DETECTIVE RRR STARS IN

ENDGAME OF SIDE EFFECTS

VILLAIN MEDNOS IS CRUSHED!

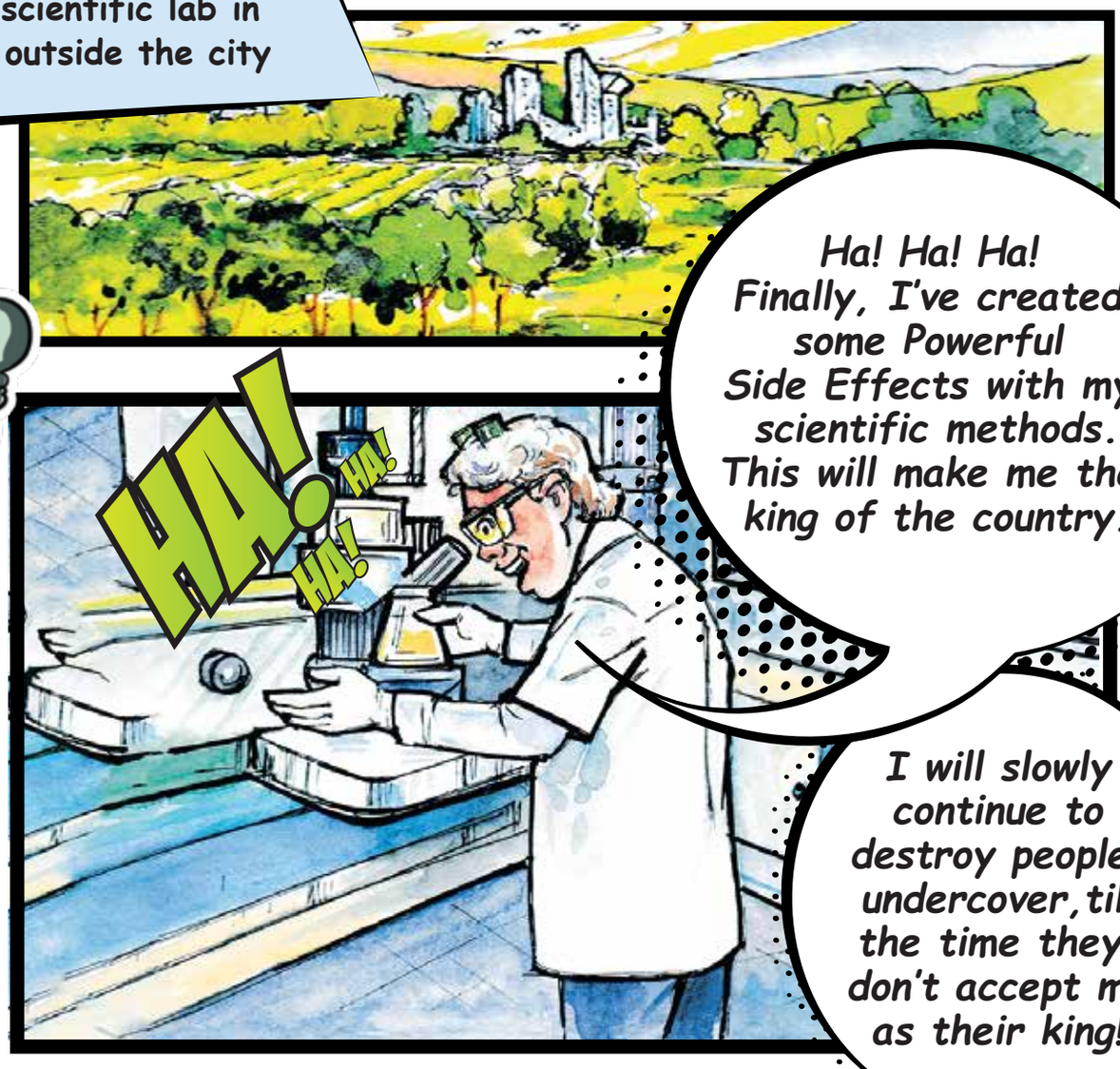
Put on your thinking caps....

- Does Google answer all my medical queries?
- Is it okay if I take medicines prescribed for my friend or family member if the symptoms seem the same?
- Can I swallow medications with a sip of any drink?
- Can I stop my antibiotics treatment or any other treatment midway, because I started to feel better?
- Spicy food and stress- are they the only culprits for ulcer?
- Do only overweight or obese people get diabetes?
- Do probiotics help prevent cold?
- Does taking multivitamins make me healthier?
- Should I take over-the-counter medications without consulting my doctor?

The answer to all these questions is - NO

BEWARE OF MYTHS AND STAY VIGILANT

A high-tech scientific lab in a farmhouse outside the city



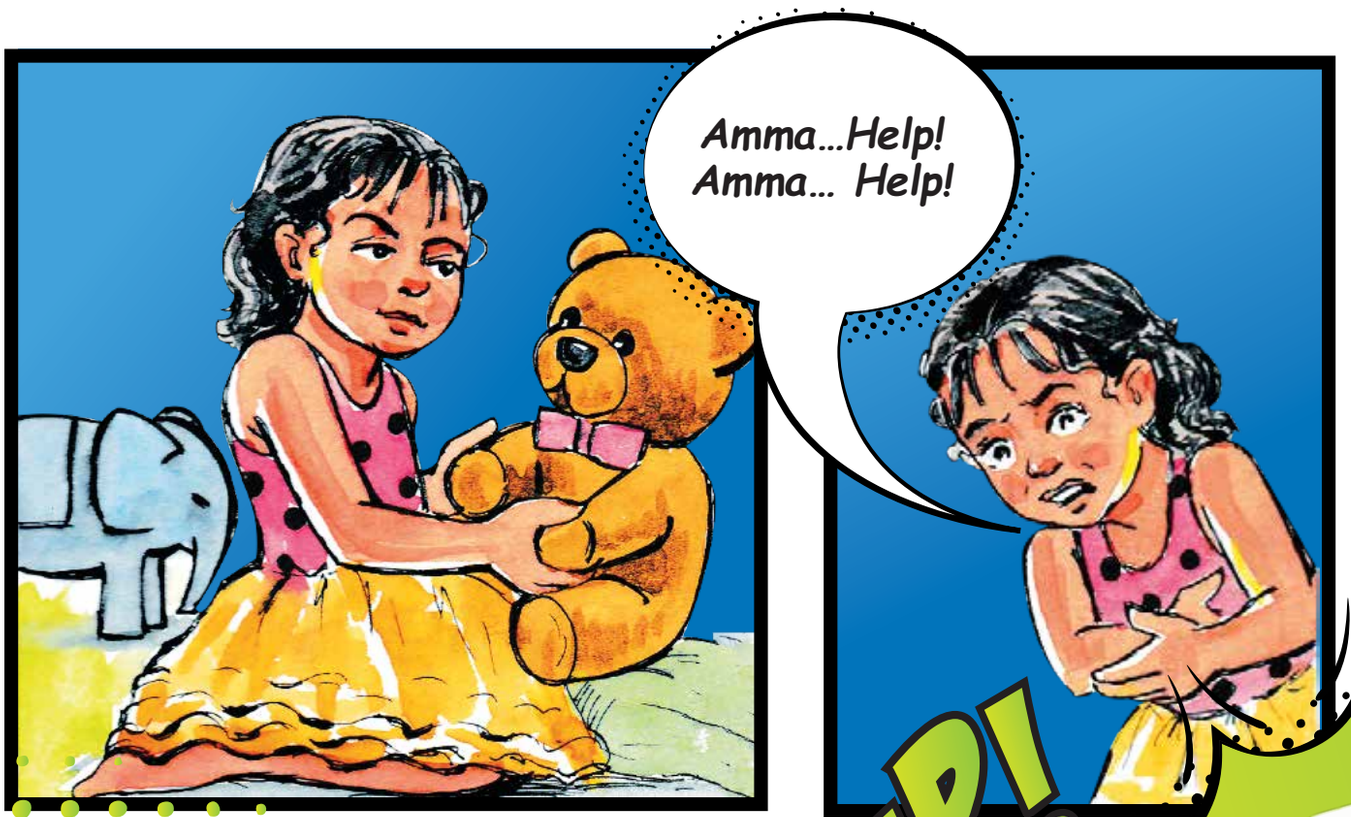
…Somewhere in Mumbai at a music concert

The Singer feels dizzy with a finger snap by Mednos

...Somewhere in Delhi

An old lady while watching T.V, starts to experience palpitations

…Also happening in Chennai



The girl suddenly starts having an episode of seizures

…and in Kolkata too

What is happening to me? Why am I feeling anxious?

SNAP!

The pregnant woman starts feeling sweaty and anxious...

WHAT IS GOING ON

The country seems to be UNDER ATTACK!!

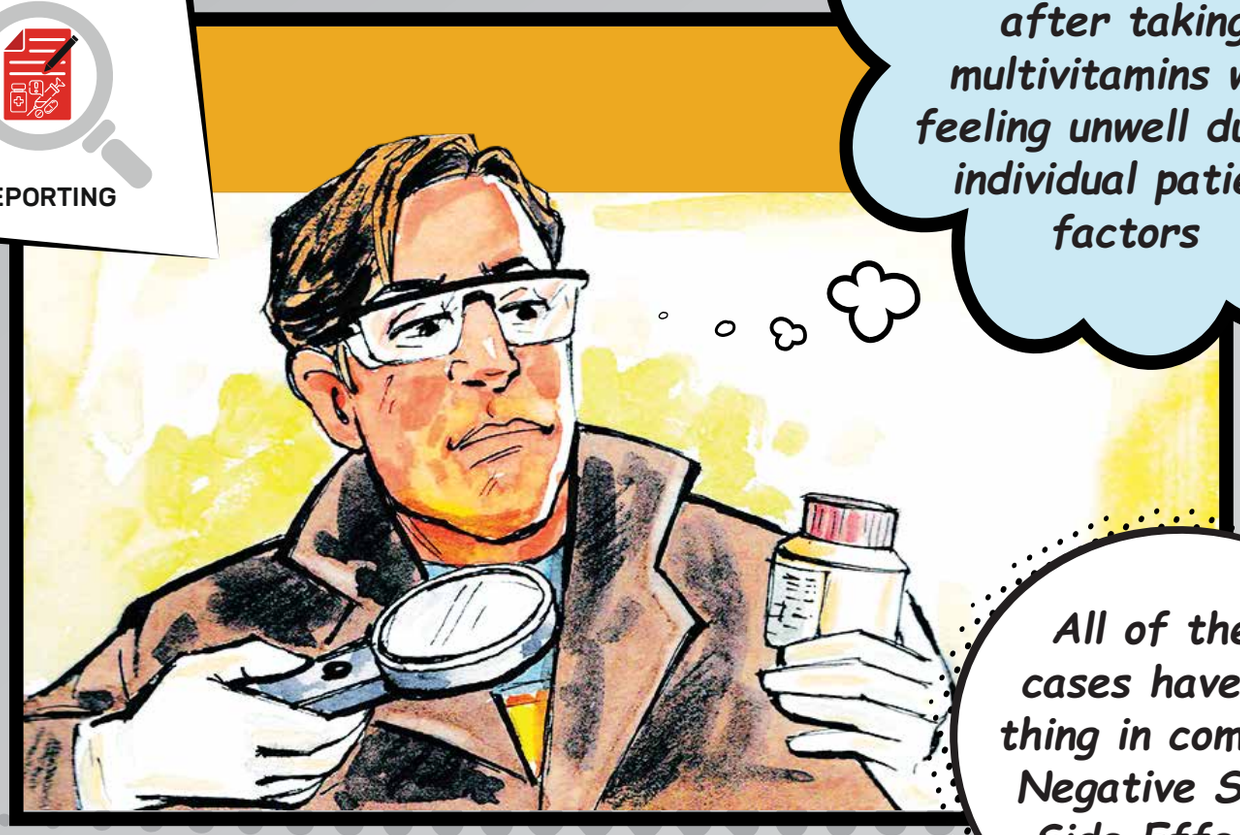
Negative reactions are taking over


Detective RRR enters the scene
Enough is Enough...
I WILL LOOK INTO
THE SITUATION
PAN INDIA


I AM DETECTIVE RRR
I Report, I'm Responsible and I'm Responsive
Time to Report! Time to identify Risk! Time to Respond!


The singer was a victim of unrecognized pharmacological effects of the drug
The old lady was feeling a bit off because of medication errors
The small kid started to react differently to the syrup due to drug-food interactions

REPORTING


The pregnant woman after taking multivitamins was feeling unwell due to individual patient factors


All of these cases have one thing in common... Negative Scary Side Effects!!


I am afraid, it must be Mednos. I can't undo the side effects experienced by the patients... But I can save them and all future case by being a Pharmacovigilante.

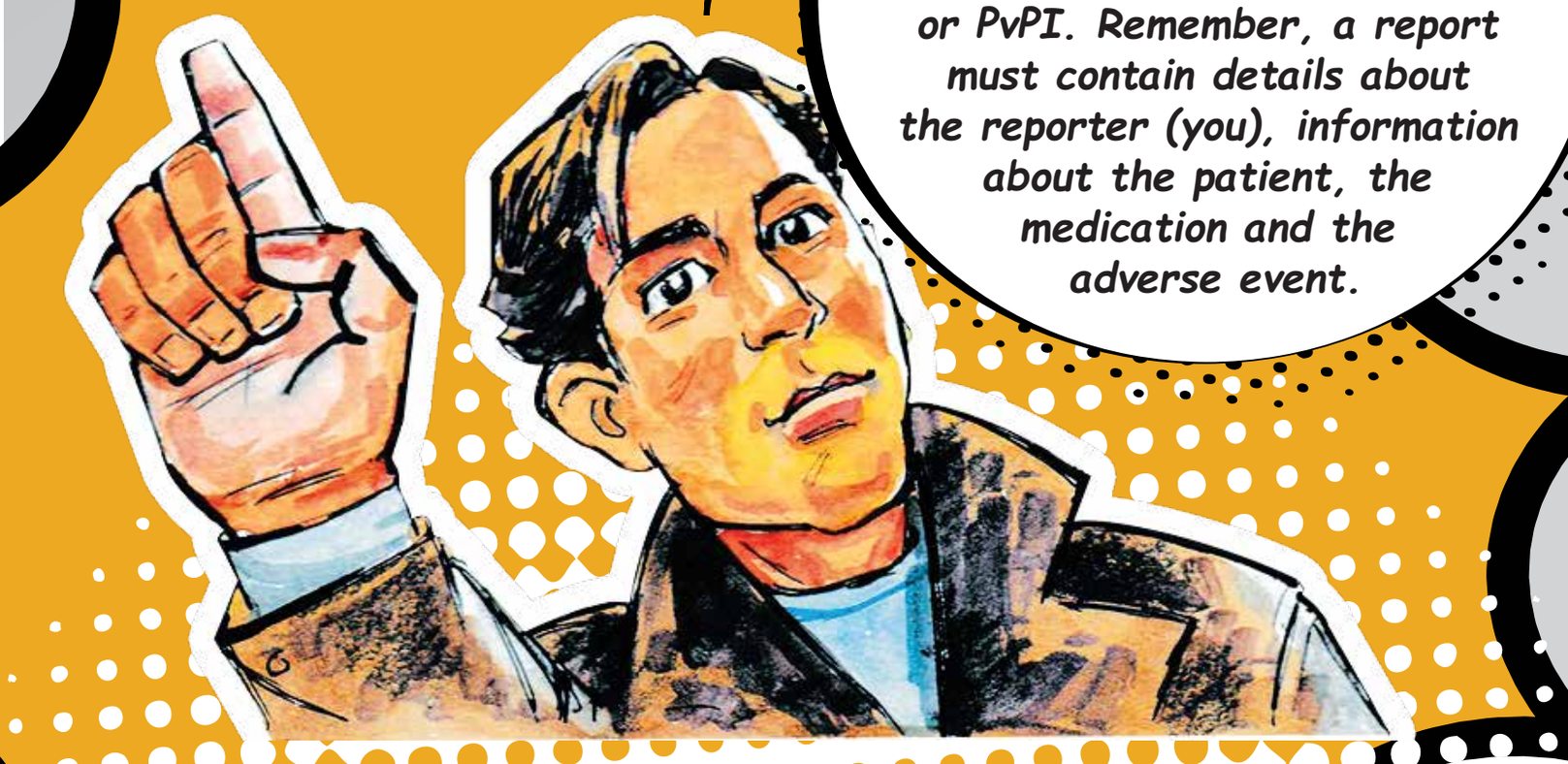
TAKE 3 SIMPLE STEPS
in Pharmacovigilance

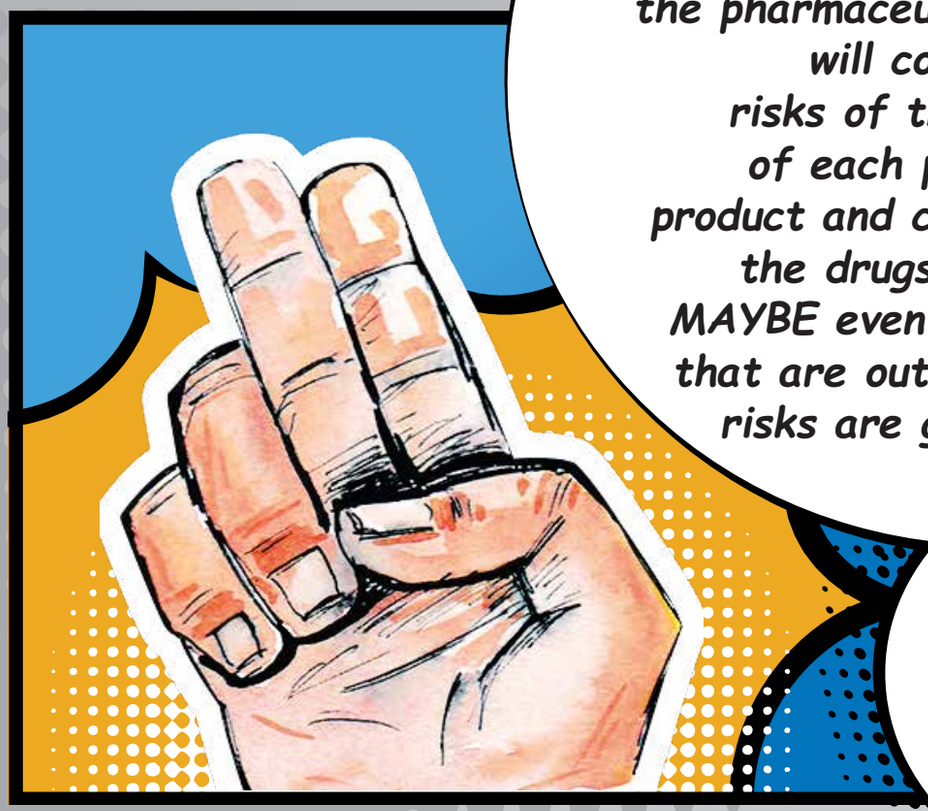
WHAT IS PHARMACOVIGILANCE?

Well, its an important function for health authorities and pharmaceutical organization that deals in collection of side effect information, analysing data and communication of product related updates to the end users and thereby building the safety profile of the medicine. How can you achieve it?

1ST REPORT...

Report the side effect experienced, after taking the medications, to the pharmaceutical Firm or PvPI. Remember, a report must contain details about the reporter (you), information about the patient, the medication and the adverse event.





2ND IDENTIFY RISKS

Based on your feedback, the pharmaceutical company/PvPI will correlate the risks of the side effects of each pharmaceutical product and can further improve the drugs accordingly – MAYBE even withdraw batches that are out in the market if risks are grave in nature.

This way we can maximize effectiveness and minimize the risks

3RD RESPOND

The pharmaceutical company/PvPI will connect back with you for follow-up information on the adverse events you reported. Be responsive to the follow-up attempts made by them; take a few minutes to help pharma companies develop even better solutions for you and all other patients.

Detective RRR locates the farmhouse and gets a hold of Mednos

RESPONSIVE

Mednos sizzles and crumbles into a heap


Crowd cheering
RESPONSIBLE
RRR!
RRR!
RRR!
RRR!
RRR!
RRR!
RRR
RRR
The singer, the old lady, the kid and the pregnant woman come to life and join in the cheering.

What is an Adverse Event?

An adverse event or "AE" is any untoward medical occurrence in a patient after administration of a medicinal product, which may or may not have been caused by that medicine.

Reporting Criteria and Patient safety

What special situations occurring in association with a medical product should trigger a report?

- Abnormal lab results
- AEs occurring from drug withdrawal or drug interactions
- Drug abuse or misuse, with or without event
- Overdose, intentionally or accidentally, with or without event
- Error in drug treatment process (medication error), with or without event
- Off-label use, with or without event
- Lack of efficacy
- Occupational exposure
- Drug exposure during pregnancy and lactation, with or without AE
- Adverse events occurring in breastfeeding infants
- Transmission of infectious agents
- Unexpected benefit

Version 1.0
संस्करण 1.0

MEDICINES SIDE EFFECT REPORTING FORM (FOR CONSUMERS)

औषधि दुष्प्रभाव सूचना फॉर्म (उपभोक्ताओं के लिए)

Indian Pharmacopoeia Commission, National Coordination Centre- Pharmacovigilance Programme of India, Ministry of Health & Family Welfare, Government of India.

भारतीय भेषज संहिता आयोग, राष्ट्रीय समन्वय केंद्र – भारतीय फार्माकोविजिलेंस कार्यक्रम,
स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार।

1.Patient Details/ रोगी का विवरण

Patient Initials/ रोगी के आद्याक्षर: ☐☐	Gender/ लिंग (√): Male/ पुरुष ☐ Female/ स्त्री ☐ Other/ अन्य ☐	Age (Year or Month)/ आयु (वर्ष या माह) :

2. Health Information/ स्वास्थ्य संबंधी जानकारी

a. Reason(s) for taking medicine(s)(Disease/Symptoms)/ दवा(दवाएं) लेने का कारण (रोग / लक्षण):

b. Medicines Advised by/ दवाई की सलाह देने वाला (√): Doctor/ डॉक्टर ☐ Pharmacist/ फॉर्मासिस्ट ☐ Friends/Relatives/ मित्र / रिश्तेदार ☐
Self (Past disease experienced/No past disease experienced)/ स्वयं (पूर्व बीमारी का अनुभव / पूर्व बीमारी का कोई अनुभव नहीं) ☐

3. Details of Person Reporting the Side Effect/ दुष्प्रभाव की सूचना देने वाले व्यक्ति का विवरण

Name (Optional)/ नाम (वैकल्पिक):

Address/ पता:

Telephone No/ टेलीफोन नं:	Email/ ईमेल:

4. Details of Medicine Taking/Taken/ ली जा रही है / ली जा चुकी दवाई का विवरण

Name of Medicines/ दवाइयों के नाम	Quantity of Medicines taken (e.g. 250 mg, Two times a day)/ ली गई दवाई की मात्रा (उदाहरण के लिए 250 मिग्रा, एक दिन में दो बार)	Expiry Date of Medicines/ दवा के निष्क्रिय होने की तिथि	Date of Start of Medicines/ दवाइयां आरंभ करने की तिथि	Date of Stop of Medicines/ दवाइयां रोकने की तिथि
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy
			dd/mm/yy	dd/mm/yy

Dosage form/खुराक का स्वरूप(√) : Tablet/ गोली (टेबलेट) ☐ Capsule/ कैप्सूल ☐ Injection/ इंजेक्शन ☐ Oral Liquids/ मौखिक तरल ☐ If Others (Please Specify.....)/यदि अन्य (कृपया निर्दिष्ट करें.....)

5. About the Side Effect/ दुष्प्रभाव के बारे में

When did the side effect start?/ दुष्प्रभाव की शुरूआत कब हुई थी? dd/mm/yy Side Effect is still Continuing (Yes/No)/

When did the side effect stop?/ दुष्प्रभाव कब समाप्त हुआ था? dd/mm/yy क्या दुष्प्रभाव जारी है (हां / नहीं): dd/mm/yy

6.How bad was the Side Effect? (Please √ the boxes that Apply)/ दुष्प्रभाव कितने हानिकाकर थे? (कृपया जो लागू हो, उस पर √ का निशान लगाएं)

☐ Did not affect daily activities/ दैनिक गतिविधिया प्रभावित नही हुई थी	☐ Affect daily activities/ दैनिक गतिविधिया प्रभावित हुई
☐ Admitted to hospital/ अस्पताल ले जाना पड़ा	☐ Death/ मृत्यु
☐ Others/ अन्य	

7.Describe the Side Effect (What did you do to manage the side effect?)/ दुष्प्रभाव की व्याख्या करें (आपने दुष्प्रभावों से छुटकारा प्राप्त करने के लिए क्या किया)?

This reporting is voluntary, has no legal implication and aims to improve patient safety. Your active participation is valuable. The information provided in this form will be forwarded to ADR Monitoring Centre for follow-up. You are requested to cooperate with the programme officials when they contact you for more details. Please do report even if you do not have all the information.

यह रिपोर्टिंग स्वैच्छिक है, कोई कानूनी निहितार्थ नही है और इसका लक्ष्य मरीज की सुरक्षा मे सुधार करना है। आपकी सक्रिय भागीदारी मूल्यवान है। इस फॉर्म मे दी गई जानकारी की अनुवर्ती कार्रवाई हेतु एडीआर निगरानी केंद्र को भेजा जाएगा। आपसे अनुरोध है कि आप कार्यक्रम के अधिकारियों का सहयोग करे जब वे अधिक जानकारी प्राप्त करने के लिए आपसे संपर्क करे। कृपया पूर्ण जानकारी न होने पर भी सूचित करें।

Please turn the page to read the instructions
निर्देशो को पढ़ने के लिए कृपया पेज पलटें

Version-1.3

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For VOLUNTARY reporting of Adverse Drug Reaction by Healthcare Professionals

INDIAN PHARMACOPOEIA COMMISSION(National Coordination Centre-Pharmacovigilance Programme of India)
Ministry of Health & Family Welfare, Government of India Sector-23, Raj Nagar, Ghaziabad-201002

A. PATIENT INFORMATION

1. Patient Initials _____	2. Age at the time of Event or Date of Birth _____	3. M ☐ F ☐ Other ☐	Reg. No. /IPD No. /OPD No. /CR No. :
		4. Weight_____Kgs	AMC Report No. :
			Worldwide Unique No. :

B. SUSPECTED ADVERSE REACTION

5. Event/Reaction start date (dd/mm/yyyy)

6. Event/Reaction stop date (dd/mm/yyyy)

6 (A). Onset Lag Time

7. Describe Event/Reaction with treatment details, if any

12. Relevant tests/ laboratory data with dates

13. Relevant medical/medication history (e.g. allergies, race, pregnancy, smoking, alcohol use, hepatic/renal dysfunction, past surgery etc.)

14. Seriousness of the reaction: No ☐ if Yes ☐(please tick anyone)

☐ Death (dd/mm/yyyy) ☐ Congenital-anomaly
☐ Life threatening ☐ Disability
☐Hospitalization/Prolonged ☐ Other Medically important

15. Outcomes

☐ Recovered ☐ Recovering ☐ Not recovered
☐ Fatal ☐ Recovered with sequelae ☐ Unknown

C. SUSPECTED MEDICATION(S)

S.No	8. Name (Brand/Generic)	Manufacturer (if known)	Batch No. / Lot No.	Exp. Date (if known)	Dose used	Route used	Frequency (OD, BD etc.)	Therapy dates		Indication	Causality Assessment
								Date started	Date stopped		
i											
ii											
iii											
iv*											

S.No as per C	9. Action Taken (please tick)						10. Reaction reappeared after reintroduction (please tick)			
	Drug withdrawn	Dose increased	Dose reduced	Dose not changed	Not applicable	Unknown	Yes	No	Effect unknown	Dose (if reintroduced
i										
ii										
iii										
iv										

11. Concomitant medical product including self-medication and herbal remedies with therapy dates (Exclude those used to treat reaction)

S.No	Name (Brand/Generic)	Dose used	Route used	Frequency (OD, BD, etc.)	Therapy dates		Indication
					Date started	Date stopped	
i							
ii							
iii*							

Additional Information:

D. REPORTER DETAILS

16. Name and Professional Address:_____
_____
Pin:_____E-mail_____
Tel. No. (with STD code)_____
Occupation:_____ Signature:_____

17. Date of this report (dd/mm/yyyy):

Sig. and Name of Receiver-

Confidentiality: The patient's identity is held in strict confidence and protected to the fullest extent. Submission of a report does not constitute an admission that medical personnel or manufacturer or the product caused or contributed to the reaction. Submission of an ADR report does not have any legal implication on the reporter.

Be Vigilant... and Report ADR...!!

What are ADRs?

Any adverse/harmful reaction *(e.g.: Itching, Rash, Vomiting, Diarrhea etc.)* that is caused after taking any medicine at therapeutic dose. Sometime ADR could be serious so be vigilant to report it.

Role of patients reporting in Pharmacovigilance

Patients can provide first hand information on the adverse reactions experienced by them after taking medicine. They helps in early detection of ADRs and provide crucial information that can help taking regulatory actions.

If you suspect/ experience any adverse drug reaction, report it through the following:-

NEAREST ADR MONITORING CENTRES
Available on: www.ipc.gov.in

ADR PvPI MOBILE APPLICATION
Available on: Google Play Store

ADR REPORTING FORM
Available on: www.ipc.gov.in

TOLL FREE
1800 180 3024
Available from: Monday to Friday (9:00 AM to 5:30 PM)

Let's join hands with PvPI for patient safety

Issued in Public Interest

National Coordination Centre - Pharmacovigilance Programme of India

A WHO Collaborating Centre for Pharmacovigilance in Public Health Programmes and Regulatory Services

Indian Pharmacopoeia Commission, Ministry of Health & Family Welfare, Government of India

Sector-23, Raj Nagar, Ghaziabad-201002

Email: pvpi.ipc@gov.in Website: www.ipc.gov.in

सत्यमेव जयते

IPC

Indian Pharmacopoeia Commission
National Coordination Centre
Pharmacovigilance Programme of India
Ministry of Health & Family Welfare, Govt. of India
Sector-23, Raj Nagar, Ghaziabad-201002
Tel. : 0120-2783400, Extn.-155

For any relevant Information/Suggestions/Query

Please Contact: Officer-in-Charge, Pharmacovigilance Programme of India

Email: pvpi.ipc@gov.in, lab.ipc@gov.in website: www.ipc.gov.in