Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrMEKINIST®

trametinib tablets

This Patient Medication Information is written for the person who will be taking **MEKINIST®**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have questions about this medication or want more information about **MEKINIST**, talk to a healthcare professional.

Your cancer may be treated with MEKINIST in combination with another medication called dabrafenib. When you take MEKINIST with dabrafenib, read the Patient Medication Information leaflet for dabrafenib as well as this one.

Serious warnings and precautions box

MEKINIST should be prescribed and managed by a physician experienced in the administration of anti-cancer drugs. Serious side effects include:

- Heart problems
- Eye problems
- Lung complications
- Skin problems, including serious cases of rash, with or without infections
- Blood clots in the veins (deep vein thrombosis) and in the lung (pulmonary embolism)
- Serious bleeding into organs (brain, lung, stomach and bowels)

Other serious side effects when taking MEKINIST with dabrafenib include:

- Severe fever

What MEKINIST is used for:

Taking MEKINIST **by itself** is used to:

- treat a type of skin cancer called melanoma. This type of melanoma cannot be removed by surgery or has spread to other parts of the body.

Taking MEKINIST **with dabrafenib** is used to:

- treat a type of skin cancer called melanoma. This type of melanoma cannot be removed by surgery or has spread to other parts of the body.
- help prevent melanoma from coming back. This is after the skin cancer was completely removed by surgery.
- treat a type of lung cancer. This type of cancer is called non-small cell lung cancer. These drugs are used together when this cancer has spread to other parts of the body.

- treat a type of brain tumour called glioma.

MEKINIST should only be used for people who have a cancer that has a certain change in a gene called “BRAF”. Before taking MEKINIST, you should have your cancer tested for this gene. Your healthcare professional will take a tumour tissue sample to test whether MEKINIST is suitable for you.

MEKINIST tablets are not recommended for children less than 6 years of age or weighing less than 26 kg.

How MEKINIST works:

MEKINIST targets proteins made from the changed (mutated) BRAF gene. This slows down or stops the growth of cancer cells.

The ingredients in MEKINIST are:

Medicinal ingredient: Trametinib

Non-medicinal ingredients: Croscarmellose sodium, hypromellose, iron oxide yellow (0.5 mg tablets), iron oxide red (2 mg tablets), magnesium stearate, mannitol, microcrystalline cellulose, polyethylene glycol, polysorbate 80 (2 mg tablets), silicon dioxide (colloidal), sodium lauryl sulphate, and titanium dioxide.

MEKINIST comes in the following dosage form:

Tablets: 0.5 mg and 2 mg

Do not use MEKINIST if:

- you are allergic to trametinib, or any of the other ingredients in MEKINIST.
- you do not have a particular change (mutation) in a gene called BRAF or if the mutation in BRAF is not known.

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

- are pregnant, may be pregnant or are planning to become pregnant. You must use effective non-hormonal birth control while you are taking MEKINIST and for at least 16 weeks after you stop taking it. Pills, patches and injections are not effective in preventing pregnancies when you are taking MEKINIST with dabrafenib, because they will not work as well. Use other birth control methods when taking the two drugs together. You must make sure that you do not get pregnant while using MEKINIST. If you do get pregnant, inform your healthcare professional immediately. MEKINIST can harm an unborn baby.
- are breastfeeding. Do not breastfeed if you are taking MEKINIST.
- are a male (who has had a vasectomy or not) with a female partner who is pregnant or may become pregnant. You should use condoms with spermicide during sexual intercourse while taking MEKINIST and for at least 16 weeks after stopping MEKINIST. Men who take MEKINIST with dabrafenib may have a reduced count of sperm due to dabrafenib; this may not return to normal levels after you stop taking dabrafenib.
- have or had any **heart problems**. This can include heart failure or problems with the way

your heart beats (such as irregular heartbeat or changes with the electrical activity of your heart, known as QT prolongation). This can also include any risk factors for Torsade de Pointes (dangerous rapid fluttering of the heart). Risk factors include diabetes, low potassium, magnesium or calcium levels, or a history of low heart rate, fainting, or loss of consciousness. Your healthcare professional should check your heart function before you start taking MEKINIST and during treatment.
- have any **eye problems**. This includes **retinal vein occlusion** (blockage of the vein draining the eye) or **chorioretinopathy** (swelling in the eye which may be caused by fluid blockage). Your healthcare professional may arrange for you to have an eye exam before you take MEKINIST and while you are taking it.
- have any **skin problems** including rash or acne-like rash.
- have developed another type of cancer while taking MEKINIST with dabrafenib.
- have any **lung or breathing problems**, including difficulty in breathing often accompanied by a dry cough, shortness of breath and fatigue. Your healthcare professional may arrange to check your lung function before you start taking MEKINIST.
- have **high blood pressure**.
- have **liver or kidney problems**.
- have had **blood clots**.
- have or have had **bleeding problems**.
- have a low number of white blood cells.
- have heart valve problems.
- have elevated blood sugar levels.
- plan to have surgery, dental or other medical procedures.

Other warnings you should know about:

Heart problems: MEKINIST can affect how well your heart pumps with each beat. People may be more likely to develop this side effect if they have an existing heart problem. You will be checked for any heart problems while you are taking MEKINIST. Signs and symptoms of heart problems include:

- Feeling like your heart is pounding, racing, or beating irregularly
- Dizziness
- Tiredness
- Feeling lightheaded
- Shortness of breath
- Swelling in the legs

Eye (vision) problems: MEKINIST can cause eye problems, including blindness. MEKINIST is not recommended if you have ever had or are at risk of certain eye conditions. These conditions include **retinal detachment** (sensation of flashing light, loss of vision) or **retinal vein occlusion**. Your healthcare professional may tell you to get an eye exam before you take MEKINIST. Your healthcare professional may also tell you to get an eye exam while you are taking MEKINIST. Your healthcare professional will ask you to stop taking MEKINIST and refer you to a specialist, if you develop signs and symptoms in your vision that include:

- Colour dots
- Halo (seeing a blurred outline around objects)

- Blurred vision

MEKINIST, when taken with dabrafenib, can cause eye inflammation called **uveitis**.

Inflammatory disease: **MEKINIST, when taken with dabrafenib, can cause an inflammatory disease mainly affecting the skin, lung, eyes and lymph nodes called sarcoidosis**. Common symptoms may include coughing, shortness of breath, swollen lymph nodes, visual disturbances, fever, fatigue, pain and swelling in the joints, and tender bumps on your skin. **Tell your healthcare professional if you get any of these symptoms**.

Lung problems: MEKINIST can cause problems with your lungs such as **interstitial lung disease or pneumonitis** (inflammation of your tissues in your lung). In some cases, these lung problems can be fatal.

Skin problems: MEKINIST can cause rash, acne-like rash, serious skin reactions and infections. Tell your healthcare professional if you if you experience any of the following symptoms:

- Rash, red skin, blistering of the lips, eyes, or mouth, skin peeling, with or without fever (**Stevens-Johnson syndrome**)
- Widespread rash, fever and enlarged lymph nodes (**drug reaction with eosinophilia and systemic symptoms (DRESS)**

Blood clots: MEKINIST, when taken alone or with dabrafenib, can cause blood clots in your arms and legs, which can travel to your lungs or other parts of the body and can lead to death. Get medical help right away if you have any of the following symptoms:

- Chest pain
- Sudden shortness of breath or trouble breathing
- Pain in your legs with or without swelling
- Swelling in your arms or legs, especially one larger than the other
- A cool or pale arm or leg

Bleeding problems: **MEKINIST, when taken alone or with dabrafenib, can cause serious bleeding problems**, including in your brain, stomach, or bowel, and can lead to death. In some cases, people may develop brain tumours. Call your healthcare professional and get medical help right away if you have any unusual signs of bleeding including:

- Headaches, dizziness, or feeling weak
- Coughing up blood or blood clots
- Vomiting blood or your vomit looks like “coffee grounds”
- Red or black stools that look like tar

Gastrointestinal problems: MEKINIST can cause diarrhoea, pain in your stomach and fever. These are possible signs of an inflamed colon. Taking MEKINIST can also increase the risk of getting holes in the wall of your intestines or stomach. This is an uncommon event. Tell your healthcare professional if you have problems in your stomach or intestines. Also, tell your healthcare professional if you get severe stomach pain while taking MEKINIST.

Muscle problems: MEKINIST can result in the breakdown of muscle (**rhabdomyolysis**). Tell your healthcare professional as soon as possible if you get any of these symptoms:

- Muscle pain that you cannot explain, muscle tenderness or weakness
- Generalized weakness (especially if you don't feel well)
- Brownish or discoloured urine

Fever (temperature 38°C or higher): Taking MEKINIST with dabrafenib may cause fever. Fever may happen more often or may be more severe when MEKINIST is taken with dabrafenib. If you get a fever, or if you feel a fever coming on, stop taking MEKINIST, or MEKINIST and dabrafenib if you are taking both and tell your healthcare professional right away. In some cases, people with fever may develop severe chills, dehydration, low blood pressure, dizziness and kidney problems. Your healthcare professional may recommend that you stop taking MEKINIST while they treat your fever with other medicines. They will tell you if and when you can re-start MEKINIST. You may receive a lower dose or your treatment may be stopped altogether.

Decrease in white blood cells (neutropenia): Taking MEKINIST with dabrafenib can cause a decrease in a certain kind of white blood cells. This may lead to infection, which can be life-threatening. Decrease in white blood cells may also lead to unexpected bruising or bleeding. Your healthcare professional will monitor you for signs of low white blood cells. Signs that certain white cell counts are low may include:

- Symptoms of infection (fever, chills, sore throat)
- Bruise or bleed easily
- Cold
- Cough

Liver problems: **Taking MEKINIST with dabrafenib** can cause problems with your liver. This may develop into serious conditions such as hepatitis and liver failure. These conditions may be fatal. Your healthcare professional will monitor you periodically. Signs that your liver may not be working properly may include:

- Loss of appetite
- Nausea
- Vomiting
- Pain in your stomach (abdomen)
- Yellowing of your skin or the whites of your eyes (jaundice)
- Dark-coloured urine
- Itching of your skin

Haemophagocytic lymphohistiocytosis or HLH: Taking MEKINIST with dabrafenib may cause HLH which is a life-threatening blood disorder in which the body's ability to fight an illness (immune system) does not work normally. HLH affects multiple organs and produces several side effects. For more information on HLH and the other side effects, please see the table "Serious side effects and what to do about them".

Tumour Lysis syndrome or TLS: Treatment with MEKINIST in combination with dabrafenib may cause you to develop TLS. This condition, which can be fatal, results from the fast death of cancer cells. For information on TLS side effects, please see the table "Serious side effects and what to do about them".

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

The following may interact with MEKINIST:

The following list includes some, but not all, of the drugs that may interact with MEKINIST to affect the electrical activity of your heart:

- Antiarrhythmics (drugs that stabilize the heart rhythm function, such as quinidine, procainamide, amiodarone, sotalol, etc.)
- Beta-blockers used to lower blood pressure
- HIV protease inhibitors

How to take MEKINIST:

Take MEKINIST:

- Exactly as your healthcare professional has told you. Check with your healthcare professional or pharmacist if you are not sure;
- Once per day on an empty stomach, at least one hour before or two hours after a meal. It is important to take MEKINIST **without food.** This is because food may affect the way MEKINIST is absorbed into your body;
- At about the same time each day;
- Swallow tablet whole with a full glass of water;
- Do not take more than one dose of MEKINIST a day.
- Take MEKINIST for as long as your healthcare professional recommends.
- **If you take MEKINIST with dabrafenib:**
    - Swallow the MEKINIST tablet and the dabrafenib capsules with a full glass of water.
    - Take MEKINIST with either the morning or the evening dose of dabrafenib. Your healthcare professional will tell you how to take dabrafenib.

Usual dose:

Taking MEKINIST by itself: in adults, the recommended daily dose of MEKINIST is one 2 mg tablet once a day.

Taking MEKINIST with dabrafenib:

In adults, the recommended daily dose is 2 mg of MEKINIST once a day with two 75 mg capsules of dabrafenib (150 mg) twice a day.

In children 6 years and older, the recommended daily dose of MEKINIST tablets is based on body weight and is determined by your healthcare professional.

Your healthcare professional may decide that you should take a lower dose if you get side effects. They may also temporarily interrupt your treatment.

Overdose:

If you think you, or a person you are caring for, have taken too much MEKINIST, 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.

Missed dose:

If you miss a dose, take it as soon as you remember. If there are less than 12 hours until your next scheduled dose, skip the missed dose. Take the next dose at your usual time. **Do not take more than one dose of MEKINIST at a time.**

Possible side effects from using MEKINIST:

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

- Diarrhea
- Nausea, vomiting
- Constipation
- Decreased appetite
- Stomach ache (abdominal pain)
- Weight increased or decreased
- Dry mouth
- Sore mouth or mouth ulcers
- Chills
- Lack of energy or feeling weak, sick or tired
- Tiredness, chills, sore throat, joint or muscles aching (flu-like illness)
- Inflammation of mucous membranes
- Swelling of the face, hands or feet localized tissue swelling
- Swelling around the eyes
- Dehydration (low levels of water or fluid)
- Headache
- Dizziness
- Skin effects such as rough scaly patches of skin, brown or thickening of the outer layers of the skin, skin tags, redness and/or swelling, chapping or cracking of the skin, rash, wart-like growths, skin lesions, rash with pus-filled blisters
- Peeling on the palms, fingers and soles of the feet which may be accompanied by tingling sensation and burning pain
- Increased sensitivity of the skin to sun
- Unusual hair loss or thinning
- Excessive sweating
- Night sweats
- Pain in the hands or feet
- Joint pain
- Muscle pain
- Muscle spasms
- Cough
- Shortness of breath, laboured breathing

- High blood pressure - MEKINIST can cause high blood pressure or make your high blood pressure worse. Your healthcare professional should check your blood pressure during treatment with MEKINIST. Tell your healthcare professional if you develop high blood pressure, if it gets worse, or if you have severe headache, light-headedness, or dizziness.
- Low blood pressure
- Slow heart rate
- Nose bleeds
- Nasal inflammation
- Urinary tract infections
- Inflammation of the follicles in the skin
- Nail disorders such as nail bed changes, nail pain, infection and swelling of the cuticles
- Problem with the nerves that can produce pain, loss of sensation or tingling in hands and feet/muscle weakness (peripheral neuropathy)

MEKINIST can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment. These will tell your healthcare professional how MEKINIST is affecting your blood, liver, kidneys and muscles.

Serious side effects and what to do about them

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very Common			
Dermatitis acneiform: Skin rash, acne-like rash, redness of the face, dry or itching skin	✓		
Fever (temperature of 38°C or higher) or any fever that may be accompanied by rigors, chills, low blood pressure or kidney problems			✓
Hyponatremia (low blood levels of sodium): tiredness, confusion, muscle twitching, convulsions			✓
Edema: generalised swelling			✓
Serious bleeding problems involving: • the brain (headaches, dizziness, feeling weak), • the lungs (coughing up blood or blood clots)			✓ ✓ ✓

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
• the intestine (vomiting blood or vomit looking like “coffee grounds”, red or black stools that look like tar) • Other (bleeding gums, unusual bleeding from the vagina, blood in urine		✓	
Common			
Allergic reaction: Rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
Atrioventricular block or bundle branch block (irregular heartbeat): shortness of breath, fatigue, dizziness, near fainting and fainting			✓
Cellulitis (infection of the deeper layers of the skin): red, swollen pain area of skin that can be warm or tender, fever, chills		✓	
Cutaneous squamous cell cancer including keratoacanthomas: skin sore, wart, or reddish bump that bleeds or does not heal		✓	
Eye (vision) problems: Seeing flashes of light, colour or black dots (floaters), blurred outline around objects (halo), partial loss of vision. These eye problems may also include: • **Retinal Vein Occlusion (RVO):** Blurred or reduced vision. This usually happens in one eye and could occur abruptly. • **Uveitis** (inflammation of the inner layer of the eye): red, swollen eye, eye pain, burning or sensitivity to light, blurred vision, headache • **Chorioretinopathy** (swelling in the eyes caused by leaking fluid): distorted, dimmed or blurred vision, dark area in the middle of your vision • **Papilloedema** (swelling of the optic disc in the eye): blurred or double vision, flickering, loss of vision • **Retinal Pigment Epithelial Detachment** (splitting of the light-sensitive membrane in		✓ ✓ ✓ ✓	✓

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
the back of the eye from its supporting layers): blurred or distorted vision (uncommon)			
Heart problems (decreased ejection fraction, left ventricular dysfunction and cardiac failure): feeling like your heart is pounding, racing, or beating irregularly, dizziness, tiredness, feeling lightheaded, fatigue, weakness, shortness of breath, and swelling in the legs		✓	
Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue		✓	
Pancreatitis (inflammation of the pancreas): severe upper stomach pain, fever, rapid heart beat, nausea, vomiting, tenderness when touching the abdomen			✓
Panniculitis (inflammation of the fatty layer under the skin): large tender red bumps under the skin		✓	
Papilloma of the skin: small non-cancerous lumps on the skin	✓		
Tubulointerstitial nephritis (inflammation of the kidney): high or low urine output, drowsiness, confusion, nausea as a sign of an inflamed kidney			✓
Venous thromboembolism (blood clots): chest pain, sudden shortness of breath or trouble breathing, pain in your legs with or without swelling, swelling in your arms and legs, or a cool, pale arm or leg			✓
Uncommon			
Gastrointestinal complications: severe stomach pain, chills, fever, nausea, vomiting of			✓

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
blood, black or bloody stools, holes in the intestinal wall			
Kidney failure (severe kidney problems): confusion; itchiness or rashes; puffiness in your face and hands; swelling in your feet or ankles; urinating less or not at all; weight gain			✓
Lung complications including **pneumonitis** / and **interstitial lung disease** (inflammation of the lung): shortness of breath and cough			✓
New melanoma (mole which has irregular shape, border, or colour, is growing, or changing shape or colour, new skin lesion)		✓	
Rhabdomyolysis (breakdown of damaged muscle): muscle pain that you cannot explain, muscle tenderness or weakness, generalized weakness (especially if you don't feel well), brownish or discoloured urine		✓	
Sarcoidosis (inflammatory disease mainly affecting the skin, lungs and eyes): coughing, shortness of breath, swollen lymph nodes, visual disturbances, fever, fatigue, pain and swelling in the joints, tender bumps on your skin		✓	
Unknown			
Guillain-Barré syndrome (a nerve condition): inflammation of the nerves which can result in pain, numbness, muscle weakness and paralysis of the arms and legs		✓	
Haemophagocytic lymphohistiocytosis or HLH (a blood disorder in which your ability to fight off an illness "immune system" does not work normally): multiple symptoms such as fever, swollen glands, bruising, skin rash, enlarged liver and/or spleen, kidney abnormalities, or heart problems occurring at the same time			✓
Neutrophilic dermatosis (skin problems		✓	

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
caused by your immune system): raised, painful, red to dark reddish-purple skin patches or painful skin ulcers or sores that appear mainly on the arms, legs, face, and neck, with a fever			
Tumour lysis syndrome (fast death of cancer cells): multiple symptoms such as irregular heartbeat, decrease in urination, confusion, severe nausea and vomiting, shortness of breath, muscle cramps or spasms, occurring at the same time			✓
Skin reaction to tattooed areas: pain, redness, swelling, hardening or thickening of the skin, small raised bumps or itching		✓	

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 (canada.ca/drug-device-reporting) 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 between 15°C to 25°C in the original package. Protect from light and moisture. Do not remove desiccant.

Once opened, store at not more than 30ºC. Protect from light and moisture. Keep the bottle

tightly closed. Do not remove desiccant. Discard any unused tablets 30 days after first opening the bottle.

Keep out of reach and sight of children.

If you want more information about MEKINIST:

- 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/drug-products/drug-product-database.html); the manufacturer's website www.novartis.ca; or by calling 1-800-363-8883.

This leaflet was prepared by Novartis Pharmaceuticals Canada Inc.

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MEKINIST is a registered trademark

Patient Medication Information

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PrMEKINIST®

trametinib for oral solution

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Serious warnings and precautions box

MEKINIST should be prescribed and managed by a physician experienced in the administration of anti-cancer drugs. Serious side effects include:

- Heart problems
- Eye problems
- Lung complications
- Skin problems, including serious cases of rash, with or without infections
- Blood clots in the veins (deep vein thrombosis) and in the lung (pulmonary embolism)
- Serious bleeding into organs (brain, lung, stomach and bowels)

Other serious side effects when taking MEKINIST with dabrafenib include:

- Severe fever

What MEKINIST is used for:

Taking MEKINIST **by itself** is used to:

- treat a type of skin cancer called melanoma. This type of melanoma cannot be removed by surgery or has spread to other parts of the body.

Taking MEKINIST **with dabrafenib** is used to:

- treat a type of skin cancer called melanoma. This type of melanoma cannot be removed by surgery or has spread to other parts of the body.
- help prevent melanoma from coming back. This is after the skin cancer was completely removed by surgery.
- treat a type of lung cancer. This type of cancer is called non-small cell lung cancer. These drugs are used together when this cancer has spread to other parts of the body.

- treat a type of brain tumour called glioma

MEKINIST should only be used for people who have a cancer that has a certain change in a gene called “BRAF”. Before taking MEKINIST, you should have your cancer tested for this gene. Your healthcare professional will take a tumour tissue sample to test whether MEKINIST is suitable for you.

MEKINIST powder for oral solution is not recommended for children less than 1 year of age or who weigh less than 8 kg.

How MEKINIST works:

MEKINIST targets proteins made from the changed (mutated) BRAF gene. This slows down or stops the growth of cancer cells.

The ingredients in MEKINIST are:

Medicinal ingredient: Trametinib

Non-medicinal ingredients: Citric acid monohydrate, disodium phosphate, flavor strawberry, methylparahydroxybenzoate, potassium sorbate, sucralose, and sulfobutylbetadex sodium.

MEKINIST comes in the following dosage forms:

Powder for oral solution: 4.7 mg per bottle.

Do not use MEKINIST if:

- you are allergic to trametinib, or any of the other ingredients in MEKINIST.
- you do not have a particular change (mutation) in a gene called BRAF or if the mutation in BRAF is not known.

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

- are pregnant, may be pregnant or are planning to become pregnant. You must use effective non-hormonal birth control while you are taking MEKINIST and for at least 16 weeks after you stop taking it. Pills, patches and injections are not effective in preventing pregnancies when you are taking MEKINIST with dabrafenib, because they will not work as well. Use other birth control methods when taking the two drugs together. You must make sure that you do not get pregnant while using MEKINIST. If you do get pregnant, inform your healthcare professional immediately. MEKINIST can harm an unborn baby.
- are breastfeeding. Do not breastfeed if you are taking MEKINIST.
- are a male (who has had a vasectomy or not) with a female partner who is pregnant or may become pregnant. You should use condoms with spermicide during sexual intercourse while taking MEKINIST and for at least 16 weeks after stopping MEKINIST. Men who take MEKINIST with dabrafenib may have a reduced count of sperm due to dabrafenib; this may not return to normal levels after you stop taking dabrafenib.
- have or had any **heart problems**. This can include heart failure or problems with the way your heart beats (such as irregular heartbeat or changes with the electrical activity of your heart, known as QT prolongation). This can also include any risk factors for Torsade de

Pointes (dangerous rapid fluttering of the heart). Risk factors include diabetes, low potassium, magnesium or calcium levels, or a history of low heart rate, fainting, or loss of consciousness. Your healthcare professional should check your heart function before you start taking MEKINIST and during treatment.
- have any **eye problems**. This includes **retinal vein occlusion** (blockage of the vein draining the eye) or **chorioretinopathy** (swelling in the eye which may be caused by fluid blockage). Your healthcare professional may arrange for you to have an eye exam before you take MEKINIST and while you are taking it.
- have any **skin problems** including rash or acne-like rash.
- have developed another type of cancer while taking MEKINIST with dabrafenib.
- have any **lung or breathing problems**, including difficulty in breathing often accompanied by a dry cough, shortness of breath and fatigue. Your healthcare professional may arrange to check your lung function before you start taking MEKINIST.
- have **high blood pressure**.
- have **liver or kidney problems**.
- have had **blood clots**.
- have or have had **bleeding problems**.
- have a low number of white blood cells.
- have heart valve problems.
- have elevated blood sugar levels.
- plan to have surgery, dental or other medical procedures.

Other warnings you should know about:

Heart problems: MEKINIST can affect how well your heart pumps with each beat. People may be more likely to develop this side effect if they have an existing heart problem. You will be checked for any heart problems while you are taking MEKINIST. Signs and symptoms of heart problems include:

- Feeling like your heart is pounding, racing, or beating irregularly
- Dizziness
- Tiredness
- Feeling lightheaded
- Shortness of breath
- Swelling in the legs

Eye (vision) problems: MEKINIST can cause eye problems, including blindness. MEKINIST is not recommended if you have ever had or are at risk of certain eye conditions. These conditions include **retinal detachment** (sensation of flashing light, loss of vision) or **retinal vein occlusion**. Your healthcare professional may tell you to get an eye exam before you take MEKINIST. Your healthcare professional may also tell you to get an eye exam while you are taking MEKINIST. Your healthcare professional will ask you to stop taking MEKINIST and refer you to a specialist, if you develop signs and symptoms in your vision that include:

- Colour dots

- Halo (seeing a blurred outline around objects)
- Blurred vision

MEKINIST, when taken with dabrafenib, can cause eye inflammation called **uveitis**.

Inflammatory disease: **MEKINIST, when taken with dabrafenib, can cause an inflammatory disease mainly affecting the skin, lung, eyes and lymph nodes called sarcoidosis**. Common symptoms may include coughing, shortness of breath, swollen lymph nodes, visual disturbances, fever, fatigue, pain and swelling in the joints, and tender bumps on your skin. **Tell your healthcare professional if you get any of these symptoms**.

Lung problems: MEKINIST can cause problems with your lungs such as **interstitial lung disease or pneumonitis** (inflammation of your tissues in your lung). In some cases, these lung problems can be fatal.

Skin problems: MEKINIST can cause rash, acne-like rash, serious skin reactions and infections. Tell your healthcare professional if you if you experience any of the following symptoms:

- Rash, red skin, blistering of the lips, eyes, or mouth, skin peeling, with or without fever (**Stevens-Johnson syndrome**)
- Widespread rash, fever and enlarged lymph nodes (**drug reaction with eosinophilia and systemic symptoms (DRESS)**

Blood clots: MEKINIST, when taken alone or with dabrafenib, can cause blood clots in your arms and legs, which can travel to your lungs or other parts of the body and can lead to death. Get medical help right away if you have any of the following symptoms:

- Chest pain
- Sudden shortness of breath or trouble breathing
- Pain in your legs with or without swelling
- Swelling in your arms or legs, especially one larger than the other
- A cool or pale arm or leg

Bleeding problems: **MEKINIST, when taken alone or with dabrafenib, can cause serious bleeding problems**, including in your brain, stomach, or bowel, and can lead to death. In some cases, people may develop brain tumours. Call your healthcare professional and get medical help right away if you have any unusual signs of bleeding including:

- Headaches, dizziness, or feeling weak
- Coughing up blood or blood clots
- Vomiting blood or your vomit looks like “coffee grounds”
- Red or black stools that look like tar

Gastrointestinal problems: MEKINIST can cause diarrhoea, pain in your stomach and fever. These are possible signs of an inflamed colon. Taking MEKINIST can also increase the risk of getting holes in the wall of your intestines or stomach. This is an uncommon event. Tell your healthcare professional if you have problems in your stomach or intestines. Also, tell your healthcare professional if you get severe stomach pain while taking MEKINIST.

Muscle problems: MEKINIST can result in the breakdown of muscle (**rhabdomyolysis**). Tell your healthcare professional as soon as possible if you get any of these symptoms:

- Muscle pain that you cannot explain, muscle tenderness or weakness
- Generalized weakness (especially if you don't feel well)
- Brownish or discoloured urine

Fever (temperature 38°C or higher): Taking MEKINIST with dabrafenib may cause fever. Fever may happen more often or may be more severe when MEKINIST is taken with dabrafenib. If you get a fever, or if you feel a fever coming on, stop taking MEKINIST, or MEKINIST and dabrafenib if you are taking both and tell your healthcare professional right away. In some cases, people with fever may develop severe chills, dehydration, low blood pressure, dizziness and kidney problems. Your healthcare professional may recommend that you stop taking MEKINIST while they treat your fever with other medicines. They will tell you if and when you can re-start MEKINIST. You may receive a lower dose or your treatment may be stopped altogether.

Decrease in white blood cells (neutropenia): Taking MEKINIST with dabrafenib can cause a decrease in a certain kind of white blood cells. This may lead to infection, which can be life-threatening. Decrease in white blood cells may also lead to unexpected bruising or bleeding. Your healthcare professional will monitor you for signs of low white blood cells. Signs that certain white cell counts are low may include:

- Symptoms of infection (fever, chills, sore throat)
- Bruise or bleed easily
- Cold
- Cough

Liver problems: **Taking MEKINIST with dabrafenib** can cause problems with your liver. This may develop into serious conditions such as hepatitis and liver failure. These conditions may be fatal. Your healthcare professional will monitor you periodically. Signs that your liver may not be working properly may include:

- Loss of appetite
- Nausea
- Vomiting
- Pain in your stomach (abdomen)
- Yellowing of your skin or the whites of your eyes (jaundice)
- Dark-coloured urine
- Itching of your skin

Haemophagocytic lymphohistiocytosis or HLH: Taking MEKINIST with dabrafenib may cause HLH which is a life-threatening blood disorder in which the body's ability to fight an illness (immune system) does not work normally. HLH affects multiple organs and produces several side effects. For more information on HLH and the other side effects, please see the

table "Serious side effects and what to do about them".

Tumour Lysis syndrome or TLS: Treatment with MEKINIST in combination with dabrafenib may cause you to develop TLS. This condition, which can be fatal, results from the fast death of cancer cells. For information on TLS side effects, please see the table "Serious side effects and what to do about them".

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

The following may interact with MEKINIST:

The following list includes some, but not all, of the drugs that may interact with MEKINIST to affect the electrical activity of your heart:

- Antiarrhythmics (drugs that stabilize the heart rhythm function, such as quinidine, procainamide, amiodarone, sotalol, etc.)
- Beta-blockers used to lower blood pressure
- HIV protease inhibitors

How to take MEKINIST:

Take MEKINIST:

- Exactly as your healthcare professional has told you. Check with your healthcare professional or pharmacist if you are not sure;
- Once per day on an empty stomach, at least one hour before or two hours after a meal. It is important to take MEKINIST **without food.** This is because food may affect the way MEKINIST is absorbed into your body;
- At about the same time each day;
- Do not take more than one dose of MEKINIST a day.
- Take MEKINIST for as long as your healthcare professional recommends.
- Take MEKINIST with dabrafenib with either the morning or the evening dose of dabrafenib. Your healthcare professional will tell you how to take dabrafenib.

Please follow below Instructions for Use on how to prepare and take MEKINIST oral solution. Talk to your healthcare professional or pharmacist if you are not sure.

PREPARATION INSTRUCTION FOR HEALTHCARE PROFESSIONAL ONLY

- To prepare MEKINIST for oral solution, tap the bottle until powder flows freely. Add 90 mL distilled or purified water to the powder in the bottle and invert or gently shake the bottle with re-attached cap for up to 5 minutes until powder is fully dissolved yielding a clear solution. Separate the dosing adapter from the oral syringe. Insert dosing adapter into bottle neck after reconstitution of the solution. Write the discard-after date. Once reconstituted, MEKINIST oral solution can be used for 35 days.
- Administer MEKINIST for oral solution from oral dosing syringe or feeding tube.
- After reconstitution, store in original bottle below 25°C and do not freeze.

When using MEKINIST for oral solution, healthcare professionals should review and discuss with the patient or caregiver(s) the Patient Information and instructions for administering MEKINIST.

Healthcare professionals should confirm that patients or caregiver(s) understand how to administer the correct daily dose.

INSTRUCTIONS FOR USE of MEKINIST

These “Instructions for Use” contain information on how to administer MEKINIST

Important Information You Need to Know Before Administering MEKINIST

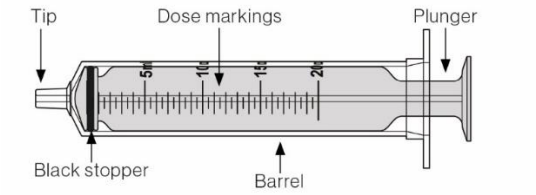
- Read these Instructions for Use carefully before you use MEKINIST for the first time and each time you get a refill. There may be new information.
- Reconstitution of powder into solution must be performed by your healthcare professional only.
- Ask your healthcare professional to show you how to administer MEKINIST correctly. Always administer MEKINIST exactly as your healthcare professional tells you to take it.
- If you have any questions about how to administer MEKINIST, contact your healthcare professional.
- You will receive the MEKINIST prescription in an amber-coloured bottle that contains the oral solution that your healthcare professional has already mixed. If you receive MEKINIST as a powder, contact the health care professional.
- Do not use the MEKINIST solution beyond discard-after date.
- If MEKINIST gets on your skin, wash the area well with soap and water. If MEKINIST gets in your eyes, rinse your eyes with water.
- **Do not** throw away any medicines via wastewater or household waste. Ask your healthcare professional how to throw away medicines you no longer use. These measures will help protect the environment.

The MEKINIST pack should contain:

1. 1 bottle containing pre-mixed MEKINIST oral solution
2. 1 oral syringe
3. 1 bottle adapter (already inserted into bottle; **do not remove** the adapter from the bottle)



Reusable oral syringe overview:



Read the important information about MEKINIST above, then go to administration instructions in **Section A.**

SECTION A. ADMINISTRATION

To administer MEKINIST**,** you will need:

1. Solution in bottle
2. Oral syringe
3. Adapter (already inserted into the bottle neck)

Contact your healthcare professional if you do not have one or more of these items.

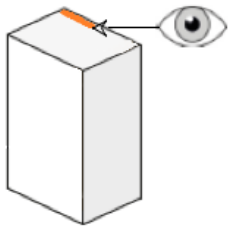
In case of spillage or contact of the MEKINIST solution with the skin or eyes, follow the information in the "**How to clean up spills**" section.

Wash and dry your hands before administering MEKINIST.

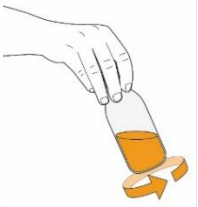


1. Check the discard-after date of the solution that your healthcare professional indicated on the label. Do not administer MEKINIST if the discard-after date has passed or there is no date.

Note: the printed expiry date on the top panel of the carton label and the bottle label does **NOT** apply to the solution. This printed expiry date applies only to the powder.



2. Gently swirl the bottle for 30 seconds to mix the solution.
   - If foam appears, allow the bottle to stand until the foam disappears.



3. Remove the child-resistant cap by pushing down the cap and turning it counter-clockwise.

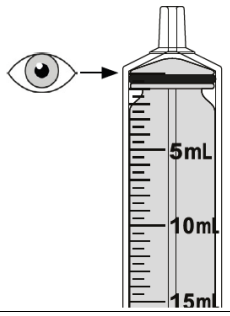


4. Check if there is a bottle adapter already inserted in the bottle neck.

Contact your healthcare professional if you are unsure or missing the adapter.



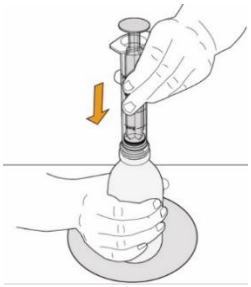
5. Push the plunger down into the oral syringe as far as it will go to remove all the air inside.



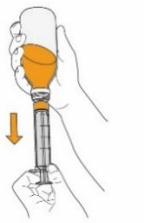
6. Place the bottle containing the prepared oral solution on a flat surface and hold it steady.

- Insert the tip of the oral syringe into the opening of the bottle adapter.
- Make sure the oral syringe is securely attached.

IMPORTANT: Due to air pressure, the plunger may move by itself when you measure your dose during step 7. Hold the plunger to prevent it moving.



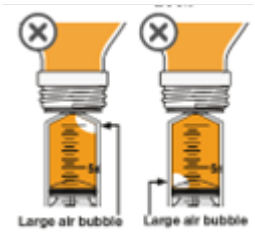
7. Carefully turn the bottle upside down and pull the plunger to measure out your dose. With the tip facing up, the **top** of the black stopper must line up with your prescribed dose in mL on the syringe barrel.



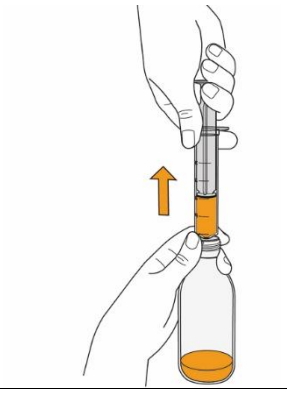
- If large air bubbles appear in the syringe, push the medication back into the bottle and withdraw

your dose again. Keep doing this until there are no air bubbles present.

- **Note:** your dose may be different than the dose shown in this figure.

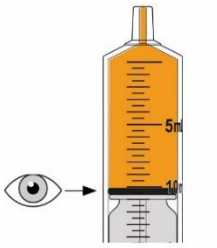


8. Continue to hold the plunger in place, turn the bottle back around and place it onto a flat surface. While still holding the plunger, remove the oral syringe from the bottle by gently pulling straight up.



9. Check again that the **top** of black stopper is at your prescribed dose. If not, repeat steps 7-8.

- If you are administering by swallowing, continue to step 10.
- If you are administering the dose by a feeding tube, go to Section B.



10. Important: If administering to a child, make sure they are sitting upright.

- Place the end of the oral syringe inside the mouth with the tip touching the inside of either cheek.
- Slowly push the plunger all the way down to give the full dose of MEKINIST.

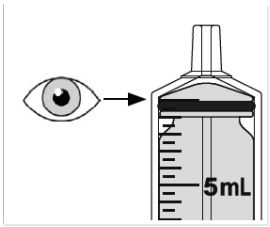
WARNING: Giving MEKINIST directly to the throat or pushing the plunger too fast may cause choking.



11. Check that there is no MEKINIST left in the syringe.

- If there is any solution left in the syringe, administer it.

Note: if your dose is larger than the syringe's capacity, repeat steps 5 to 10 until the total prescribed dose is given.



12. Do not remove the adapter.

- Place the cap back on the bottle and turn it clockwise to close it.
- Make sure the cap is securely attached onto the bottle.



13. Cleaning and storage instructions are detailed in Section C and Section D.

SECTION B. ADMINISTRATION BY A FEEDING TUBE

Please follow this section **only** if you're going to administer MEKINIST by a **feeding tube**. To administer by a feeding tube, read the following information then move to Step 1.

- The solution is suitable for administration by a feeding tube.
- Use a Nasogastric (NG) or Gastric (G) feeding tube with a **minimum** size of French 4.
- Always use the 20 mL oral syringe provided in this pack to administer MEKINIST.
- You may need an ENFIT adapter (not included in pack) to connect the 20 mL oral syringe to the feeding tube.

1. Flush the feeding tube according to the manufacturer's instructions immediately before administering MEKINIST.

2. Follow steps 1-9 in Section A, then move to Step 3 in this section.

3. Connect the 20 mL syringe containing MEKINIST to the feeding tube. You may need an ENFIT adapter to connect the syringe to the tube.

4. Apply steady pressure to the syringe plunger to dispense the solution into the feeding tube.

5. Check there is no MEKINIST left in the syringe. If there is any solution left in the syringe, administer it.

6. Flush the tube again according to the manufacturer's instructions.

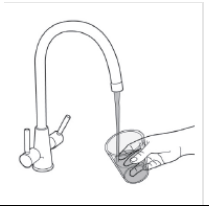
7. Go to Section C for cleaning the reusable syringe.

SECTION C. CLEANING THE REUSABLE SYRINGE

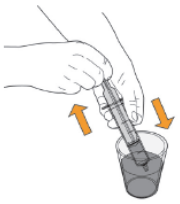
In case of spillage, follow the information in the **"How to clean up spills"** section.

Keep the oral syringe separate from other kitchen items.

1. Fill a glass with warm, soapy water.



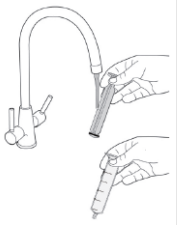
2. Place the tip of the oral syringe into the glass with the warm water. Pull water in and push the water out of the oral syringe 4 to 5 times.



3. Remove the plunger from the barrel.



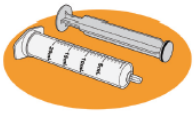
4. Rinse the glass, plunger and barrel under warm tap water.



5. Leave the plunger and barrel on a clean paper towel to air dry before next use.

   Always keep the syringe out of reach of children.

   Note: use a new oral syringe for each new bottle of MEKINIST.



How to clean up spills

Follow these steps if you spill any MEKINIST oral solution:

- Put on plastic gloves.
- Soak up the solution completely using an absorbent material, such as paper towels.
- Place the absorbent material into a sealable plastic bag.
- Wipe all surfaces exposed to the solution with an alcohol wipe.
- Place the bag, gloves and wipes into a second plastic bag and seal.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away the plastic bag or any medicines you no longer use.

Section D. STORAGE

Ready-to-use solution storage

Keep MEKINIST solution out of sight and reach of children.

Store the solution in the original bottle in an upright position below 25°C.

Do not freeze the bottle.

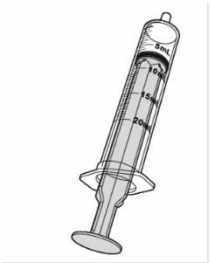
Store the solution upright, in the box provided and away from direct light with the cap tightly closed.

Do not use the solution beyond the discard-after date.



Oral syringe storage

- Keep the oral syringe out of sight and reach of children.
- Store the cleaned and dried oral syringe in the box provided alongside your powder/solution.



DISPOSAL

- Ask your pharmacist how to throw away medicines out of date or no longer needed.
- Use a new syringe for each new bottle of MEKINIST, and ask your pharmacist how to throw away the syringes that are no longer needed.
- **Do not** throw away any medicines via wastewater or household waste.

Usual dose:

The recommended dose of MEKINIST powder for oral solution is based on body weight and is determined by your healthcare professional.

Your healthcare professional may decide that you should take a lower dose if you get side effects. They may also temporarily interrupt your treatment.

Overdose:

If you think you, or a person you are caring for, have taken too much MEKINIST, 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.

Missed dose:

If you miss a dose, take it as soon as you remember. If there are less than 12 hours until your next scheduled dose, skip the missed dose. Take the next dose at your usual time. **Do not take more than one dose of MEKINIST at a time.**

Possible side effects from using MEKINIST:

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

- Diarrhea
- Nausea, vomiting
- Constipation
- Decreased appetite
- Stomach ache (abdominal pain)
- Weight increased or decreased
- Dry mouth
- Sore mouth or mouth ulcers
- Chills
- Lack of energy or feeling weak, sick or tired
- Tiredness, chills, sore throat, joint or muscles aching (flu-like illness)
- Inflammation of mucous membranes
- Swelling of the face, hands or feet localized tissue swelling
- Swelling around the eyes
- Dehydration (low levels of water or fluid)
- Headache
- Dizziness
- Skin effects such as rough scaly patches of skin, brown or yellowish thickening of the outer layers of the skin, skin tags, redness and/or swelling, chapping or cracking of the skin, rash, wart-like growths, skin lesions, rash with pus-filled blisters
- Peeling on the palms, fingers and soles of the feet which may be accompanied by tingling sensation and burning pain
- Increased sensitivity of the skin to sun
- Unusual hair loss or thinning
- Excessive sweating
- Night sweats
- Pain in the hands or feet
- Joint pain
- Muscle pain
- Muscle spasms
- Cough
- Shortness of breath, laboured breathing

- High blood pressure - MEKINIST can cause high blood pressure or make your high blood pressure worse. Your healthcare professional should check your blood pressure during treatment with MEKINIST. Tell your healthcare professional if you develop high blood pressure, if it gets worse, or if you have severe headache, light-headedness, or dizziness.
- Low blood pressure
- Slow heart rate
- Nose bleeds
- Nasal inflammation
- Urinary tract infections
- Inflammation of the follicles in the skin
- Nail disorders such as nail bed changes, nail pain, infection and swelling of the cuticles
- Problem with the nerves that can produce pain, loss of sensation or tingling in hands and feet/muscle weakness (peripheral neuropathy)

MEKINIST can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment. These will tell your healthcare professional how MEKINIST is affecting your blood, liver, kidneys and muscles.

Serious side effects and what to do about them

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very common			
Dermatitis acneiform: Skin rash, acne-like rash, redness of the face, dry or itching skin	✓		
Fever (temperature of 38°C or higher) or any fever that may be accompanied by rigors, chills, low blood pressure or kidney problems			✓
Hyponatremia (low blood levels of sodium): tiredness, confusion, muscle twitching, convulsions			✓
Edema: generalised swelling			✓
Serious bleeding problems involving: • the brain (headaches, dizziness, feeling weak), • the lungs (coughing up blood or blood clots)			✓ ✓

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
• the intestine (vomiting blood or vomit looking like “coffee grounds”, red or black stools that look like tar) • Other (bleeding gums, unusual bleeding from the vagina, blood in urine		✓	✓
Common			
Allergic reaction: Rash, hives, swelling of the face, lips, tongue or throat, difficulty swallowing or breathing			✓
Atrioventricular block or bundle branch block (irregular heartbeat): shortness of breath, fatigue, dizziness, near fainting and fainting			✓
Cellulitis (infection of the deeper layers of the skin): red, swollen pain area of skin that can be warm or tender, fever, chills		✓	
Cutaneous squamous cell cancer including keratoacanthomas: skin sore, wart, or reddish bump that bleeds or does not heal		✓	
Eye (vision) problems: Seeing flashes of light, colour or black dots (floaters), blurred outline around objects (halo), partial loss of vision. These eye problems may also include: • **Retinal Vein Occlusion (RVO):** Blurred or reduced vision. This usually happens in one eye and could occur abruptly. • **Uveitis** (inflammation of the inner layer of the eye): red, swollen eye, eye pain, burning or sensitivity to light, blurred vision, headache • **Chorioretinopathy** (swelling in the eyes caused by leaking fluid): distorted, dimmed or blurred vision, dark area in the middle of your vision • **Papilloedema** (swelling of the optic disc in the eye): blurred or double vision, flickering, loss of vision • **Retinal Pigment Epithelial Detachment** (splitting of the light-sensitive membrane in		✓ ✓ ✓ ✓	✓

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
the back of the eye from its supporting layers): blurred or distorted vision (uncommon)			
Heart problems (decreased ejection fraction, left ventricular dysfunction and cardiac failure): feeling like your heart is pounding, racing, or beating irregularly, dizziness, tiredness, feeling lightheaded, fatigue, weakness, shortness of breath, and swelling in the legs		✓	
Hyperglycemia (high blood sugar): increased thirst, frequent urination, dry skin, headache, blurred vision and fatigue		✓	
Pancreatitis (inflammation of the pancreas): severe upper stomach pain, fever, rapid heart beat, nausea, vomiting, tenderness when touching the abdomen			✓
Panniculitis (inflammation of the fatty layer under the skin): large tender red bumps under the skin		✓	
Papilloma of the skin: small non-cancerous lumps on the skin	✓		
Tubulointerstitial nephritis (inflammation of the kidney): high or low urine output, drowsiness, confusion, nausea as a sign of an inflamed kidney			✓
Venous thromboembolism (blood clots): chest pain, sudden shortness of breath or trouble breathing, pain in your legs with or without swelling, swelling in your arms and legs, or a cool, pale arm or leg			✓
Uncommon			
Gastrointestinal complications: severe stomach pain, chills, fever, nausea, vomiting of			✓

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
blood, black or bloody stools, holes in the intestinal wall			
Kidney failure (severe kidney problems): confusion; itchiness or rashes; puffiness in your face and hands; swelling in your feet or ankles; urinating less or not at all; weight gain			✓
Lung complications including **pneumonitis** / and **interstitial lung disease** (inflammation of the lung): shortness of breath and cough			✓
New melanoma (mole which has irregular shape, border, or colour, is growing, or changing shape or colour, new skin lesion)		✓	
Rhabdomyolysis (breakdown of damaged muscle): muscle pain that you cannot explain, muscle tenderness or weakness, generalized weakness (especially if you don't feel well), brownish or discoloured urine		✓	
Sarcoidosis (inflammatory disease mainly affecting the skin, lungs and eyes): coughing, shortness of breath, swollen lymph nodes, visual disturbances, fever, fatigue, pain and swelling in the joints, tender bumps on your skin		✓	
Unknown			
Guillain-Barré syndrome (a nerve condition): inflammation of the nerves which can result in pain, numbness, muscle weakness and paralysis of the arms and legs		✓	
Haemophagocytic lymphohistiocytosis or HLH (a blood disorder in which your ability to fight off an illness "immune system" does not work normally): multiple symptoms such as fever, swollen glands, bruising, skin rash, enlarged liver and/or spleen, kidney abnormalities, or heart problems occurring at the same time			✓

Frequency / Side Effect / Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Neutrophilic dermatosis (skin problems caused by your immune system): raised, painful, red to dark reddish-purple skin patches or painful skin ulcers or sores that appear mainly on the arms, legs, face, and neck, with a fever		✓	
Tumour lysis syndrome (fast death of cancer cells)**:** multiple symptoms such as irregular heartbeat, decrease in urination, confusion, severe nausea and vomiting, shortness of breath, muscle cramps or spasms, occurring at the same time			✓
Skin reaction to tattooed areas: pain, redness, swelling, hardening or thickening of the skin, small raised bumps or itching		✓	

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 (canada.ca/drug-device-reporting) 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 refrigerated, 2°C to 8°C until reconstitution.

Protect from light and moisture. Keep the bottle tightly closed.

After reconstitution, store the solution in the original bottle in an upright position below 25°C and do not freeze. Discard any unused solution 35 days after reconstitution.

Keep out of reach and sight of children.

If you want more information about MEKINIST:

- 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/drug-products/drug-product-database.html); the manufacturer's website www.novartis.ca; or by calling 1-800-363-8883.

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