

FOLOTYN[®] injection patient guide



You have been prescribed *FOLOTYN[®]* injection to treat peripheral T-cell lymphoma (PTCL) after previous treatments have not worked or have stopped working. PTCL is a cancer of the lymphatic system. It occurs when T-cells, a type of white blood cell, multiply too quickly. *FOLOTYN[®]* injection contains the anti-cancer (chemotherapy) medication, pralatrexate. *FOLOTYN[®]* injection works by slowing or stopping the growth of the cancer cells.¹

As with many other anti-cancer therapies, *FOLOTYN[®]* injection may cause some unwanted side effects. This patient guide provides you with advice on what you can do to help decrease the risk of experiencing some of these side effects or decreasing their severity.

Before you start *FOLOTYN[®]* injection therapy

Your doctor will usually advise you to start taking certain medicines or vitamin supplements before you start therapy with *FOLOTYN[®]* injection. These are taken to help avoid or decrease the severity of some side effects that can occur with *FOLOTYN[®]* injection.¹

Daily folic acid

Typically you will be asked to take folic acid by mouth for about 10 days before your first dose of *FOLOTYN[®]* injection. You should continue taking folic acid every day until your doctor tells you to stop, which is generally about 30 days after *FOLOTYN[®]* injection therapy has stopped. Your doctor will tell you the exact dose of folic acid to take each day, which generally is about 1 to 1.25 mg/day.^{1,2}

Regular vitamin B₁₂ injections

In addition to taking folic acid, your doctor will give you a vitamin B₁₂ injection into the muscle before your first dose of *FOLOTYN[®]* injection. Extra vitamin B₁₂ injections will be given to you every 8 to 10 weeks during your treatment with *FOLOTYN[®]* injection.¹

In addition to taking these supplements, your doctor may advise you to do some other things before you start *FOLOTYN[®]* injection therapy.

Dental check up

One of the possible side effects of *FOLOTYN[®]* injection is inflammation of the lining of the mouth, known as mucositis, which can cause soreness and ulcers in the mouth.³ There are a number of actions that you can take to help prevent and reduce the severity of mucositis. An important early action is to see a dentist about three to four weeks before you start *FOLOTYN[®]* injection therapy so that they can clean your teeth and gums and carry out any corrective dental procedures.⁴ If you wear dentures, these should be checked by the dentist to make sure that they fit well, as poorly fitting dentures can irritate your gums and worsen mucositis.⁵

Quit smoking

Smoking cigarettes can also impact the health of your mouth and gums. If you are a smoker, you should talk to your doctor or pharmacist about help to quit smoking. Quitting smoking can help prevent or decrease the severity of mucositis.⁴

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How is FOLOTYN® injection given?

FOLOTYN® injection will be given to you by a doctor or nurse experienced in treating cancer. It will be given as an infusion into your vein over 3 to 5 minutes.¹

Typically you will be given FOLOTYN® injection once a week for 6 weeks, with no treatment on the seventh week. This seven-week course represents one treatment cycle. You may receive several treatment cycles depending on your response to FOLOTYN® injection.¹

Before you are given each FOLOTYN® injection (intravenous infusion) your doctor or nurse will test your blood and check your general health including the health of your mouth. Your doctor may change your dose or delay treatment based on your blood tests and on your health.¹

While you are taking FOLOTYN® injection, remember to continue to take your folic acid supplement every day. Also, you should receive an injection of vitamin B₁₂ every 8 to 10 weeks.¹

Potential side effects while being treated with FOLOTYN® injection

FOLOTYN® injection therapy may cause some unwanted side effects including low blood counts, inflammation of mucous membranes (mucositis) and skin reactions.¹

Low blood cell counts and infection risk

FOLOTYN® injection therapy may affect your bone marrow and cause you to have low blood cell counts, including platelets, white and red blood cells. You will have weekly blood tests to check on your blood cell counts and if they are too low, the dose of FOLOTYN® injection may be reduced or delayed until the number of blood cells increases again.^{1,2}

One of the important white blood cells are neutrophils. Neutrophils help fight infections and if your chemotherapy causes the number of neutrophils to become too low it reduces your ability to fight infections.³

Serious illness can occur if an infection is not treated straight away. If you develop signs of an infection or if you feel unwell it is important to contact your doctor or healthcare team or go to your nearest emergency department to be checked.

Signs of infection include:³

- Fever, a temperature above 38° C
- Chills, shivers or shakes
- Pain, redness, heat, swelling or drainage from a wound or venous access site
- Pain, burning or blood in the urine
- Diarrhoea with a fever
- Sore throat with a fever.

Mucous membrane inflammation (mucositis)

FOLOTYN® injection therapy can cause redness and sores. Sores and ulcers in your mouth can be very painful, can affect your ability to eat and drink and can become infected.³

As symptoms can worsen quickly, it is important to contact your doctor or healthcare team if you have:^{3,4}

- Trouble eating, swallowing or talking
- Painful spots, sores, bleeding or ulcers in your mouth or on your lips
- Infection in your mouth, such as thrush.

Skin reactions

You may experience skin reactions when treated with FOLOTYN® injection. Most commonly these reactions are mild and only last for a short time, but sometimes these reactions can be severe. Severe skin reactions tend to occur in patients who have had skin problems before or if you have lymphoma in or under your skin. Skin reactions typically occur when you first start FOLOTYN® injection therapy and they may get worse with continued treatment. Your doctor may reduce your dose or stop FOLOTYN® injection therapy to help manage some skin reactions.^{1,2}

Other things to be aware of

Other common side effects of FOLOTYN® injection include gastrointestinal symptoms such as nausea, vomiting and constipation, fatigue or tiredness, and nose bleeds. If you experience dizziness, blurred vision or tiredness, do not drive or operate machinery.¹

Other side effects can occur. If you experience anything unusual after starting FOLOTYN® injection therapy discuss it with your doctor or healthcare team.

Steps to prevent and manage side effects

Preventing infections

There are some steps you can take to help reduce your exposure to viruses and bacteria when you have low white blood cell counts. These include:³

- Avoiding crowded places (e.g. buses, trains, etc.) until your white blood cell count has improved
- Avoid close contact with people who have coughs or colds or other infectious diseases such as shingles, chicken pox or measles
- Always wash your hands before preparing food, eating and after going to the bathroom or sneezing
- Clean cuts, scrapes, sores immediately with warm water, soap and antiseptic
- Check with your doctor before receiving any immunisations
- Wear protective gloves and footwear when working outside and avoid contact with soil and potting mix
- Avoid handling pet poo or cleaning fish tanks
- Avoid suppositories or enemas. If constipated ask your healthcare team how to manage this.
- Ensure all foods you eat are safe by preparing them in a clean kitchen, using clean chopping boards, knives, etc. Thoroughly wash fresh fruit and vegetables and avoid reheating food; however, if food needs to be reheated, it should be heated until it is hot throughout.

Your healthcare team may provide you with additional advice, especially if your ability to fight infection is severely affected.

Preventing mucositis

There are a number of things you can do to help prevent or reduce the severity of mucositis associated with *FOLOTYN*[®] injection therapy.

Folic acid and vitamin B12 injections

The first step is to take folic acid daily and have a vitamin B₁₂ injection every 8 to 10 weeks as instructed by your doctor.¹

Leucovorin (folinic acid)

Your doctor may also ask you to take a medication called calcium folinate (Leucovorin); this is usually taken 3 times daily for the 2 days following each *FOLOTYN*[®] injection. It must be taken at least 6 hours apart, i.e. morning, day and night. Your doctor will tell you the exact dose of calcium folinate (Leucovorin) to take each day.

Dental care

At least 3 to 4 weeks before you start *FOLOTYN*[®] injection therapy, visit the dentist to clean your teeth and gums, carry out any corrective procedures and if you wear dentures check that they fit well.⁴ Regular visits to the dentist to help maintain good oral health is also beneficial.⁴ You may want to ask your healthcare team if they can recommend a dentist who regularly manages patients with cancer.

Take steps to maintain good oral hygiene, including:^{3,4,6,7}

- Brush teeth or dentures, at least 4 times per day, e.g. after each meal and before going to bed, with a soft toothbrush
- Replace your toothbrush regularly to minimise infection
- Rinse your mouth with sodium bicarbonate solution or salt water before and after meals and before going to bed
- Remove dentures whenever possible
- Avoid toothpastes with whitening agents and products that irritate the mouth and gums, such as strong-flavoured mouthwashes and mouthwashes that contain alcohol
- Keep lips moist with moisturisers, but avoid using oil-based products.

Watch what you eat and drink:³

- Drink plenty of fluids, aim to drink at least eight glasses of clear fluids per day if you can
- Eat small, frequent, high protein, high energy meals
- Eat soft, minced or pureed foods
- Add extra sauces or gravies to moisten meals
- Avoid foods that are acidic, hot, coarse, hard, salty or spicy
- Avoid alcohol.

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Treating mucositis

If you develop sores or ulcers in your mouth it is important to continue preventative oral care measures. However, your healthcare team may suggest that you clean your teeth and rinse your mouth more regularly.⁶ You may also find it is less irritating to clean your teeth with sponge sticks instead of a soft toothbrush.⁶

You may need to adjust what you eat, such as eating foods that don't require a lot of chewing.⁵ You may want to get some extra expert advice from a dietitian.

If the sores in your mouth are painful, your doctor or healthcare team may suggest you use some medications to relieve your pain (analgesics). These may include medications that work inside the mouth such as anaesthetic or analgesic mouthwashes and gels, as well as oral analgesics such as paracetamol or opioid (morphine-like) analgesics. In general, it is best to take pain relief at regular time intervals to provide continuous pain relief. If you are having difficulty taking oral medications, discuss this with your doctor as there may be other treatment options to help relieve your pain.^{4,8} Your doctor or pharmacist will advise what pain relief medication will be best for you. Before taking non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen, check with your doctor or pharmacist.²

If you develop ulcers in the mouth your doctor or healthcare team may recommend you use special pastes to provide a protective coating over the ulcer to help reduce further irritation.^{5,9}

Pregnancy

FOLOTYN® injection may cause birth defects if either the male or female is being treated with FOLOTYN® injection therapy at the time of conception. Abstinence or the use of a barrier method of birth control (e.g. condoms) is recommended for patients being treated with FOLOTYN® injection therapy. Male patients should continue to use a reliable form of contraception for 6 months after stopping FOLOTYN® injections. Tell your doctor immediately if you or your partner become pregnant while being treated with FOLOTYN® injections or within 6 months of stopping FOLOTYN® injection therapy.

More information

Your doctor, pharmacist and nurse have more information about this medicine and your personal situation. You should ask them for more information or to answer any specific questions that you have about your treatment. You can also refer to the FOLOTYN® injection Consumer Medicines Information for more information about FOLOTYN® injection. The Consumer Medicines Information is available from <https://www.mundipharma.com.au/products/oncology/>



References: 1. FOLOTYN® solution for infusion Consumer Medicine Information, November 2016. 2. Folutyn® solution for infusion 20 mg in 1 mL and 40 mg in 2 mL Product Information, November 2016. 3. eviQ cancer treatments online. Information for patients: Managing the side effects of chemotherapy. Cancer Institute of NSW. 4. eviQ cancer treatments online. Oral mucositis. ID 210 v2, Cancer Institute of NSW. 5. Negrin RS, Toljanic JA. Oral toxicity associated with chemotherapy. UpToDate, 2017. 6. eviQ cancer treatments online. Oral mucositis assessment tool. ID 10 v4. Cancer Institute of NSW. 7. The Oral Cancer Foundation. Mucositis. The Oral Cancer Foundation. 2016. 8. Barasch A, Epstein JB. Management of cancer therapy-induced oral mucositis. *Dermatol Ther* 2011;24:424-431. 9. Australian Medicines Handbook online, 2017. Australian Medicines Handbook Pty Ltd.



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