attempt to inject this medicine yourself.
- Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting a pharmacist.
- Do not use this medicine if the packaging is torn or shows signs of tampering.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how Folic Acid Injection affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Folic Acid Injection is usually stored in the doctor's surgery or clinic, or at the pharmacy.

If you need to store Folic Acid Injection keep it in the original pack until it is time for it to be given. Unopened vials of Folic Acid Injection are to be stored at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light.

Seal box immediately after removal of each vial and store in a dark place.

Keep it where young children cannot reach it.

When to discard your medicine

Each vial is for SINGLE USE in one patient on one occasion only. It will be used once only and then it will be discarded. It must never be stored after it is opened or used for more than one person.

Getting rid of any unwanted medicine

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any vials that are left over.

Do not use this medicine after the expiry date. It may not work and it may be harmful to you.

6. Are there any side effects?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being given or treated with Folic Acid Injection.

This medicine helps most people, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists. You may not experience any of them.

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

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• shortness of breath, troubled breathing, tightness of chest, wheezing• reddened skin• fever• general weakness or discomfort• skin rash or itching	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.

The above list includes rare allergic side effects and you may need urgent medical attention.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell, even if it is not on this list. This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Ask your doctor or pharmacist if you don't understand anything in this list.

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 Folic Acid 15 mg in 1 mL Injection contains

Active ingredient (main ingredient)	Folic acid
Other ingredients (inactive ingredients)	Disodium edetate Sodium hydroxide Water for injections

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

Folic Acid Injection does not contain gluten, lactose, sucrose, tartrazine or any other azo dyes.

What Folic Acid 15 mg in 1 mL Injection looks like

Folic Acid Injection is a clear, yellow coloured solution contained in a 2 mL amber glass vial sealed with a rubber stopper and an aluminium seal.

Australian Registration Number: AUST R 106971

This medicine may be available in 3 pack sizes:

10 x 1 mL vials per carton

6 x 1 mL vials per carton

1 x 1 mL vial per carton

Who distributes Folic Acid Injection

Biological Therapies

A Division of Orthomolecular Medisearch
Laboratories Pty Ltd

5 / 20 – 30 Malcolm Road, Braeside VIC 3195

Australia

Tel: + 61 3 9587 3948

Fax: +61 3 9587 1720

Website: www.biologicaltherapies.com.au

Email: biol@biol.com.au

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