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)

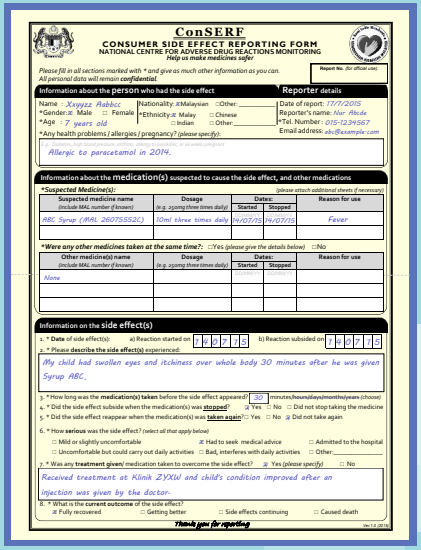
Go to ConSERF webform to report online

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



ConSERF

CONSUMER SIDE EFFECT REPORTING FORM

NATIONAL CENTRE FOR ADVERSE DRUG REACTIONS MONITORING

Help us make medicines safer

Please fill in all sections marked with * and give as much other information as you can.
All personal data will remain **confidential**.

Report No. (for official use):

Information about the person who had the side effect | **Reporter details**

Name : Xxyzzz Rabbcc
*Gender: ☒ Male ☐ Female
*Age : 7 years old
Nationality: ☒ Malaysian ☐ Other:
*Ethnicity: ☒ Malay ☐ Chinese ☐ Indian ☐ Other:
Date of report: 17/7/2015
Reporter's name: Nur Abcde
*Tel. Number : 015-1234567
Email address: abc@example.com

*Any health problems / allergies / pregnancy? (please specify):

Allergic to paracetamol in 2014.

Information about the medication(s) suspected to cause the side effect, and other medications

*Suspected Medicine(s): (please attach additional sheets if necessary)

Suspected medicine name (include MAL number if known)	Dosage (e.g. 2x5ml 3 times daily)	Dates: Started	Dates: Stopped	Reason for use
ABC Syrup (MAL 2607553Z)	10ml three times daily	14/07/15	16/07/15	Fever

*Were any other medicines taken at the same time? ☐ Yes (please give the details below) ☐ No

Other medicine(s) name (include MAL number if known)	Dosage (e.g. 2x5ml 3 times daily)	Dates: Started	Dates: Stopped	Reason for use
None				

Information on the side effect(s)

1. * Date of side effect(s): a) Reaction started on 14/07/15 b) Reaction subsided on 17/07/15
2. * Please describe the side effect(s) experienced:
My child had swollen eyes and itchiness over whole body 30 minutes after he was given Syrup ABC.
3. * How long was the medication(s) taken before the side effect appeared? 30 minutes/hours/days/months/years (choose)
4. * Did the side effect subside when the medication(s) was stopped? ☒ Yes ☐ No ☐ Did not stop taking the medicine
5. * Did the side effect reappear when the medication(s) was taken again? ☐ Yes ☐ No ☒ Did not take again
6. * How serious was the side effect? (select all that apply below)
☐ Mild or slightly uncomfortable ☒ Had to seek medical advice ☐ Admitted to the hospital
☐ Uncomfortable but could carry out daily activities ☐ Bad, interfere with daily activities ☐ Other:
7. * Was any treatment given/ medication taken to overcome the side effect? ☒ Yes (please specify) ☐ No
Received treatment at Klinik ZYXW and child's condition improved after an injection was given by the doctor.
8. * What is the current outcome of the side effect?
☒ Fully recovered ☐ Getting better ☐ Side effects continuing ☐ Caused death

Thank you for reporting

Ver 1.0 (08.15)

The role of NPRA

All ADRs occuring in Malaysia that are reported to the NPRA are evaluated to identify potential medine 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

Published by

National Pharmaceutical Regulatory Agency (NPRA)

Lot 36, Jalan Universiti,
46200 Petaling Jaya, Selangor.

www.npra.gov.my

fv@npra.gov.my