PATIENT ALERT CARD

when receiving Hyrimoz
(for adults as well as paediatric patients)

Version: 01

Approved by SÚKL: 05/2019

It is necessary to show this card to every doctor or health care professional during each visit to a medical facility.

Patients shall keep this card on them for 5 months after their last dose of the treatment.

Hyrimoz contains an active ingredient adalimumab that reduces certain immune reactions. It is a medication that improves the course of some inflammatory diseases.

The active ingredient adalimumab is a human monoclonal antibody produced by cultured cells.

PATIENT

Name: .....

Diagnosis: .....

Address: .....

Severe adverse events can appear in patients receiving Hyrimoz, such as:

- **Infections** – Hyrimoz can cause the patient to become more susceptible to infections or it can worsen the infection they already suffer from. This includes infections such as common cold or severe infections such as tuberculosis.
- **Heart failure** – Some patients experienced the development of heart failure or worsening of the existing condition.
- **Tumour disease** – The risk of developing certain types of tumour disease can be increased if you or your child are treated with Hyrimoz.
- **Nerve disorders (tingling, prickling or numbness)** – these can appear or if already existing they can worsen.

Patients should inform their doctor if:

- they have an infection or symptoms suggestive of infection (fever, injury, feeling tired, trouble with teeth, etc.),
- they are suffering from tuberculosis, or have been in close contact with a person suffering from tuberculosis,
- they are carriers of hepatitis B virus (HBV), have an active infection or think they are at risk of this infection,
- they suffer or suffered from serious heart disease or heart failure,
- they have or have had tumour disease,
- they have the sensation of numbness or tingling or they are suffering from a nervous system disorder,such as multiple sclerosis.

Patients should seek immediate medical advice if they experience the following symptoms:

- **Allergic reactions** – chest tightness, trouble breathing or swallowing, swelling of the face or hands and feet, dizziness, severe rash
- **Infection** – fever, chills, sweating, vomiting, diarrhoea, stomach ache, cough, burning on urination, skin inflammation, injury, muscle pain, trouble with teeth
- **Heart failure** – shortness of breath, leg and feet swelling, sudden weight gain
- **Tumour disease** – nightsweating, swelling of glands in the neck, armpits or groins, weight loss, significant changes in the skin, severe itching

This Patient Alert Card does not list all possible adverse events that may occur. For more information about adverse events, please read the Hyrimoz leaflet or consult your doctor.

It is important that patients inform their doctor immediately about any unusual symptoms which occurred during treatment.

Patients should inform their doctor about:

- any intervention or surgery they are planning,
- any changes in their health,
- any new drugs they are taking.

EXAMINATION:

The patient was examined for the incidence of ACTIVE or LATENT TUBERCULOSIS prior to the initiation of the treatment by Hyrimoz.

YEAR			
Tuberculin skin test			
Chest X-ray			
Other (e.g. QFT)			

Date of the first injection	
Dose	
Date of the last injection (only if ending the treatment)	

MEDICATIONS THE PATIENT IS TAKING:

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Name and address of the doctor:

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Email:.....Tel.No.:.....

The medicine should be stored in a thermo-case at temperatures between +2 °C to +8 °C. Temperature should not vary.
Medicine should not be exposed to light and must not freeze!

CONTACT PERSONS

Name: .....

..... Tel. No.: .....

Name: .....

..... Tel. No.: .....

Name: .....

..... Tel. No.: .....

▼ This product is under additional monitoring. This will facilitate rapid collection of new safety information. You can contribute by reporting any adverse reactions that you experience.

Should you or your child experience any of the adverse reactions, please tell your doctor or pharmacist, and do so also in case of any adverse reactions that are not described in the Patient Information Leaflet. You can also report adverse reactions directly, via the national adverse drug reaction reporting system.

For details regarding reporting, please refer to: http://www.olecich.cz/hlaseni-pro-sukl/nahlasit-nezadouci-ucinek.

The mailing address is: Státní ústav pro kontrolu léčiv, odbor farmakovigilance, Šrobárova 48, Praha 10, 100 41, email: farmakovigilance@sukl.cz.

It is necessary to provide also the exact trade name and batch number. By reporting adverse drug reactions you can contribute to the collection of further information on the safety of this product.

This information may be also reported to companySandoz, s.r.o. address is: Sandoz s.r.o., Gemini, building B; Na Pankráci 1724/129, 140 00 Praha 4, Email: farmakovigilance.cz@novartis.com or tel.: 800 40 40 50.

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