



BAHAGIAN REGULATORI FARMASI NEGARA (NPRA)
Kementerian Kesihatan Malaysia

NATIONAL PHARMACEUTICAL REGULATORY AGENCY (NPRA)
Ministry of Health, Malaysia

Medicine Side Effects Reporting for CONSUMERS



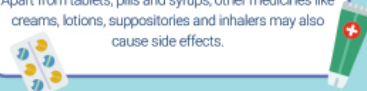
What is a side effect?

A side effect or adverse drug reaction is **any unwanted effect of a medicine that occurs to a person taking the medicine at a normal dose.**

Side effects may vary among individuals, and different medicines cause different kind of side effects. Side effects may be mild, moderate, or even requiring medical attention or hospitalisation.

Examples of some commonly reported side effects are itching, rash, swelling, nausea and headache.

Apart from tablets, pills and syrups, other medicines like creams, lotions, suppositories and inhalers may also cause side effects.



What to do if you experience a side effect?

STEP 1: TALK TO YOUR DOCTOR OR PHARMACIST

If you suspect that you are experiencing a side effect from a medicine, note down the following important details to discuss with your doctor or pharmacist. If possible, bring your medicine with you.

- Name of medicine
- The dose taken
- How long after taking the medicine did the side effect occur?
- Name of other medicines taken at the same time

STEP 2: REPORT TO THE NPRA

Please use **ConSERf** to report to the NPRA the side effects that you suspect may be due to the medicine.

Why report a side effect?

Side effects should be reported as some side effects may emerge after the medicine is available in the community for some time and more people start to use it. Majority of information about side effects are obtained through spontaneous reporting.

- ✦ Reporting of previously unknown or rare side effects can help NPRA **detect new side effects** for the medicine.
- ✦ Reporting of side effects which are already documented helps NPRA **monitor the prevalence of these side effects.**

When you report your experience with a medicine, it improves healthcare professionals' **understanding on medicine side effects.** This will help in the **implementation of preventive measures to strengthen the safe use of medicines for everyone.**

Your report may help save a life!

What can be reported?

Please report any side effects suspected may be due to:

- ✔ **Controlled medicines** (medicines obtained with doctor's prescription)
- ✔ **Over-The-Counter (OTC) medicines** (self-purchased at pharmacies/shops)
- ✔ **Vitamins and health supplements**
- ✔ **Traditional medicines**



How to report a side effect?



Visit the NPRA website at

<https://www.npra.gov.my>
Consumers > Reporting Side Effects to Medicines (ConSERF)

Go to ConSERF webform to report online OR Download the form and fill it in, then email to fv@npra.gov.my

Contact us for more information on ConSERF

Example of ConSERF printed form

The role of NPRA

All ADRs occurring in Malaysia that are reported to the NPRA are evaluated to identify potential medicine safety issues.

Evaluation of ADR reports have led to the formation of precautionary steps to minimise the risk of medicine side effects, via regulatory actions such as:



- Restriction of the use of certain medicines;
- Updates to medicine package inserts with new safety information;
- Suspension or removal of medicines from the market.

All ADR reports received are analysed and recorded into the Malaysian ADR Database, as well as the World Health Organisation (WHO) global ADR database for international monitoring of medicine safety.

Visit the WHO website !

You can search the WHO database for information on ADRs that are reported globally by using VigiAccess™, at the website below:

www.vigiaccess.org

Keeping medicines safe for the nation

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