Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]JEMPERLI (jem-PER-lee)

dostarlimab for injection

This Patient Medication Information is written for the person who will be taking **Jemperli**. 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 more questions about **Jemperli**, talk to a healthcare professional.

What Jemperli is used for:

Jemperli is a prescription medicine used in adults to treat:

- a kind of cancer called endometrial cancer (cancer of the lining of the womb) in adults that is shown by a laboratory test to be mismatch repair deficient (dMMR) or microsatellite instability-high (MSI-H) that has progressed on or following prior treatment with a platinum containing regimen.
- a kind of cancer called endometrial cancer (cancer of the lining of the womb) in combination with carboplatin and paclitaxel, if the cancer has spread outside your uterus (womb) and you have not received any systemic anti-cancer treatment for the advanced disease, or if your cancer has returned for the first time and cannot be cured by surgery or radiation.

How Jemperli works:

Jemperli contains the active substance dostarlimab, which is a monoclonal antibody, a type of protein designed to recognise and attach to a specific target substance in the body.

Jemperli works by helping your immune system fight your cancer.

Jemperli may be given in combination with other anticancer medicines. It is important that you also read the package leaflets for the other anticancer medicines you may be receiving. If you have any questions about these medicines, ask your doctor.

The ingredients in Jemperli are:

Medicinal ingredients: dostarlimab

Non-medicinal ingredients: trisodium citrate, dihydrate; citric acid, monohydrate; L-arginine hydrochloride; sodium chloride; polysorbate 80; and water for injection (see "Do not use Jemperli if").

Jemperli comes in the following dosage form:

Solution for infusion, 500 mg dostarlimab per vial

Do not use Jemperli if:

- if you are allergic to dostarlimab or any of the other ingredients of this medicine (listed in "The ingredients in Jemperli are:"). Talk to your doctor before you are given Jemperli if you are not sure

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

- have immune system problems
- have lung or breathing problems
- have liver or kidney problems
- have serious skin problems
- have any other medical problems including but not limited to:
  - had an allergic reaction to other monoclonal antibody therapies;
  - have or have had chronic viral infection of the liver, including hepatitis B (HBV) or hepatitis C (HCV);
  - have human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS);
  - have had a solid organ transplant or a bone marrow (stem cell) transplant that used donor stem cells (allogeneic); or
  - take other medicines that make your immune system weak. Examples of these may include steroids, such as prednisone.

Pregnancy

- **You must not be given Jemperli if you are pregnant** unless your doctor specifically recommends it.
- If you are pregnant, think you may be pregnant or are planning to become pregnant, ask your doctor for advice before you are given this medicine.
- You should not become pregnant while you are being treated with Jemperli. Jemperli can cause harmful effects or death to your unborn baby.
- If you are a woman who could become pregnant, you must use effective contraception while you are being treated with Jemperli and for at least 4 months after your last dose.

Breast-feeding

- **You must not breast-feed during treatment and for at least 4 months after your last dose of Jemperli.**
- A risk to the newborns/infants cannot be excluded.
- If you are breast-feeding, ask your doctor for advice before you are given this medicine.
- The active ingredient of Jemperli may pass into your breast milk.
- You and your doctor should decide if you will take Jemperli or breast-feed, you should not do both.

Children:

- It is not known if Jemperli is safe and effective in children less than 18 years of age. Therefore, **Health Canada has not authorized an indication for children less than 18 years of age**.

Elderly

- No overall differences in safety or efficacy were reported between elderly patients (65 years and over) and younger patients (less than 65 years). No dose adjustment is recommended for patients who are aged 65 years or over. There are limited clinical data with dostarlimab in patients aged 75 years or over.

Other warnings you should know about:

There are possible side effects of Jemperli treatment in people who have received a transplant

- **Rejection of a transplanted organ**. People who have had an organ transplant may have an increased risk of organ transplant rejection. Your doctor should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had.
- **Jemperli can cause complications, including graft-versus-host-disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic)**. These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with Jemperli. Your healthcare professional will monitor you for these complications.

Jemperli can have serious side effects, which can sometimes become life-threatening and can lead to death. These side effects may happen at any time during treatment, or even after your treatment has ended. You may get more than one side effect at the same time.

You need to be aware of possible symptoms, so your doctor can give you treatment for side effects if necessary.

Driving and using machines:

If you experience side effects that affect your ability to concentrate and react, do not drive or use machines until you feel better.

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 Jemperli:

- *Some medicines may interfere with the effect of* Jemperli*, especially medicines that make your immune system weak-for example corticosteroids, such as prednisone.*

Once you are treated with Jemperli, your doctor may give you corticosteroids to reduce any side effects that you may have.

How to take Jemperli:

Jemperli will be given to you in a hospital or clinic under the supervision of a doctor experienced in cancer treatment.

Your doctor will give you Jemperli as a drip into a vein *(intravenous infusion)* for about 30 minutes.

Your doctor will decide how many treatments you need.

Usual dose:

When Jemperli is given on its own, the recommended dose of Jemperli is 500 mg every 3 weeks for first 4 doses, followed by 1000 mg every 6 weeks for all doses thereafter, for up to 3 years.

When Jemperli is given in combination with chemotherapy, the recommended dose of Jemperli is 500 mg every 3 weeks for 6 doses, followed by 1000 mg every 6 weeks for all doses thereafter.

Overdose:

If you think you, or a person you are caring for, have taken too much Jemperli, 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 an appointment to receive Jemperli

- Contact your doctor or hospital immediately to reschedule your appointment.
- It is very important that you do not miss a dose of this medicine.

Possible side effects from using Jemperli:
When you get Jemperli, you can have some serious side effects. These side effects can sometimes become life-threatening and can lead to death. These side effects may happen anytime during treatment or even after your treatment has ended. You may experience more than one side effect at the same time. The following lists do not include all the possible side effects you may feel when taking Jemperli. If you experience any side effects not listed here, contact your healthcare professional.

The following side effects have been reported with dostarlimab alone or in combination with chemotherapy:

Very Common

- feeling sick *(nausea)*; being sick *(vomiting)*
- skin redness or rash; blistering of the skin or mucous membranes; itchy skin; dry skin
- high temperature; fever
- feeling sad or depressed
- hair loss
- changes in test results: high blood pressure, increased creatinine levels in blood, decreased potassium levels in blood

Common

- muscle or joint pain
- chills

If you are being treated with Jemperli and have any of the following serious side effects, call or see your doctor or nurse right away. Your doctor may give you other medicines in order to prevent more severe complications and reduce your symptoms. Your doctor may withhold the next dose of Jemperli or stop your treatment with Jemperli.

Serious side effects and what to do about them

Symptom / effect		Talk to your healthcare professional		Stop taking this drug and get immediate medical help
		Only if severe	In all cases	
VERY COMMON (monotherapy*)	Low red blood cells count *(anemia)*		X	
VERY COMMON (monotherapy, combination*)	**Increased liver enzyme levels in the blood**: feeling tired or weak		X	
	Skin problems			
VERY COMMON (monotherapy)	**Inflammation of the skin:** rash, itching, peeling or skin sores; ulcers in the mouth, nose, throat or genital area		X	
VERY COMMON (combination)	**Skin conditions:** dry skin, skin rash		X	
	Thyroid gland problems			
VERY COMMON (combination) **COMMON** (monotherapy)	**Underactive thyroid gland**: weight gain, feeling cold, constipation, abdominal pain, deeper voice, muscle aches, fatigue, dizziness or fainting, headache that will not go away or unusual headache		X	
COMMON (monotherapy, combination)	**Overactive thyroid gland:** rapid heartbeat, feeling anxious, weight loss, increased sweating, hair loss		X	
UNCOMMON (combination)	**Inflammation of the thyroid gland:** weight gain, constipation, dry skin, muscle weakness, fatigue		X	
COMMON (monotherapy, combination)	**Inflammation of the lungs** (*pneumonitis*): shortness of breath, chest pain, new or worse cough		X	
	Food pipe, stomach or bowel problems			
COMMON (monotherapy, combination)	**Inflammation of the lining of the bowel** *(colon)*: diarrhea, or more bowel movements than usual; black, tarry, sticky stools, blood or mucus in stools; severe stomach pain or tenderness; feeling sick (*nausea*), being sick (*vomiting*)		X	
COMMON (monotherapy)	**Inflammation of the stomach:** decreased appetite, upper belly pain, feeling sick (*nausea*), being sick (*vomiting*)		X	
COMMON (combination) **UNCOMMON** (monotherapy)	**Decreased secretion of adrenal hormones:** Feeling tired, muscle weakness, loss of appetite, weight loss, abdominal pain		X	

Symptom / effect		Talk to your healthcare professional		Stop taking this drug and get immediate medical help
		Only if severe	In all cases	
UNCOMMON (monotherapy, combination)	**Inflammation of the eye:** changes in the coloured part of the eye (*the iris*) and the area around the iris, changes to eyesight, pain		X	
UNCOMMON (monotherapy)	**Inflammation of the kidneys**: changes in amount or colour of urine, swelling of the ankles, loss of appetite, blood in the urine		X	
COMMON (combination) **UNCOMMON** (monotherapy)	**Inflammation of the pancreas**: upper belly pain, feeling sick (nausea) being sick (vomiting)		X	
UNCOMMON (monotherapy, combination)	**Inflammation of the pituitary gland, in the base of the brain**: rapid heartbeat, weight loss or weight gain, increased sweating, hair loss, feeling cold, constipation, abdominal pain, deeper voice, muscle aches, dizziness or fainting, headache that will not go away or unusual headache		X	
FREQUENCY UNKNOWN (monotherapy) **UNCOMMON** (combination) **UNCOMMON** (combination)	**Brain and nervous system** *(Guillain-Barré syndrome, encephalitis):* inflammation of the nerves that can cause pain, weakness, or paralysis in the extremities. Neck stiffness, headache, fever, chills, vomiting, eye sensitivity to light, dry mouth, impaired speech, confusion pricking or pins and needles sensations in the hands and feet, difficulty walking or lifting objects, abnormal heart beat/rate or blood pressure (*Encephalitis*): confusion, fever, memory problems, seizures		X X	
UNCOMMON (combination) **FREQUENCY UNKNOWN** (monotherapy)	**Inflammation of the Heart muscle** *(myocarditis)*: trouble breathing, dizziness or fainting, fever, chest pain and chest tightness, flu-like symptoms		X	
FREQUENCY UNKNOWN (monotherapy)	**Muscle weakness and rapid fatigue of the muscles** *(myasthenic syndrome/myasthenia gravis):* aching muscles, weakness of eye muscles, drooping eyelids, dry eyes and blurred vision, difficulty speaking or swallowing, sleepiness, dizziness		X	

Symptom / effect		Talk to your healthcare professional		Stop taking this drug and get immediate medical help
		Only if severe	In all cases	
UNCOMMON (combination) **FREQUENCY UNKNOWN** (monotherapy)	**Inflammation of the liver** *(hepatitis)***:** feeling sick *(nausea)*, being sick *(vomiting)*; loss of appetite; pain on the right side of the abdomen (stomach); yellowing of the skin or the whites of the eyes; dark-coloured urine**;** bleeding or bruising more easily than normal		X	
UNCOMMON (combination) **FREQUENCY UNKNOWN** (monotherapy)	**Inflammation of other organs:** (sarcoidosis): swollen lymph nodes, rash or tender lumps on skin, cough, or eye pain severe or persistent muscle or joint pains, severe muscle weakness, swollen or cold hands or feet, feeling tired		X	
FREQUENCY UNKNOWN (monotherapy)	**Infusion-related reactions:** shortness of breath or wheezing, itching or rash, flushing, dizziness, chills or shaking, fever, drop in blood pressure (feeling like passing out)		X	
FREQUENCY UNKNOWN (monotherapy)	**Spinal cord** *(myelitis)*: pain, numbness, tingling or weakness in the arms or legs, bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating and constipation		X	
FREQUENCY UNKNOWN (monotherapy) **UNCOMMON** (combination) **FREQUENCY UNKNOWN** (monotherapy)	**Diabetes Problems** **Type 1 diabetes** **Diabetic complications** (*diabetic ketoacidosis)*		X X	

*In the table, when Jemperli is given on its own, this is called 'monotherapy'. When Jemperli is given in combination with chemotherapy, this is called 'combination'.

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

Storage:

It is unlikely that you will be asked to store Jemperli yourself. It will be stored in the hospital or clinic where it is given to you.

Store in a refrigerator (2°C – 8°C). Do not freeze. Store in the original package in order to protect from light. Keep out of reach and sight of children.

If you want more information about Jemperli:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (Drug Product Database: Access the database); the manufacturer's website www.gsk.ca, or by calling 1-800-387-7374.

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