



**National Agency for Medicines
and Medical Devices of Romania**

**RECOMMENDATIONS FOR
REPORTING SIDE EFFECTS
AFTER TAKING A
MEDICINAL PRODUCT**



FOR PATIENTS COMING FROM UKRAINE



WHAT IS A SIDE EFFECT?

- A side effect or adverse reaction is an unwanted or unintentional reaction that a person may experience after taking a medicinal product. In many cases, side effects to medicinal products are mild and do not mean that you have to stop taking the medicinal product. However, for some people the side effects can sometimes be more serious and may require a change in treatment or, in rare cases, some additional medical treatment.
- This leaflet provides useful information about what you should do if you believe that you have had a side effect to a medicinal product.

HOW DO I REPORT SUSPECTED SIDE EFFECTS AFTER TAKING MEDICINAL PRODUCTS?

- We advise people coming from Ukraine, who may experience a suspected side effect after the administration of a medicinal product, to contact a healthcare professional, for assessment and advice.
- You can report suspected side effects through a healthcare professional (nurse, pharmacist, physician) - in order to avoid language misunderstanding.

WHAT SIDE EFFECTS SHOULD I REPORT?

- First and foremost, you should report side effects which are not listed in the package leaflet or which you find very burdensome (serious). See a doctor if you are experiencing troublesome side effects.
- Your report can provide us with valuable new information about how side effects are affecting use of medicinal products and quality of life amongst patients.

The report will be even more valuable if you provide as much information as possible.

HOW TO REPORT SIDE EFFECTS

A healthcare professional will give you all support you need!

You can report a side effect by:

- Contacting a physician or pharmacist who can notify us, the NATIONAL AGENCY FOR MEDICINES AND MEDICAL DEVICES OF ROMANIA, at the following link:
<https://www.anm.ro/medicamente-de-uz-uman/farmacovigilenta/raporteaza-o-reactie-adversa/>
- Using the online report. Please find below the QR code for reporting side effects:
Please be informed, the following reporting forms are available only in RO language:



Reporting side effects for medicinal products



Reporting side effects for COVID-19 vaccines

- Also, you may send an e-mail with all the details of the suspected side effect(s), as described down below, at the following e-mail address: adr@anm.ro. The e-mail should be sent in EN or RO language.

PLEASE INCLUDE THE FOLLOWING INFORMATION WHEN REPORTING SUSPECTED SIDE EFFECTS:

- name of the suspected medicinal product or the suspected vaccine
- when you started to take the medicinal product or date of vaccination
- specifying the country in whose territory the side effect(s) occurred
- description of the sequence of side effect(s) or other events, in as much detail as possible
- when the suspected side effect(s) first started
- whether the side effect(s) is still ongoing or has been resolved
- any previous or concomitant medical conditions or treatment (if applicable)
- results of any blood tests, ultrasounds, x-rays or any other relevant medical document(s) (if applicable)

IF YOU ARE REPORTING SIDE EFFECTS FOR A VACCINE:

- brand name of the vaccine AND batch number
- which dose the side effect(s) occurred after (i.e. first, second, third dose)
- whether a different type of vaccine was given at different doses.

www.anm.ro

We encourage people to report suspected **side effects!**

