

Patient Card

JEMPERLI (dostarlimab)

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

JEMPERLI 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 **doctor** 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 JEMPERLI or stop treatment.

For further information, please refer to the Package Leaflet (PL) or contact GSK Tel: +966 12 653 6666 or via gcc.Medinfo@gsk.com

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 (JEMPERLI).
- Be sure to notify any health care professional you see that you are being treated with JEMPERLI and show them this card.

Below is a helpful checklist of Signs and Symptoms for you to closely monitor. Contact your doctor or your oncology healthcare provider 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
- Changes in eyesight
- 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 JEMPERLI. **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.

To report an adverse event/s associated with the use of GSK product/s, please contact us via saudi.safety@gsk.com For any side effect(s), please contact The National Pharmacovigilance Centre (NPC- Saudi Food and Drug Authority (SFDA):

SFDA call center: 19999

E-mail: npc.drug@sfda.gov.sa

Website: <http://ade.sfda.gov.sa/>



By reporting side effects, you can help provide more information on the safety of this medicine.

Important Contact Information

Name of Specialist

Phone

After-hours Phone

My Name

My Phone

Emergency Contact (Name)

Emergency Contact (Phone)

Important Information for Health Care Providers

This patient is being treated with JEMPERLI 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-mediated adverse reactions including but not limited to those listed on this card. Early diagnosis and appropriate management are essential to minimize 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, JEMPERLI 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.

For further information, please refer to the Summary of Product Characteristics for JEMPERLI or contact GSK Tel: +966 12 653 6666 or via gcc.Medinfo@gsk.com

This card is produced as a service to patients by GSK

This document is approved by the Executive Directorate of Pharmacovigilance, at SFDA.

For extra copies please contact +(966) (0) 56 904 9882

معلومات التواصل الهامة

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معلومات مهمة لمقدمي الرعاية الصحية

يتم علاج هذا المريض باستخدام جيمبيرلي والذي يمكن أن يسبب تفاعلات عكسية مرتبطة بالمناعة يمكن أن تظهر في أي وقت أثناء العلاج أو بعد العلاج. قد تحدث التفاعلات العكسية المرتبطة بالمناعة في أي عضو أو نسيج وقد تؤثر على أكثر من نظام في الجسم في نفس الوقت. يجب أن يخضع المريض لفحص العلامات والأعراض المتعلقة بالتفاعلات العكسية المرتبطة بالمناعة بما في ذلك ولا تقتصر على تلك المدرجة في هذه البطاقة. التشخيص المبكر ضروري للتقليل من أي تداعيات متعلقة بالتفاعلات العكسية المرتبطة بالمناعة.

بالنسبة للاشتباه في وجود تفاعلات عكسية مرتبطة بالمناعة، تأكد من إجراء تقييم كافٍ لتأكيد السببية أو استبعاد الأسباب الأخرى. استنادًا إلى شدة الردة السلبية، يجب إيقاف جيمبيرلي مؤقتًا أو بشكل دائم، ووصف الكورتيكوستيرويدات أو أي علاج مناسب آخر.

التوجيهات المحددة لإدارة التفاعلات العكسية المرتبطة بالمناعة متوفرة في ملخص خصائص المنتج لجيمبيرلي.

هذه البطاقة تمثل خدمة للمرضى من قبل شركة GSK

تمت مراجعة هذه الوثيقة والموافقة عليها من قبل الهيئة العامة للغذاء والدواء.

للحصول على نسخ إضافية برجاء التواصل من خلال الرقم : +(966)(0)569049882

للمزيد من المعلومات، يرجى الرجوع إلى ملخص خصائص الدواء
لجيمبيرلي أو الاتصال بـ GSK للمعلومات الصحية على
gcc.medinfo@gsk.com او رقم الهاتف: +966 12 653 6666