

FOLOTYN®

solution for infusion

Pralatrexate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about FOLOTYN solution for infusion. 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 you taking FOLOTYN against the benefits they expect it will have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What FOLOTYN is used for

FOLOTYN solution for infusion contains pralatrexate. Pralatrexate is an anti-cancer (chemotherapy) medicine that belongs to a group of medicines called antifolates.

FOLOTYN is used to treat patients aged 18 years or older with peripheral T-cell lymphoma (PTCL) after previous treatments have not worked or have stopped working.

PTCL is a rare type of non-Hodgkin's lymphoma (a cancer of the lymphatic system). It occurs when T-cells, a type of white blood cell, multiply too quickly. PTCL may be found in the lymph nodes, skin, bone marrow, the liver, or spleen.

FOLOTYN works by slowing or stopping the growth of cancer cells.

Your doctor, however, may prescribe it for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

Before FOLOTYN is given

When you must not be given it

FOLOTYN solution for infusion should not be given to you if you are allergic to pralatrexate or any of the ingredients listed at the end of this leaflet.

FOLOTYN solution for infusion should not be given to you if you are breastfeeding.

It is not known if FOLOTYN solution for infusion passes into breast milk, which may harm your baby. You and your doctor should decide whether you will be treated with FOLOTYN solution for infusion or whether you will breast feed your baby, but you should not do both.

Do not accept treatment with this medicine after the expiry date (EXP) printed on the pack.

If it is given to you after the expiry date has passed, it may not work as well.

Before you begin your treatment

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- liver problems
- kidney problems
- extensive skin disease or a history of adverse skin reactions

FOLOTYN solution for infusion is not recommended if you have end stage kidney disease or are undergoing dialysis, unless the benefit outweighs the risk.

Females: Tell your doctor if you are pregnant or planning to become pregnant. FOLOTYN is not recommended for use during pregnancy.

The effects of FOLOTYN in pregnant women are not known. FOLOTYN solution for infusion may harm the unborn baby.

Males: Tell your doctor if your partner intends to become pregnant while you are being treated with FOLOTYN or within 6 months after you have stopped treatment with FOLOTYN.

FOLOTYN may cause birth defects if either the male or female is receiving treatment at the time of conception. A barrier method of birth control or abstinence is recommended to avoid pregnancy while being treated. Males should also use reliable contraceptive measures for 6 months after the end of treatment.

This medicine is not recommended to be used to treat

a child of adolescent younger than 18 years of age.

Safety and effectiveness in children and adolescents younger than 18 years of age has not been established.

If you have not told your doctor about any of the above, tell them before you are treated with FOLOTYN solution for infusion.

Taking other medicines

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

Some medicines and FOLOTYN solution for infusion may interfere with each other. These include:

- other medicines used to treat cancer (e.g. carboplatin, cisplatin, oxaliplatin, etoposide and teniposide)
- methotrexate, a medicine used to treat cancer, psoriasis and rheumatoid arthritis
- cyclosporine, a medicine used to suppress the immune system
- frusemide and other loop diuretics (also known as fluid and water tablets), medicines used to reduce swelling and lower blood pressure
- ibuprofen and other non-steroidal anti-inflammatory drugs called NSAIDs used to relieve pain, swelling and inflammation
- omeprazole and pantoprazole, medicines used to treat heartburn and stomach ulcers
- penicillin, aminoglycosides, trimethoprim and sulfamethoxazole, antibiotics used to treat bacterial infections
- probenecid, a medicine used to treat gout.

These medicines may be affected by FOLOTYN solution for infusion, may affect how well FOLOTYN works or may increase side effects. You may need to use different

amounts of your medicines, or take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while being treated with this medicine.

How FOLOTYN is given

Taking premedication

Your doctor should advise you to take certain medicines or vitamin supplements before starting and while being given FOLOTYN to help minimise side effects.

Typically, you will be instructed to take folic acid by mouth for about 10 days before your first dose of FOLOTYN.

You should continue taking folic acid every day until your doctor tells you to stop.

Your doctor will also give you a vitamin B12 injection into the muscle before your first dose of FOLOTYN, and about every 8 to 10 weeks during treatment with FOLOTYN.

How much will be given

Your doctor will decide what dose of FOLOTYN you will receive.

The dose given will be based on your body surface area, which your doctor will calculate from your height and weight. Your dose will also depend on how you react to the treatment.

You will usually be given FOLOTYN once a week for 6 weeks, with no treatment on the 7th week.

Several treatment cycles of FOLOTYN may be given depending on your response to treatment.

You will have regular blood tests during treatment to see if FOLOTYN is having any unwanted effects. Your doctor may change

your dose or delay treatment based on the results of your blood tests and on your general condition.

Follow any instructions given to you by your doctor, nurse and pharmacist exactly.

How FOLOTYN is given

FOLOTYN solution for infusion will be administered to you under the supervision of a doctor or nurse experienced in treating cancer. It will be given as an infusion into your vein over 3 to 5 minutes. Each vial is for single use only.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

If you have been given too much (overdose)

As FOLOTYN is given to you under the supervision of your doctor, it is very unlikely that you will receive too much.

However, if you experience severe side effects after being treated with FOLOTYN, tell your doctor immediately or go to Accident and Emergency at the nearest hospital.

While there is limited experience with overdose, symptoms may include more severe or prolonged mucous membrane inflammation (redness and sores in the lining of your mouth and may also affect your lips, throat, digestive tract and genitals) and decreased blood cell counts (unusual bruising or bleeding, increased risk of infections and unusual tiredness or weakness).

When seeking medical attention, take this leaflet with you to show the doctor. Also tell them about any other medicines which have been taken.

While you are being treated with FOLOTYN

Things you must do

Before you start on a new medicine, remind your doctor and pharmacist that you are receiving FOLOTYN solution for infusion.

Tell any other doctors, dentists and pharmacists who treat you that you are receiving this medicine.

If you are going to have surgery, tell your surgeon or anaesthetist that you are receiving this medicine.

Follow any specific instructions given to you by your doctor for vitamin supplementation with folic acid and vitamin B12 to help minimise side effects.

Use an effective method of birth control while you are being treated with FOLOTYN. Males should also use reliable contraceptive measures for 6 months after the end of treatment.

A barrier method of birth control, such as a condom, should be used. Your doctor will tell you what forms of contraception are suitable and when it is safe to stop using contraception if you wish to do so.

If you or your partner becomes pregnant while being given this medicine or within 6 months after stopping treatment, tell your doctor immediately.

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

Tell your doctor if you are having any problems or difficulties while you are being treated with FOLOTYN solution for infusion.

Things you must not do

FOLOTYN solution for infusion must not be used to treat any other complaint, unless advised by your doctor.

It should not be administered to anyone else.

Do not inject FOLOTYN yourself. Always let your doctor or nurse do this.

Do not stop or change your treatment with FOLOTYN solution for infusion unless advised by your doctor.

Things to be careful of

Do not drive or operate machinery until you know how FOLOTYN solution for infusion affects you.

FOLOTYN solution for infusion may cause fatigue, blurred vision, or dizziness. If you experience any of these side effects, do not drive or operate machinery.

Be aware of the following potential problems while being treated with FOLOTYN:

- **Low blood cell counts:**
FOLOTYN solution for infusion can affect your bone marrow and cause you to have low blood cell counts (platelets, white blood cells and red blood cells). Your doctor will do weekly blood tests and may decide to change the dose or stop your treatment.
- **Mucous membrane inflammation:**
FOLOTYN solution for infusion can cause redness and sores in the lining of your mouth and may also affect your lips, throat, digestive tract and genitals. Your doctor may change the dose or stop your treatment if this happens. You will be advised how to maintain nutrition and control the discomfort.
- **Skin reactions:**
You may experience severe skin reactions during treatment with FOLOTYN, especially if you have lymphoma in or under your skin. Skin reactions often occur when you first start treatment with FOLOTYN, but may increase in severity with continuing treatment. Your doctor may reduce the dose or

stop your treatment if this happens.

- **Pneumonitis (swelling of the lungs):**
Symptoms may include coughing, difficulty breathing or wheezing.
- **Tumour lysis syndrome:**
Treatment with FOLOTYN may result in tumour lysis syndrome, caused by the breakdown products from dying cancer cells. Symptoms include nausea and vomiting, weakness and tiredness, changes to your heart beat and kidney problems.

Side effects

This medicine is to help treat PTCL, but it may have unwanted side effects in some people.

All medicines may have some unwanted side effects. Sometimes they are serious but often they are not. Your doctor has weighted the risks of the medicine against the expected benefits it will have for you.

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

You may not experience all of the side effects listed here.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are being treated with FOLOTYN solution for infusion.

Other side effects that are not listed here may also occur in some people.

Tell your doctor if you notice any of the following and they worry you:

- **constipation, indigestion**
- **loss of appetite, weight loss**
- **pain in the stomach or abdomen**
- **painful, stiff or swollen joints; pain or spasm of the muscles**
- **generalised pain in the back, neck or chest**

- effects on the eye, including irritation, itching, redness, increased tears, blurred vision
- headaches
- numbness, tingling or pins and needles sensation
- dizziness
- hair loss
- hoarseness, sore throat coughing, difficulty or pain when swallowing
- ringing sound in the ears
- difficulty sleeping
- anxiety.

Tell your doctor immediately if you notice any of the following:

- **inflammation, redness or sores of the mouth.**

Discomfort or pain can happen as early as a few days after treatment with FOLOTYN. Ask your doctor about how to reduce the risk of this and how to maintain your nutrition and control discomfort.

- **inflammation, redness or sores of the nose, genitals or anus (back passage)**

- **thirst, dry mouth, flushed skin, darker coloured urine, fatigue, weakness or light-headedness.**

You may be dehydrated (insufficient fluid intake or fluid loss from the body). Follow your doctor's instructions to help prevent or treat dehydration.

- **unusual bleeding, such as nosebleeds, bruising under your skin or reddish/pinkish urine**

- **any bleeding from the mouth, genitals or anus (back passage)**

- **feeling weak, tired, getting tired easily, pale skin or shortness of breath**

- **infections, e.g. fever, chills, cough, shortness of breath, pain or burning on urination.** Fever is a common early sign of infection. Serious illness can

occur if an infection is not treated straight away.

- **shingles or chicken pox**
- **fungal infection in the mouth, throat, or vagina**
- **severe skin reactions, e.g. itchiness, redness, rash, peeling or loss of skin, sores or blisters that may happen as early as a few days after treatment with FOLOTYN.** If skin reactions are severe, they can lead to serious illness.
- **nausea, vomiting, diarrhoea**
- **fast or irregular heart beats**
- **yellow colouring of the skin and eyes**
- **swelling of the legs and ankles.**

The above list includes serious side effects that may require special attention.

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

- **you have an allergic reaction:** shortness of breath, wheezing, shallow or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin
- **chest pain when breathing, difficulty or fast breathing**

The above list includes very serious side effects. You may require urgent medical attention or hospitalisation.

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

Other side effects not listed above may also occur in some people. Some of these side effects (for example, abnormal blood cell counts) can only be found when your doctor does tests to check your progress.

When seeking medical attention, take this leaflet with you to show the doctor.

After being treated with FOLOTYN

Storage

If you are being given FOLOTYN solution for infusion in hospital, unopened vials will be stored in the pharmacy or on the ward.

FOLOTYN solution for infusion is stored in a refrigerator where the temperature stays between 2°C to 8°C and protected from light. It may be stored in the original carton for a single period at up to 30°C for 120 hours.

Disposal

Once opened, your doctor, nurse or pharmacist will discard any unused portion of this medicine.

Product description

What it looks like

FOLOTYN solution for infusion is available in glass vials containing a clear yellow solution. It is available in two presentations:

- 20 mg in 1 mL
- 40 mg in 1 mL

FOLOTYN solution for infusion is supplied in packs containing 1 single-use vial with chlorobutyl stopper.

Ingredients

Active ingredients:

- 20 mg in 1 mL solution for infusion contains 20 mg pralatrexate in every mL of solution.
- 40 mg in 2 mL solution for infusion contains 20 mg pralatrexate in every mL of solution.

Inactive ingredients:

- sodium chloride
- hydrochloric acid
- sodium hydroxide

- water for injections.

Manufacturer/Sponsor

FOLOTYN solution for infusion is made in Germany.

FOLOTYN solution for infusion is supplied in Australia by:

Mundipharma Pty Limited

ABN 87 081 322 509

88 Phillip Street

Sydney, NSW, 2000

Phone: 1800 188 009

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Australian Registration Numbers for FOLOTYN solution for injection:

20 mg in 1 mL: AUST R 192493

40 mg in 2 mL: AUST R 192492

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