Přední strana

Str. 1

PATIENT ALERT CARD

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

Rozměr zavřeného průkazu 105 × 73 mm

Str. 2

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.

HUMIRA 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 .....

Str. 3

Rozměr otevřeného průkazu 210 × 73 mm

Str. 4

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

- **Infections –** Humira 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 Humira.
- **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 –** shortnessof 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 Humira leaflet or consult your doctor.

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

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Str. 6

Patients should inform their doctor about:

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

EXAMINATION:

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

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)	

Str. 7

MEDICATIONS THE PATIENT IS TAKING:

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

Name and address of the doctor:

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E-mail: ..... Tel. No.: .....

CONTACT PERSONS

Name: .....

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

Name: .....

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

Name: .....

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

If you or your child experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in the leaflet. You can also report side effects directly via the national reporting system.

More information about reporting can be found at:
http://www.olecich.cz/hlaseni-pro-sukl/nahlasit-nezadouci-ucinek

The postal address is State Institute for Drug Control, Pharmacovigilance Department, Šrobárova 48, Praha 10, 100 41, e-mail: **farmakovigilance@sukl.cz.**

It is appropriate to provide the specific trade mark and the batch number.

By reporting side effects you can help provide more information on the safety of this medicine. This information can also be reported to the company AbbVie s.r.o., Tel. No. +420 233 098 111, e-mail: **info-cz@abbvie.com.**

Zadní strana