#### PATIENT MEDICATION INFORMATION

#### READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

#### PrMethotrexate Tablets, USP

Read this carefully before you start taking **Methotrexate Tablets**, **USP** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Methotrexate Tablets**, **USP**.

## **Serious Warnings and Precautions**

- Methotrexate Tablets, USP should be prescribed by a healthcare professional who is experienced with the use of methotrexate.
- Methotrexate Tablets, USP can cause serious side effects which may result in death.

#### Pregnancy:

- Methotrexate Tablets, USP can cause birth defects or death of an unborn baby when used in pregnant women.
- Female patients who are able to get pregnant:
  - A pregnancy test should be done before you start Methotrexate Tablets, USP to show that you are not pregnant.
  - If you have psoriasis or rheumatoid arthritis and are pregnant, do not take Methotrexate Tablets, USP.
  - If you have cancer and you are pregnant or planning to get pregnant: Before starting Methotrexate Tablets, USP, talk to your healthcare professional about whether the benefits to you outweigh the risks to your baby.
  - Avoid getting pregnant while taking Methotrexate Tablets, USP and for at least 3 months to 1 year after your treatment.
  - Tell your healthcare professional right away if you think you have become pregnant while taking Methotrexate Tablets, USP.
- Male patients:
  - Do not father a child while you are taking Methotrexate Tablets, USP and for at least 3 months to 1 year after your treatment.
  - Tell your healthcare professional right away if you think your partner has become pregnant while you are taking Methotrexate Tablets, USP.

# What is Methotrexate Tablets, USP used for?

Methotrexate Tablets, USP is used to treat certain types of cancers, severe psoriasis, psoriatic arthritis and severe rheumatoid arthritis.

## How does Methotrexate Tablets, USP work?

Methotrexate Tablets, USP works by blocking an enzyme needed by body cells to live. This interferes with the growth of some cells, such as skin cells in psoriasis that are growing rapidly. In rheumatoid arthritis, Methotrexate Tablets, USP acts on the inflammatory cells that cause joint swelling. Methotrexate Tablets, USP therapy is used to control psoriasis and rheumatoid arthritis but it will not cure them. In cancer, Methotrexate Tablets, USP works by blocking an enzyme process in cancer cells so that they cannot grow. Some normal cells in the body may be affected as well.

# What are the ingredients in Methotrexate Tablets, USP?

Medicinal ingredient: Methotrexate

Non-medicinal ingredients: Maize starch, Lactose monohydrate, Magnesium stearate, Polysorbate 80, Microcrystalline cellulose, and Starch pregelatinized (Prejel PA5)

### Methotrexate Tablets, USP comes in the following dosage forms:

Tablets: 10 mg

### Do not use Methotrexate Tablets, USP if:

- you are allergic to methotrexate, any of the non-medicinal ingredients including lactose, or any component of the container.
- you have severe kidney problems or are on dialysis.
- you are pregnant or plan to become pregnant and have psoriasis or rheumatoid arthritis. If you have cancer and are pregnant or planning a pregnancy, talk to your healthcare professional about whether the benefits to you outweigh the risks to your baby.
- you are breast-feeding.
- you have psoriasis or rheumatoid arthritis and the following:
  - alcoholism (drink excessive alcohol)
  - have chronic liver disease
  - have immune system problems
  - blood or bone marrow problems
- you are going to receive a general anesthetic called nitrous oxide. It is also known as laughing gas.

# To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Methotrexate Tablets, USP. Talk about any health conditions or problems you may have, including if you:

- Both male and female patients must use effective birth control methods all the time while taking Methotrexate Tablets, USP and for a few months after the last dose of the drug.
- have peptic ulcer disease or ulcerative colitis
- have a problem with your bone marrow
- have mild or moderate kidney problems
- have or have had liver problems, including if you have or have had hepatitis B or hepatitis C infection and fatty changes or inflammation in your liver
- have an active infection.

- have previously had radiation to your head or spine
- drink alcohol
- are taking non-steroidal anti-inflammatory drugs, cytarabine or medicines to treat stomach acid called proton pump inhibitors (like omeprazole, esomeprazole or pantoprazole)
- are also receiving or have received radiation therapy
- are experiencing weakness (debility)
- are over 65 years of age. This is because side effects and medication errors may be more likely in these patients.

## Other warnings you should know about:

- **Liver problems**: Taking Methotrexate Tablets, USP may cause liver problems, which could be fatal. If you have rheumatoid arthritis and regularly drink a lot of alcohol or have psoriasis, your healthcare professional may do a biopsy of your liver before you start treatment. They may repeat it regularly throughout your treatment to see how the medication is affecting your liver.
- Do not drink alcohol.
- Vaccination: Talk to your healthcare professional if you need a vaccination. Live vaccines may
  cause severe infections. Avoid getting a live vaccine or coming in to contact with anyone who
  has had a live vaccination. Your ability to fight an infection is decreased while taking
  Methotrexate Tablets, USP.
- **Sensitivity to sunlight:** Methotrexate Tablets, USP increases sensitivity to sunlight. Avoid sun exposure and do not use a sunlamp while taking this drug.
- Pulmonary alveolar hemorrhage: Methotrexate can cause sudden bleeding in the lungs. This is
  called Pulmonary alveolar hemorrhage. If you suddenly spit or cough up blood, go to the hospital
  right away. You will need emergency care. This side effect may happen in patients who have
  other health problems like rheumatic disorder (such as pain in your joints) or vasculitis (such as
  swelling in an artery or vein).
- Fertility:
  - Females: Methotrexate Tablets, USP can cause abnormal periods and other vaginal bleeding problems for a short time during and after treatment. It can also affect your eggs. These conditions may make it harder for you to get pregnant.
  - Males: Methotrexate Tablets, USP can lower sperm count during and after treatment. This may affect your ability to father a child.

If you are concerned about the possible impact to your fertility, talk to your healthcare professional before taking Methotrexate Tablets, USP.

- Driving and using machines: Methotrexate Tablets, USP can cause fatigue and dizziness. Before
  you drive or do tasks that require special attention, wait until you know how you respond to
  Methotrexate Tablets, USP.
- Monitoring: Before you start to take Methotrexate Tablets, USP, your healthcare professional will do blood tests and a chest x-ray. Blood tests will be repeated about once per month. As you are starting your treatment or if your dose of Methotrexate Tablets, USP changes, your healthcare professional may repeat these tests more often. The blood tests will measure your blood counts and check how your liver and kidneys are working. You may also need to have other tests to measure how your lungs are working.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

### **Serious Drug Interactions**

Do not take Methotrexate Injection, USP if you are going to receive a general anesthetic called nitrous oxide (laughing gas).

## The following may interact with Methotrexate Tablets, USP:

- medicines to reduce pain, fever or inflammation called non-steroidal anti-inflammatory drugs (NSAIDs) including acetylsalicylic acid (ASA), phenylbutazone
- certain Disease Modifying Antirheumatic drugs (DMARDs) including gold (taken by mouth or injection), penicillamine, hydroxychloroquine, sulfasalazine, leflunomide, or azathioprine
- medicines used to treat acne called retinoids
- a medicine to suppress the immune system called cyclosporin
- a medicine used to treat seizures called phenytoin
- a medicine used to treat gout called probenecid
- medicines used to treat bacterial and fungal infections including amphotericine B, penicillins, tetracycline, vancomycin, nystatin, neomycin, polymyxin B, kanamycin, trimethoprim/sulfamethoxazole, ciprofloxacin, pristinamycin, chloramphenicol
- a medicine used to treat asthma called theophylline
- the vitamin folic acid or vitamin preparations that contain folic acid
- medicines used to treat cancer including chemotherapy, cytarabine, mercaptopurine, Lasparaginase, folinic acid and radiation therapy
- medicines used to treat acid related stomach problems called proton pump inhibitors (PPIs) including omeprazole, esomeprazole, and pantoprazole
- a medicine to treat parasites called pyrimethamine
- a medicine used to treat irregular heartbeat called amiodarone
- medicines used to treat diabetes called sulfonylureas, aminobenzoic acid, sulfonamides, also known as "sulfa drugs"
- packed red blood cells, used for blood transfusions
- Psoralen Plus Ultraviolet Light (PUVA) therapy, which is used to treat skin conditions
- the medicine Triamterene, which is a diuretic or "water pill"

The absorption of Methotrexate Tablets, USP is reduced by food, particularly milk.

#### How to take Methotrexate Tablets, USP:

- Always take Methotrexate Tablets, USP exactly as directed by your healthcare professional. Check with them if you are unsure.
- Swallow tablet whole.
- Your healthcare professional will tell you how often to take Methotrexate Tablets, USP. How often you take it will depend on why you are taking this medicine.
- For rheumatoid arthritis or psoriasis: Take Methotrexate Tablets, USP once per week. It should never be taken every day of the week. However, in some cases, your healthcare professional may instruct you to take Methotrexate Tablets, USP every 12 hours for 3 doses.

- **For cancer:** how often you take Methotrexate Tablets, USP depends on the type of cancer you have.
- Do not take more or less Methotrexate Tablets, USP, and do not take it more often than your healthcare professional has told you.
- The exact amount of medicine you need has been carefully worked out. Taking too much may increase the chance of side effects and may lead to hospitalization or death. Taking too little may not improve your condition.
- If you are taking Methotrexate Tablets, USP once per week, pick a day of the week when you are most likely to remember to take it. Take your dose on the same day each week.
- Each time you refill your prescription, check to see whether the dose and/or the number of tablets you need to take have changed.
- Methotrexate Tablets, USP is often given together with certain other medicines. If you are using a
  combination of medicines, make sure that you take each one at the proper time and do not mix
  them. Ask your healthcare professional to help you plan a way to remember to take your
  medicines at the right times.
- While you are using Methotrexate Tablets, USP, your healthcare professional may want you to drink extra fluids so that you will pass more urine. This will help the drug to pass from the body, and will help to prevent kidney problems and keep your kidneys working well.
- Wear gloves when handling Methotrexate Tablets, USP.

#### **Usual dose:**

The dose of Methotrexate Tablets, USP will be different for different patients. The dose you receive will depend on:

- why you are taking this medicine
- your weight and height
- if you are also taking other medicines.

Your healthcare professional may lower your dose if you have side effects including problems with your liver or kidneys.

## Overdose:

If you think you, or a person you are caring for, have taken too much Methotrexate Tablets, USP, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Always take your labelled medicine with you, even if it is empty.

## Missed dose:

If you missed a scheduled dose, contact your healthcare professional for instruction.

If you vomit shortly after taking a dose of Methotrexate Tablets, USP, check with your healthcare professional. They will tell you whether to take the dose again or to wait until the next scheduled dose.

### What are possible side effects from using Methotrexate Tablets, USP?

These are not all the possible side effects you may have when taking Methotrexate Tablets, USP. If you experience any side effects not listed here, tell your healthcare professional.

Along with their needed effects, medicines like Methotrexate Tablets, USP can cause unwanted effects. Also, because of the way these medicines act on the body, there is a chance that they might cause other unwanted effects that may not occur until months or years after the medicine is used. These delayed effects may include certain types of cancer, such as leukemia. Discuss these possible effects with your healthcare professional.

- Upset stomach, stomach pain, vomiting, nausea, loss of appetite, dizziness, chills and fever, diarrhea or sores on lips or mouth
- A fall in the number of white blood cells. This may reduce your resistance to infection and increase your chances of cold sores, blood poisoning or swelling of blood vessels.
- Tiredness (fatigue)
- Headaches, hair loss, mood changes, confusion, ringing in the ears, sore eyes, skin rashes, increased sensitivity to sunlight, unexplained weight loss
- Blurred vision, short-term blindness
- Drowsiness, weakness
- Hoarseness
- Pin-point red spots on the skin
- Reddening or whitening of the skin, acne, boils
- Impotence or loss of interest in sex
- Diabetes, thinning of the bones, painful muscles and joints
- Low blood pressure
- Gastrointestinal ulcers

Methotrexate Tablets, USP commonly causes nausea and vomiting. Even if you begin to feel ill, do not stop using this medicine without first checking with your healthcare professional. Ask your healthcare professional for ways to lessen these effects.

Methotrexate Tablets, USP can cause abnormal test results. Your healthcare professional will decide when to perform tests and will interpret the results. This includes blood and urine tests to check how your kidneys are working.

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get
	Only if severe	In all cases	immediate medical help
VERY COMMON			
Nausea and vomiting		✓	
COMMON			
Gastrointestinal Problems: diarrhea, dehydration, abdominal pain, tenderness, chills, fever, extreme thirst, mouth ulcers or inflammation, colitis (inflammation of the colon), difficulty passing urine or stool			<b>✓</b>
Infections: sore throat, fever, chills, or swelling of glands		✓	
Inflammation of the lungs and lung damage: persistent dry cough, shortness of breath, fever		<b>√</b>	
Myelosuppression (decreased blood cell counts) including:  Anemia (low red blood cells): tiredness, loss of energy, looking pale, shortness of breath, weakness  Leukopenia (low white blood cell count): infections, fatigue, fever, aches, pains and flu-like symptoms  Thrombocytopenia (low platelet count): bruising,		✓	<b>√</b>
more bleeding than usual after an injury, fatigue, weakness			
LESS COMMON	T		I
<b>Lung problems:</b> chest pain, cough, shortness of breath or fever			✓
Severe headaches			✓
RARE			
Severe allergic reaction: skin rash, itching, chest tightness, wheezing, dizziness, hives, faintness, rapid heartbeat, shortness of breath and/or a swollen face, lips, or tongue			<b>√</b>

Serious side effects and what to do about them  Frequency/Side Effect/Symptom Talk to your healthcare Stop taking this					
Frequency/Side Effect/Symptom	Talk to your healthcare professional		drug and get		
	Only if severe	In all cases	immediate medical help		
Urinary tract infection: pain or difficulty					
urinating, lower back or side pain, blood in urine		✓			
or stools, dark urine					
Liver problems: yellowing of the whites of the					
eyes or skin (jaundice), nausea, tiredness, loss of					
appetite, fever, skin rash, joint pain and					
inflammation, pain in the upper right abdomen,			✓		
pale stools and					
dark-coloured urine					
Renal Failure/kidney damage (inability of the					
kidneys to work properly): swelling of the hands,					
ankles or feet, nausea, vomiting, blood in the					
urine, changes in frequency or amount of urine,			✓		
pain or difficulty urinating, lower back or side					
pain, dark urine					
Convulsions: seizure, spasms, shaking or					
fits			✓		
<b>Lymphoma</b> (cancer of the lymph glands): painless					
swelling of lymph node, swollen tonsils, fever,					
chills, night sweats, feeling tired, itching,					
unexplained weight loss,		✓			
loss of appetite, persistent coughing/difficulty					
breathing or not being able to					
breathe, and headache					
<b>Heart damage:</b> fast heartbeat, palpitations, chest pain, difficulty breathing, fainting			✓		
Gastrointestinal bleeding: bloody vomit,			_		
black tarry stool					
UNKNOWN					
Central Nervous System problems: behaviour					
changes, decreased consciousness, headache,					
weakness, numbness, vision loss or double vision,			<b>✓</b>		
seizures, vomiting, loss of memory					

Serious side effects and what to do about them				
Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get	
	Only if severe	In all cases	immediate medical help	
Drug reaction with eosinophilia and systemic symptoms (DRESS; allergic reactions): fever, rash, hives, swelling of eyes, lips or tongue			✓	
Pulmonary alveolar haemorrhage: suddenly spit or cough up blood			✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

## **Reporting side effects**

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<u>canada.ca/drug-device-reporting</u>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

#### Storage:

- Store Methotrexate Tablets, USP between 15°C and 25°C. Keep the tablet container in the outer carton in order to protect from light.
- Do not keep outdated medicine or medicine you no longer need.
- Keep out of reach and sight of children.

#### If you want more information about Methotrexate Tablets, USP:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website (https://www.canada.ca/en/health-canada/services/drugs-health-products/drugproducts/drugproduct-database.html)); the manufacturer's website www.pfizer.ca; or by calling 1-800-463-6001.

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