SIDE EFFECT REPORTING FORM FOR PATIENTS & CONSUMERS

ALL PERSONAL INFORMATION WILL REMAIN CONFIDENTIAL

General Instructions

Please complete as much information as possible.

An electronic version of this report form can be downloaded from: *www.medicinesauthority.gov.mt/adrportal*

The form can by sent free post [no stamp required] to the Medicines Authority. Fold, staple and post this form.
Alternatively, the form can be submitted electronically to Post Licensing at Medicines Authority: postlicensing.medicinesauthority@gov.mt
[Filled in using ink and scanned / filled in MS Word]

Who experienced the side effect?

You ☐ Your child ☐
Someone else ☐

Please confirm if the side effect occurred in Malta

Yes ☐ No ☐

Contact e-mail of person reporting (to be used for acknowledgment and follow-up)

Date of this report
(Date when this form was filled)

DD	/	MM	/	YYYY

Patient Details - Information about the person who experienced the side effect
(Supply as much information as you can, all personal information will remain confidential)

Initials	Gender	Age (in years, at time of reaction)	Weight (in kg, at the time of reaction)	Ethnicity	Is the patient pregnant?
	Male ☐ **Female** ☐				Yes ☐ No ☐ Unknown ☐ N/A ☐

Suspect Medicine / Vaccine Details
(Description of medicines / vaccines which you think are causing the side effect. You can report more than one)

Name of the medicine	Active Ingredient	Dosage (e.g., 25 mg, tablet)	Prescribed for	Date started DD / MM / YYYY	Date stopped DD / MM / YYYY	Medicine not stopped
						☐
						☐
						☐

Side Effect(s) Details

Description of side effect(s) and how it happened. You can list more than one side effect.	Date started DD / MM / YYYY	Date stopped DD / MM / YYYY	Side Effect ongoing?
Side effect 1:			☐
Side effect 2:			☐
Side effect 3:			☐

Other Medicines being taken [Not suspected to have caused the side effect]
(including over the counter or prescription medicinal products or supplements which were being taken regularly or irregularly during the past 3 months).

Name of the medicine	Active Ingredient	Dosage (e.g., 25 mg, tablet)	Prescribed for	Date started DD / MM / YYYY	Date stopped DD / MM / YYYY	Medicine not stopped
						☐
						☐
						☐

☐ **No other medicines taken.**

How serious do you consider this reaction?
Please let us know how severely you, or the patient you are reporting about, were affected by the side effect / negative reaction(s):

	Not serious	Caused permanent disability or incapacity	Caused or prolonged hospitalization	Caused a Birth defect	Life threatening	Caused Death / Was Fatal
Side effect 1	☐	☐	☐	☐	☐	☐
Side effect 2	☐	☐	☐	☐	☐	☐
Side effect 3	☐	☐	☐	☐	☐	☐

Outcome of reaction at the time of the report (Tick the most appropriate box)

	Side effect 1	Side effect 2	Side effect 3
The patient recovered without long term effects	☐	☐	☐
The patient is currently recovering from the side effect experienced	☐	☐	☐
The patient is currently still experiencing the side effect	☐	☐	☐
The patient recovered but expereinced long term effects	☐	☐	☐
The patient died from the side effect	☐	☐	☐
The outcome of the side effect on the patient is unknown	☐	☐	☐

Further details on this side effect report (Tick the most appropriate box)

	Yes	No
Was the suspect medicine stopped because of the reaction?	☐	☐
Did the reaction stop or improve after the suspect medicine was stopped?	☐	☐
Was the suspect medicine restarted after it was stopped?	☐	☐
Did the patient experience the same reaction again after restarting the suspect medicine?	☐	☐
Has the manufacturer been notified of the side-effect?	☐	☐
Is this the first time that you reported this side-effect?	☐	☐
Was treatment required for this side-effect?	☐	☐

If yes, please describe:

Any other relevant medical information about the patient?
(For example, does the patient have any underlying medical conditions or allergies? Underlying medical conditions could include liver or kidney disease, heart problems, diabetes, high cholesterol etc…)

☐ **No relevant medical conditions or allergies to report.**

Anything else that you wish to add to this report to better describe the reaction(s)?
(Use this to box to add any other information which you feel is relevant. For example, a more complete description of the sequence of events, any treatment received, similar past reactions, diagnostic lab tests carried out, or any other relevant information).

☐ **I have nothing else to add.**

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by the Licensee

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necessary if posted
in Malta and Gozo

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