## Who can report side effects?

In Croatia, health professionals and drug manufacturers have a legal obligation to report side effects. Patients/users of medicines can also report side effects, which is particularly valuable because patients may report side effects earlier than health professionals and they tend to provide a more detailed description of side effects. You can report side effects that have happened to you personally, your child or someone you are responsible for, e.g. mother, spouse.

## How is confidentiality of personal information ensured?

Side effect report includes personal information on patient/user of medicine and/or reporter. We ask for these details so that we can get in touch if more information on reported side effect is needed. Personal information included in the side effect report is strictly confidential and will only be used to determine the safe use of medicines. Personal data will not be passed to any third person without your express permission. If you have provided your physician's contact information, it is possible that we will contact her/him to collect more information about the reported side effect.

## What happens after I report side effect?

We may contact you or your physician to ask for additional information relating to the report.
All reports are entered into our database and are used for analyses of the relationships between medicines and side effects. If we consider it necessary, we may add warnings to the patient information leaflet that comes with the medicine. We may also update information on how the medicine should be used – for instance, limiting the dosage, or saying that it should not be used by particular groups of patients. Rarely, we may take the medicine off the market, in case we consider that the risks of the medicine outweigh its benefits.

## Where can I obtain more information about the side effects of medicines?

Information about a particular medicine can be found in the patient information leaflet supplied with the medicine, that can also be found at www.halmed.hr, under the section For patients - Information on Medicines.
New safety information can be found at www.halmed.hr, under the News section, or by subscribing to the HALMED's newsletter.
You can send your questions to HALMED via www.halmed.hr, under the Enquiries section.

**The Agency for Medicinal Products and Medical Devices (HALMED) is a regulatory body that approves the registration of medicines in the Republic of Croatia. HALMED's goal is to protect public health by ensuring the safety, efficacy and quality of medicines. In order to achieve that, we evaluate the safety of drugs after putting them on the market, while using side effect reports as valuable sources of information.**

HALMED

Agency for Medicinal Products and Medical Devices of Croatia

# Reporting Side Effects

## – A Patient Guide

**Let's make medicines safer for everyone**

**www.halmed.hr**

## What is a side effect?

Side effects, also known as adverse reactions, are unwanted and/or harmful reactions to the drug or vaccine. All medicines can cause side effects, although not everybody gets them. Side effects can range from minor irritations, such as a skin rash, to serious and life-threatening reactions, such as a heart attack or liver damage. They can occur within minutes after taking a medicine, or can take years to develop.

## If you are worried about a symptom you think may be a side effect...

1. Read the patient information leaflet supplied with the medicine – it lists the known side effects, and advises you what to do.
2. Ask your doctor or pharmacist for advice.
3. Report the side effect to your national medicines agency (in Croatia: HALMED), especially if it is not mentioned in the patient information leaflet.

Always talk to your doctor if you have any symptom that worries you.

## Why should I report a side effect?

All medicines have benefits and risks. Although medicines are thoroughly tested prior to their registration, some side effects can be detected only after a medicine is in use by the general population.

HALMED therefore collects and reviews side effect reports sent by health workers, drug manufacturers and patients/users of medicines.
When you report a side effect to HALMED, the data from your report is, together with other data, used to assess the safety of a medicine. By reporting side effects you are directly contributing to improving the safe use of medicines for everyone.

# How can I report side effect?

- **Directly via web page www.halmed.hr**
- **By filling in Adverse Reaction Notification form.**

**You can send your report by post to the Agency for Medicinal Products and Medical Devices (HALMED).**
**Ksaverska cesta 4, 10000 Zagreb,**
**by telefax to the number 01 4884 110,**
**or by e-mail to nuspojave@halmed.hr.**

## What should I report as a side effect?

You do not have to be certain that a particular problem was caused by a medicine – reporting the suspicion of an adverse effect is enough.
HALMED receives reports on side effects of medicines, vaccines, medical devices and dietary supplements.
Four essential pieces of information need to be included in a side effect report:
1.The symptoms or a description of the side effect
2.Information about the person who experienced the side effect (as a minimum, their initials, sex, and age at the time of the side effect)
3.The name of the medicine(s) thought to have caused the side effect
4.the name and full address of the reporter, so that HALMED can make contact with the reporter for further information, if necessary.

## When it is especially important to report a side effect?

- If you have side effect which is not listed in the patient information leaflet – this way the new side effects, not previously observed in clinical trials of medicine, are being detected.
- If you have severe or serious side effect, that negatively affects the quality of your life –detecting these side effects enables HALMED to limit the usage of certain medicine, if necessary.
- If the side effect is a consequence of improper use of medicine (for example, the person accidentally took the medicine that was not intended for her/him, or the poisoning/medicine overdose occurred) – this way it can be detected how the medicine works in unexpected situations and how this can be prevented.
- If the side effect occurred in people who belong to special populations such as children, pregnant women, elderly and chronically ill people (for example, with liver or kidney disease) – the use of medicine in these populations usually requires special warnings and precautions for use.