Medication Information Sheet

PRALAtrexate (PRA-luh-TREK-sayt)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Folotyn®

Appearance: Clear yellow liquid

What is this medication for?

• For treating a type of cancer called T-cell Lymphoma.

What should I do before I have this medication?

- Tell your health care team if you have or had significant medical condition(s), especially if you have / had:
 - liver or kidney problems
 - lung problems or
 - any allergies
- To lower the chance of side effects, your health care team will prescribe oral folic acid and vitamin B₁₂ given by injection.
 - Folic Acid: You will need to start folic acid 10 days before your first dose of pralatrexate.
 - Vitamin B12 injection: You will receive your first injection of vitamin B12 before your first dose of pralatrexate.
 - You will need to continue with folic acid and vitamin B12 during your treatment. See "how is this medication given" section.
- Tell your health care team about all of the other medications you are taking.
- Keep taking other medications that have been prescribed for you, unless you have been told not to by your health care team.

How will this medication affect sex, pregnancy and breastfeeding?

Talk to your health care team about:

- How this treatment may affect your sexual health.
- How this treatment may affect your ability to have a baby, if this applies to you.

This treatment may harm an unborn baby. Tell your health care team if you or your partner are pregnant, become pregnant during treatment, or are breastfeeding.

- If there is **any** chance of pregnancy happening, you and your partner together must use **2 effective forms of birth control** at the same time until **8 weeks** after your last treatment dose. Talk to your health care team about which birth control options are best for you.
- Do not breastfeed while on this treatment.

How is this medication given?

- This medication is given by injection into a vein over 3 to 5 minutes as an IV push (injected into a vein).
- Pralatrexate is given in cycles, one time each week for 6 weeks, with no treatment on the 7th week (6 weeks on, 1 week off). Talk to your health care team about your treatment schedule.
- If you missed your treatment appointment, talk to your health care team to find out what to do.

To Protect Healthy Cells and Lower your Chance of Side Effects

You will be given a prescription for folic acid tablets to take by mouth and vitamin B₁₂ that will be given by a needle into your muscle.

Take folic acid every day until your health care team tells you to stop. You will receive another vitamin B₁₂ injections every 8 to 10 weeks during your pralatrexate treatment.

Talk to your health care team about exactly how to take these medications.

To Prevent Tumor Lysis Syndrome (TLS)

TLS can happen when a large number of cancer cells die quickly and your body cannot get rid of them fast enough. TLS can make you very sick. Ask your health care team if you are at risk for TLS.

If you are at risk for TLS, you may be given medications before your pralatrexate treatment to help prevent it.

These are called anti-uricemics (such as allopurinol), or others.

What else do I need to know while on this medication?

- Will this medication interact with other medications or natural health products?
 - This medication can interact with other medications, vitamins, foods and natural health products. Interactions can make the treatment not work as well or cause severe side effects.
 - Tell your health care team about all of your:
 - prescription and over-the-counter (non-prescription) medications and all other drugs, such as marijuana (medical or recreational)
 - natural health products such as vitamins, herbal teas, homeopathic medicines, and other supplements
 - Check with your health care team before starting or stopping any of them.
- What should I do if I feel unwell, have pain, a headache or a fever?
 - Always check your temperature to see if you have a fever before taking any medications for fever or pain (such as acetaminophen (Tylenol) or ibuprofen (Advil)).
 - Fever can be a sign of infection that may need treatment right away.
 - If you take these medications before you check for fever, they may lower your temperature and you may not know you have an infection.

How to check for fever:

Keep a digital (electronic) thermometer at home and take your temperature if you feel hot or unwell (for example, chills, headache, mild pain).

- You have a fever if your temperature taken in your mouth (oral temperature) is:
 - 38.3°C (100.9°F) or higher at any time

OR

■ 38.0°C (100.4°F) or higher for at least one hour.

If you do have a fever:

Try to contact your health care team. If you are not able to talk to them for advice,

you MUST get emergency medical help right away.

Ask your health care team for the <u>Fever</u> pamphlet for more information.

If you do not have a fever but have mild symptoms such as headache or mild pain:

- Ask your health care team about the right medication for you. Acetaminophen (Tylenol®)
 is a safe choice for most people.
- Talk to your health care team before you start taking lbuprofen (Advil®, Motrin®), naproxen (Aleve®) or ASA (Aspirin®), as they may increase your chance of bleeding or interact with your cancer treatment.
- Talk to your health care team if you already take low dose aspirin for a medical condition (such as a heart problem). It may still be safe to take.

What to DO while on this medication:

- DO check with your health care team before getting any vaccinations, surgery, dental work or other medical procedures.
- DO tell your health care team about any serious infections that you have now or have had in the
 past.
- DO consider asking someone to drive you to and from the hospital on your treatment days. You may feel drowsy or dizzy after your treatment.

What NOT to DO while on this medication:

DO NOT smoke or drink alcohol while on treatment without talking to your health care team first.
 Smoking and drinking can make side effects worse and make your treatment not work as well.

What are the side effects of this medication?

The following table lists side effects that you may have when getting pralatrexate. The table is set up to list the most common side effects first and the least common last. It is unlikely that you will have all of the side effects listed and you may have some that are not listed.

Read over the side effect table so that you know what to look for and when to get help. Keep this paper during your treatment so that you can refer to it if you need to.

Very Common Side Effects (50 or more out of 100 people)	
Side effects and what to do	When to contact health care team
Mouth sores	Talk to your health care team as soon
(maybe severe)	as you notice any sores or if it hurts
What to look for?	to eat, drink,
 Redness or sores inside your mouth, on your lips, throat, digestive tract, and genitals. 	swallow or do other tasks
 In more severe cases they be very painful. It may be hard for you to swallow, eat, brush your teeth, sit comfortably, or do other tasks. 	
What to do?	
To help prevent mouth sores:	
 Take care of your mouth by gently brushing and flossing regularly. Rinse your mouth often with a homemade mouthwash. To make a homemade mouthwash, mix 1 teaspoonful of baking soda and 1 teaspoonful of salt in 4 cups (1L) of water. 	
 Do not use store-bought mouthwashes, especially those with alcohol, because they may irritate your mouth. 	
If you have mouth sores:	
 Avoid hot, spicy, acidic, hard or crunchy foods. Your doctor may prescribe a special mouthwash to relieve mouth sores and prevent infection. 	
If you have sores on other parts of your body:	
 Talk to your health care team as soon as you notice any sores or if it hurts for you to eat, drink, swallow, or do other tasks. 	
Ask your health care team for the Oral Care (Mouth Care) pamphlet for more information.	

Side effects and what to do	When to contact health care team
Low neutrophils (white blood cells) in the blood (neutropenia) (maybe severe)	If you have a fever try to contact your health care team.
When neutrophils are low, you are at risk of getting an infection more easily. Ask your health care team for the Neutropenia (Low white blood cell count) pamphlet for more information.	If you are unable to talk to the team for advice, you MUST get emergency medical help right.
What to look for?	medical neip right.
 If you feel hot or unwell (for example if you have chills or a new cough), you must check your temperature to see if you have a fever. Do not take medications that treat a fever before you take your temperature (for example, Tylenol®, acetaminophen, Advil® or ibuprofen). Do not eat or drink anything hot or cold right before taking your temperature. 	
You have a fever if your temperature taken in your mouth (oral temperature) is:	
 38.3°C (100.9°F) or higher at any time OR 38.0°C (100.4°F) or higher for at least one hour. 	
00.0 0 (100.4 1) of higher for at least one flour.	
What to do?	
If your health care team has told you that you have low neutrophils:	
 Wash your hands often to prevent infection. Check with your health care team before getting any vaccines, surgeries, medical procedures or visiting your dentist. Keep a digital thermometer at home so you can easily check for a fever. 	
If you have a fever:	
If you have a fever, try to contact your health care team. If you are unable to talk to the team for advice, you must get emergency medical help right away.	

Side effects and what to do	When to contact health care team
Low platelets in the blood	
(maybe severe)	
When your platelets are low, you are at risk for bleeding and bruising. Ask your health care team for the Low Platelet Count pamphlet for more information.	
What to look for?	Talk to your health
Watch for signs of bleeding:	care team if you have any signs of
 bleeding from your gums 	bleeding. If you
 unusual or heavy nosebleeds 	have bleeding that
 bruising easily or more than normal 	doesn't stop or is
 black coloured stools (poo) or blood in your stools (poo) 	severe (very
 coughing up red or brown coloured mucus 	heavy), you MUST
 dizziness, constant headache or changes in your vision 	get emergency
 heavy vaginal bleeding 	help right away.
 red or pink coloured urine (pee) 	
What to do?	
f your health care team has told you that you have low platelets:	
Tell your pharmacist that your platelet count may be low before taking any	
prescriptions or over-the-counter medication.	
Check with your healthcare team before you go to the dentist.	
Take care of your mouth and use a soft toothbrush.	
Try to prevent cuts and bruises.	
Ask your health care team what activities are safe for you.	
Your treatment may have to be delayed if you have low platelets. Your health	
care team may recommend a blood transfusion.	
f you have signs of bleeding:	
If you have a small bleed, clean the area with soap and water or a saline	
(saltwater) rinse. Apply pressure for at least 10 minutes.	
f you have bleeding that does not stop or is severe (very heavy), you must get emergency medical help right away.	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
Nausea and vomiting	Talk to your health care team if
 What to look for? Nausea is feeling like you need to throw up. You may also feel light-headed. You may feel nausea within hours to days after your treatment. 	nausea lasts more than 48 hours or vomiting lasts more than 24 hours or if severe
What to do?	
To help prevent nausea:	
 It is easier to prevent nausea than to treat it once it happens. Take your anti-nausea medication(s) as prescribed, even if you do not feel like throwing up. Drink clear liquids and have small meals. Get fresh air and rest. Do not eat spicy, fried foods or foods with a strong smell. Limit caffeine (like coffee, tea) and avoid alcohol. 	
If you have nausea or vomiting:	
 Take your rescue (as-needed) anti-nausea medication(s) as prescribed. Ask your health care team for the <u>Nausea & Vomiting</u> pamphlet for more information. Talk to your health care team if: 	
 nausea lasts more than 48 hours vomiting lasts more than 24 hours or if it is severe 	
Fatigue	Talk to your health
What to look for?	care team if it does not improve
 Feeling of tiredness or low energy that lasts a long time and does not go away with rest or sleep. 	or if it is severe
What to do?	
 Be active. Aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. Check with your health care team before starting any new exercise. Pace yourself, do not rush. Put off less important activities. Rest when you need 	
to.Ask family or friends to help you with things like housework, shopping, and child	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
 or pet care. Eat well and drink at least 6 to 8 glasses of water or other liquids every day (unless your health care team has told you to drink more or less). Avoid driving or using machinery if you are feeling tired. 	
Ask your health care team for the <u>Fatigue</u> pamphlet for more information.	
Anemia (low red blood cells)	Talk to your health
What to look for?	care team if it does not improve or if it is severe
You may feel more tired or weaker than normal.	
Pale skin and cold hands and feet.	
You may feel short of breath, dizzy or lightheaded.	
 This may occur in days to weeks after your treatment starts. 	
What to do?	
If your health care team has told you that you have anemia (low red blood cells):	
Rest often and eat well.	
Light exercise, such as walking may help.	
You may need medication or a blood transfusion.	
If it is very bad, your doctor may need to make changes to your treatment	
regimen.	
Constipation	Talk to your health
What to look for?	care team if it does not improve
Having bowel movements (going poo) less often than normal.	or if it is severe
Small hard stools (poo) that look like pellets.	
The need to push hard and strain to have any stool (poo) come out.	
Stomach ache or cramps.	
A bloated belly, feeling of fullness, or discomfort.	
Leaking of watery stools (poo).	
Lots of gas or burping.	
Nausea or vomiting.	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
What to do?	
To help prevent constipation:	
 Try to eat more fiber rich foods like fruits with skin, leafy greens and whole grains. Drink at least 6 to 8 cups of liquids each day unless your health care team has told you to drink more or less. Be Active. Exercise can help to keep you regular. If you take opioid pain medication, ask your health care team if eating more fibre is right for you. 	
To help treat constipation:	
 If you have not had a bowel movement in 2 to 3 days you may need to take a laxative (medication to help you poo) to help you have regular bowel movements. Ask your health care team what to do. 	
Ask your health care team for the Constipation Pamphlet for more information.	
Headache, Flu-like symptoms	Talk to your health
You may feel like you have the flu for around 2 days after your IV treatment. These flu- like symptoms may not be signs of an infection.	care team if it does not improve or if it is severe
What to look for?	
 You may have chills, headache and muscle pain. You may feel tired and have a poor appetite. Symptoms may happen at any time after you receive your treatment and usually go away as your body gets used to the medication. 	
What to do?	
 Check your temperature to see if you have a fever. Read the above section "What should I do if I feel unwell, have pain, a headache or a fever?" on page 3. If you do have a fever, try to speak to your health care team. If you are unable to talk to them for advice, you MUST get emergency medical help right away. 	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
RACIAL ANNO III.	T-11: 4
 What to look for? You may have mild swelling or puffiness in your arms and/or legs. Rarely, this may be severe. 	Talk to your health care team if it does not improve or if it is severe
What to do?	
To help prevent swelling:	
Eat a low-salt diet.	
If you have swelling:	
Wear loose-fitting clothing.For swollen legs or feet, keep your feet up when sitting.	
Cough and feeling short of breath	Talk to your health
What to look for?	care team. If you are not able to talk
You may have a cough and feel short of breath.Symptoms that commonly occur with a cough are:	to your health care team for advice, and you have a
Wheezing or a whistling breathingRunny nose	fever or severe symptoms, you
Sore throat	MUST get emergency
HeartburnWeight loss	medical help right
Fever and chills	away
 Rarely this may be severe with chest pain, trouble breathing or coughing up blood. 	
What to do?	
Check your temperature to see if you have a fever. Read the above section "What should I do if I feel unwell, have pain, a headache or a fever?" on	
 page 3. If you have a fever, try to talk to your health care team. If you are not able to talk to them for advice, you MUST get emergency medical help right 	

Common Side Effects (25 to 49 out of 100 people)	
Side effects and what to do	When to contact health care team
 away. If you have a severe cough with chest pain, trouble breathing or you are coughing up blood, get medical help right away. 	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
What to look for? Loose, watery, unformed stool (poo) that may happen days to weeks after you get your treatment.	Talk to your health care team if no improvement after 24 hours of taking diarrhea medication or if severe (more than 7 times in one
What to do? If you have diarrhea:	day)
 Take anti-diarrhea medication if your health care team prescribed it or told you to take it. Do not eat foods or drinks with artificial sweetener (like chewing gum or 'diet' drinks), coffee and alcohol. Eat many small meals and snacks instead of 2 or 3 large meals. Drink at least 6 to 8 cups of liquids each day, unless your health care team has told you to drink more or less. Talk to your health care team if you can't drink 6 to 8 cups of liquids each day when you have diarrhea. You may need to drink special liquids with salt and sugar, called Oral Rehydration Therapy. Talk to your health care team if your diarrhea does not improve after 24 hours of taking diarrhea medication or if you have diarrhea more than 7 times in one day. Ask your health care team for the Diarrhea pamphlet for more information.	
Too much or too little salt in your body What to look for?	Get emergency medical help right
Muscle spasms, cramping, weakness, twitching, or convulsions.	away for severe symptoms

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
Irregular heartbeat, confusion or blood pressure changes.	
What to do?	
Get emergency medical help right away for severe symptoms.	
Low appetite	Talk to your health
What to look for?	care team if it does not improve
Loss of interest in food or not feeling hungry.Weight loss.	or if it is severe
What to do?	
 Try to eat your favourite foods. Eat small meals throughout the day. You may need to take meal supplements to help keep your weight up. Talk to your health care team if you have no appetite. 	
Ask your health care team for the Loss of Appetite pamphlet for more information.	
Rash; dry, itchy skin	Talk to your health
(maybe severe)	care team if no improvement or if
What to look for?	severe
 You may have cracked, rough, flaking or peeling areas of the skin. Your skin may look red and feel warm, like a sunburn. Your skin may itch, burn, sting or feel very tender when touched. 	
What to do?	
To prevent and treat dry skin:	
 Use fragrance-free skin moisturizer. Protect your skin from the sun and the cold. Use sunscreen with UVA and UVB protection and a SPF of at least 30. Avoid perfumed products and lotions that contain alcohol. Drink 6 to 8 cups of non-alcoholic, non-caffeinated liquids each day, unless your health care team has told you to drink more or less. 	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
Rash may be severe in some rare cases and cause your skin to blister or peel. If this happens, get emergency medical help right away.	
Mild joint, muscle pain or cramps	Talk to your health care team if it
What to look for?New pain in your muscles or joints, muscle cramps, or feeling achy.	does not improve or if it is severe
What to do?	
 Take pain medication (acetaminophen or opioids such as codeine, morphine, hydromorphone, oxycodone) as prescribed. Read the above section: "What should I do if I feel unwell, have pain, a headache or a fever?" on page 3 before taking acetaminophen (Tylenol®), ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or Aspirin. These medications may hide an infection that needs treatment or they may increase your risk of bleeding. Rest often and try light exercise (such as walking) as it may help. 	
Ask your health care team for the Pain pamphlet for more information.	
Liver problems	Get emergency medical help right
Your health care team may check your liver function with a blood test. The liver changes do not usually cause any symptoms.	away
What to look for?	
 Rarely, you may develop yellowish skin or eyes, unusually dark pee or pain on the right side of your belly. This may be severe. 	
What to do?	
If you have any symptoms of liver problems, get emergency medical help right away.	
Pains or cramps in the belly	Talk to your health care team if it
What to look for?	does not improve or if it is severe
Pain or cramps in your belly.	

Less Common Side Effects (10 to 24 out of 100 people)	
Side effects and what to do	When to contact health care team
Constipation and diarrhea can cause pain in your belly.	
 What to do? If the pain is severe, gets worse or doesn't go away, talk to your health care team about other possible causes. 	
Night Sweats	Talk to your health
What to look for?Extreme sweating that may soak your nightclothes or bedding.	care team if no improvement or if severe
What to do?Talk to your health care team if no improvement or if severe.	
Heart problems What to look for?	Get emergency medical help right away
 You may have an irregular heartbeat, shortness of breath, chest pain or fainting spells. Swelling in your legs, ankles and belly. Sharp pain in the centre or left side of the chest (often worsens when taking a deep breath). Extreme tiredness that prevents you from exercising or doing normal activities. 	
What to do?	
Get emergency medical help right away.	

Other rare, but serious side effects are possible. If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:

- Signs of an allergic reaction: fever, itchiness, rash, swollen lips, face or tongue, chest and throat tightness. It may happen during or shortly after your treatment
- Needing to go pee less than usual
- Unexpected weight gain

Who do I contact if I have questions or need help?
My cancer health care provider is:
During the day I should contact:
Evenings, weekends and holidays:
Other Notes:

For more links on how to manage your symptoms go to www.cancercareontario.ca/symptoms.

The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.

PRALAtrexate

A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.