Important Contact Information

Name of Specialist

Phone

After-hours Phone

My Name

My Phone

Emergency Contact (Name)

Emergency Contact (Phone)

NP-EM-DST-CRD-240002
Ver. 1.0, November 2024

Patient Card

JEMPERLI (dostarlimab)

Important safety information to minimise the risk of immune-mediated side effects

Dostarlimab can cause side effects that can sometimes become serious or 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 experience side effects in more than one part of your body at the same time.

Contact your specialist immediately if you have any of the listed symptoms, if your symptoms get worse, or if you experience other symptoms that are not listed on this card. **Getting medical treatment right away may keep the problem from becoming more serious.** Your doctor may give you other medicines to treat your symptoms. Your doctor may also withhold the next dose of dostarlimab or stop treatment.

For further information, consult the Package Leaflet (PL) at www.ema.europa.eu/en/medicines/human/EPAR/jemperli or call GSK Medical Information on Tel: +356 80065004.

IMPORTANT

- Do not attempt to diagnose or treat side effects yourself
- **Take this card with you at all times,** including when you travel, if you go to the Accident and Emergency department, or when you must see another doctor
- Carry this card for at least 4 months after the last dose of dostarlimab
- Be sure to notify any health care professional you see that you are being treated with dostarlimab and show them this card

Below is a helpful checklist of Signs and Symptoms for you to closely monitor.

Call your Oncology Care Team if you have any of these signs or symptoms or if they get worse.

Lungs
- Shortness of breath
- Chest pain
- Cough

Intestines
- Diarrhea (loose, more frequent bowel movements)
- Black, tarry, sticky bowel movements
- Blood or mucus in bowel movements
- Severe stomach-area pain or tenderness

Liver
- Feeling sick to your stomach and/or throwing up
- Loss of appetite (not feeling hungry)
- Pain on right side of the stomach
- Yellowing of skin or whites of eyes
- Dark urine (tea-colored)
- Bleeding or bruising more easily than normal

Kidneys
- Decrease in the amount of urine
- Swelling of the ankles
- Red (bloody) urine

Skin
- Rash, itching, peeling or blistering of skin
- Sores or ulcers in the mouth, nose, throat or genital area

Hormone glands
- Rapid heartbeat
- Weight loss or weight gain
- Increased sweating
- Hair loss
- Feeling cold
- Extreme tiredness
- Feeling more hungry or thirsty than usual
- Needing to urinate more often
- Constipation (hard, infrequent bowel movements)
- Deeper voice
- Dizziness or fainting
- Headaches that will not go away or unusual headache

Eyes
- Changes in eyesight

Other
- Severe or persistent muscle pain or weakness
- Confusion or memory problems
- Seizures
- Changes in mood or behavior
- Tingling or numbness of arms or legs
- Fever or flu-like symptoms
- Irregular heartbeat

These are not the only side effects of dostarlimab **If you get any side effects, talk to your doctor, pharmacist or nurse.**This includes any possible side effects not listed in the package leaflet. Side effects or medication errors may be reported using the Medicines Authority ADR reporting form, which is available online at http://www.medicinesauthority.gov.mt/adrportal, and sent by post or email to;
P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000
E: postlicensing.medicinesauthority@gov.mt
Adverse events should also be reported to GSK on Tel: +356 80065004 or email: mt.safety@gsk.com.
By reporting side effects, you can help provide more information on the safety of this medicine.

Important Information for Health Care Providers

This patient is being treated with dostarlimab, which can cause immune-mediated adverse reactions that may appear any time during treatment or after treatment.
Immune-mediated adverse reactions may occur in any organ or tissue and may affect more than one body system simultaneously. Assess patients for signs and symptoms of immune-related adverse reactions including but not limited to those listed on this card. Early diagnosis and appropriate management are essential to minimise any consequences of immune-mediated adverse reactions.

For suspected immune-mediated adverse reactions, ensure adequate evaluation to confirm aetiology or exclude other causes. Based on the severity of the adverse reaction, dostarlimab should be withheld or permanently discontinued, and corticosteroids or other appropriate therapy administered.

Specific guidelines for managing immune-mediated adverse reactions are available in the Summary of Product Characteristics for Jemperli.

Consultation with an oncologist or other medical specialist may be helpful for the management of immune-mediated adverse reactions.

Please consult the Summary of Product Characteristics for JEMPERLI at www.ema.europa.eu/en/medicines/human/EPAR/jemperli or call GSK Medical Information on Tel: +356 80065004 for more information.