

Biological Therapies Folic Acid 5 mg in 1 mL Injection

for Intramuscular, Subcutaneous or Intravenous Injection

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Biological Therapies Folic Acid Injection. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of giving Folic Acid Injection against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Biological Therapies Folic Acid Injection is used for

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.

Folic Acid Injection requires a prescription from a doctor.

Before you have Biological Therapies Folic Acid Injection

When you must not use it:

Do not have Folic Acid Injection given 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.

- **The solution in the vial is not clear or contains particles.**
- **The packaging is torn or shows signs of tampering**
- **The expiry date on the pack has passed**

If you have this medicine after the expiry date, it may not work.

If you are not sure whether you should have Folic Acid Injection given, talk to your doctor.

Before you have it injected:

Your doctor may test if you have an allergy to Folic Acid by injecting a small amount under your skin

If you have any of the following medical illnesses or conditions, you must tell your doctor. Your doctor will discuss the risks and benefits of using Folic Acid Injection if you have any of these illnesses or conditions.

Tell your doctor if:

- **You have had an allergy to any of the ingredients in this medicine, any other medicines or any other substances, such as foods, preservatives or dyes.**

If you have not told your doctor about any allergies you might have, tell them before you have Folic Acid Injection given.

If Taking Other Medicines:

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

Your doctor or pharmacist has more information about medicines to be careful with, use correctly or to avoid while you are being treated with Folic Acid.

How Biological Therapies Folic Acid Injection is used

Folic Acid Injection 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 to have administered:

Your doctor will tell you how much Folic Acid Injection will need to be given.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

How long to use it:

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 forget an appointment or need to change an appointment:

You will need to make 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 is given (overdose):

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

But if you think that you or anyone else may have been given too much Folic Acid Injection immediately telephone your doctor or Poisons Information Centre (telephone 13 11 26) or go to accident and emergency at your nearest hospital. Do this

even if there are no signs of discomfort or poisoning.

While you are using Biological Therapies Folic Acid Injection

Things you must do:

- **Tell all doctors, dentists and pharmacists who are treating you that you are using Folic Acid Injection.**
- **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.**

Be sure to keep all appointments with your doctor so that your progress can be checked.

Things you must not do:

- **Do not inject Folic Acid Injection yourself.**
- **Do not take any other medicines, whether they require a prescription or not, without first telling your doctor or consulting a pharmacist.**

Side effects

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

Folic Acid Injection helps most people with folic acid deficiency and related disorders, 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 treatment if you get some of the side effects.

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

If any of the following happen, tell your doctor immediately, or go to accident and emergency at your nearest hospital:

- shortness of breath, troubled breathing, tightness of chest, wheezing
- reddened skin
- fever
- general weakness or discomfort
- skin rash or itching

These are rare allergic side effects and may require urgent medical attention.

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.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

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

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

You should not experience any of them.

How to Store Biological Therapies Folic Acid Injection

Unopened vials of Folic Acid Injection are to be stored at 2°C to 8°C (Refrigerate. Do not freeze). Protect from light. Keep out of reach of children

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

This product 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.

Product Description

What it looks like:

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

Folic Acid 5 mg in 1 mL Injection is contained in a 2 mL amber glass vial and has three pack sizes:

- 10 x 1 mL vials per carton
- 6 x 1 mL vials per carton
- 1 x 1 mL vial per carton

Ingredients per vial:

Active ingredient:

Folic acid 5 mg

Excipient ingredients:

- Disodium edetate
- Sodium hydroxide
- Water for injections

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

Supplier

Folic acid 5 mg in 1 mL Injection is supplied and manufactured in Australia by:

Biological Therapies

A Division of Orthomolecular Medisearch

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