

Important Information for Health Care Providers

This patient is being treated with ZYNYZ® (retifanlimab), which can cause immune-mediated adverse reactions that may appear any time during treatment or even after treatment. Assess patients for signs and symptoms of immune-mediated adverse reactions. Early diagnosis and appropriate management are essential to minimise any consequences of immune-mediated adverse reactions.

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

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

For more information, please refer to the ZYNYZ Package Leaflet, which contains patient information or refer to the following website: www.ema.europa.eu/en/documents/product-information/zynyz-epar-product-information_en.pdf or call Swixx Biopharma Medical Information at +30 214 444 9670 or contact medinfo.malta@swixxbiopharma.com.

IMPORTANT

- Do not attempt to treat side effects yourself.
- Do not stop your treatment with ZYNYZ unless you have discussed this with your doctor.
- Carry this card with you at all times, especially when you are traveling, every time you go to the emergency room, or when you need to see another doctor.
- Carry this card for at least 4 months after the last dose of retifanlimab.
- If you experience any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this card. You can also report side effects directly to the Maltese Medicines Authority using the Medicines Authority ADR reporting form, which is available online at <https://medicinesauthority.gov.mt/adrportal>, and sent by post or email to:
P: Pharmacovigilance Section at Post-Licensing Directorate, Medicines Authority, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000
E: postlicensing.medicinesauthority@gov.mt
Additionally, to the Incyte local representative Swixx Biopharma S.M.S.A. Pharmacovigilance Department on +30 214 444 9670 (24h), email: medinfo.malta@swixxbiopharma.com
Reporting side effects may help provide more information about the safety of this medicine.

PATIENT CARD

ZYNYZ™ (retifanlimab)

ZYNYZ®
(retifanlimab) 500 mg
solution for infusion

Important safety information to minimise the risk of immune-mediated adverse reactions

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

Contact your specialist right away if you develop any signs or symptoms, including those not listed on this card. 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 ZYNYZ or stop treatment.

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Lungs

- Breathing difficulties
- New or worsening cough
- Chest pain

Intestines

- Frequent diarrhoea often with blood and/or mucus
- More bowel movements than usual
- Stools that are bloody, black or tarry
- Severe abdominal pain or tenderness
- Nausea or vomiting

Liver

- Loss of appetite
- Persistent Nausea or vomiting
- Pain on the right side of stomach
- Eye and/or skin yellowing
- Drowsiness
- Dark-coloured urine
- Bleeding or bruising more easily than normal

Kidneys

- Decreased volume of urine
- Foamy urine
- Passing blood or traces of blood in the urine that may change its colour
- Swollen ankles
- Loss of appetite

Hormone glands

- Fast heartbeat
- Dizziness or fainting
- Extreme tiredness
- Persistent or unusual headaches
- Weight change
- Feeling cold
- Hair loss
- Constipation

Type 1 diabetes or diabetic ketoacidosis

- Feeling more hungry or thirsty than usual
- Frequent urination
- Weight loss
- Feeling tired or sick
- Difficulty thinking clearly
- Fast and deep breathing
- Breath that smells sweet or fruity
- Sweet or metallic taste in the mouth
- Stomach pain
- Sleepiness
- Different odour to urine or sweat

Skin

- Rash or itching
- Blistering or ulcers in the mouth or in the lining of the nose, throat or genital area

Other organs

- Changes in eyesight
- Inflammation of joints, muscles, nerves, pancreas, or of the heart muscle

Important Contact Information

Name of Specialist

Office Phone

After-hours phone

My Name

My Phone

Emergency Contact (Name)

Emergency Contact (Phone)