If you or your child experiences 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 name and the batch number.

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

Version 1.0 • Approved by SUKL: Mar/2020

PATIENT REMINDER CARD
Adalimumab▽

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Trade name of the medicine (for adults as well as paediatric patients)

Some of the medicinal products containing adalimumab are under additional monitoring, which is indicated by the symbol of a black inverted triangle on the packaging and in the texts accompanying the medicinal product as follows:

▽ This medicinal product is under additional monitoring. This will allow for rapid collection of new safety information. You may contribute by reporting any adverse reactions that you experience.

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Velikost po složení : 90 x 60 mm

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.

Adalimumab 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 adalimumab, such as:

- Infections – adalimumab 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.
- Tumour disease – The risk of developing certain types of tumour disease can be increased if you or your child is treated with adalimumab.
- 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 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;
- Tumour disease – night sweating, swelling of glands in the neck, armpits or groins, weight loss, significant changes in the skin, severe itching.

This overview of adverse drug reactions is not complete, and it is necessary to familiarise yourselves with other potential adverse reactions the list of which is available from the Patient Information Leaflet. The Patient Information Leaflet (PIL) is distributed in each package of the medicinal product and it may be also found at http://www.olecich.cz under the abbreviation PIL if you enter the name of the medicinal product.

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

Patients should inform their doctor about:

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

Vaccinations:

- Patients on adalimumab may receive concurrent vaccinations, except for live vaccines.
- If adalimumab was received during pregnancy, it is important to inform pediatrician before the baby receives any vaccine. The baby should not receive a "live vaccine", such as BCG (Bacillus Calmette–Guérin, used to prevent tuberculosis) within 5 months following the mother's last adalimumab injection during pregnancy.

Examination:

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

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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DOCTOR

Name and address

E-mail

Tel. no.

CONTACT PERSONS

Name

Tel. no. .....

Name

Tel. no. .....

Name

Tel. no. .....

Instructions for storaging:

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