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BIO-MED
PRIVATE LIMITED

VACCINE SIDE EFFECT REPORTING FORM

Patient details

Patient name: **Gender:** **Age:**

Health information

Reason of the taking Drug/Vaccine (disease/symptoms) :

Drug/ Vaccine advised by : Doctor □ **Pharmacist □** **Friend□** **Self□**

Details of the Person reporting the Side Effects :

Name :

Address :

Telephone : Email :

Details of vaccine taken :

Name of Drug/vaccine (write vaccine & diluent details in separate rows)	Quantity taken & dose no. (zero/ first/ second etc. As applicable)	Name of manufacturer	Batch/ lot no.	Expiry date	Date of Administration/vaccination

Dosage form : Liquid □ /Oral Liquid □ Other □

About the side effect :

When did the Side Effect start ? [ ] Side effect is still continuing (Yes/No)

When did the Side Effect stop ? [ ]

Relationship to Drug/Vaccine: 1 = Not related, 2 = Unlikely, 3 = Possible, 4 = Probably, 5 = Definitely, 6 = Not Assessable.

Other Drug/Vaccine administered at the same time? No□ Yes□ if yes, specify below.

Vaccine	Manufacturer	Batch No.	Route/Site	No. of previous Doses

Kindly mark all the side effects in appropriate boxes .Please use this form for the side effects occurred from the date of administration /vaccination.

S. No	Parameter	Grade	DAY Details after administration/vaccination of Drug/vaccine	Date of resolution & Relationship to drug/vaccine

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Local adverse events (at the injection site)										
1	**Pain**	**None**	☐	☐	☐	☐	☐	☐	☐	
		Mild	☐	☐	☐	☐	☐	☐	☐	
		Moderate	☐	☐	☐	☐	☐	☐	☐	
		Severe	☐	☐	☐	☐	☐	☐	☐	
None: Absent; **Mild**: Minor reaction to touch; **Moderate**: Painful to touch; **Severe**: Spontaneously painful										
2	**Pruritus/Itching**	**None**	☐	☐	☐	☐	☐	☐	☐	
		Mild	☐	☐	☐	☐	☐	☐	☐	
		Moderate	☐	☐	☐	☐	☐	☐	☐	
		Severe	☐	☐	☐	☐	☐	☐	☐	
None: Absent; **Mild:** Itching localized to injection site and relieved spontaneously or within <48 hours of treatment; **Moderate:** Itching beyond injection site, not generalized or localized and requiring >48 hours of treatment; **Severe:** itching causing inability to perform usual social & functional activities										
3	**Fever**	**None**	☐	☐	☐	☐	☐	☐	☐	
		Mild	☐	☐	☐	☐	☐	☐	☐	
		Moderate	☐	☐	☐	☐	☐	☐	☐	
		Severe	☐	☐	☐	☐	☐	☐	☐	
		Life Threatening	☐	☐	☐	☐	☐	☐	☐	
None: Absent; **Mild:**38.0 – 38.4°C (100.4 – 101.1°F); **Moderate:** 38.5 -38.9°C (101.2 – 102.0°F); **Severe:** 39 - 40°C (102.1 - 104°F); **Life Threatening:** >40°C (>104°F)										
4	**Redness**	**None**	☐	☐	☐	☐	☐	☐	☐	
		Mild	☐	☐	☐	☐	☐	☐	☐	
		Moderate	☐	☐	☐	☐	☐	☐	☐	
		Severe	☐	☐	☐	☐	☐	☐	☐	
None: Absent; **Mild**: Localized skin erruption; **Moderate**: Diffuse skin eruption from body surface area ; **Severe**: Generalized skin erruption involving >50% from the body surface area.										
5	**Headache**	**None**	☐	☐	☐	☐	☐	☐	☐	
		Mild	☐	☐	☐	☐	☐	☐	☐	
		Moderate	☐	☐	☐	☐	☐	☐	☐	
		Severe	☐	☐	☐	☐	☐	☐	☐	
None: Absent; **Mild**: No interference with daily activity; **Moderate**: Some interference with daily activity; **Severe**: Significant interference and prevents daily activity (Non Bearable).										
Other than mentioned above (Please specify)										

Describe treatment used (if any) for any of the above reported events (brand/ generic name of medications and the course of treatments):

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*Outcome measures: 1 = Recovered, 2 = Recovered with sequelae, 3 = Event continuing without treatment, 4 = Event continuing and controlled with treatment, 5 = Event continuing and not controlled with treatment, 6 = Unknown ,7 =Death

Reporter Name:-
Signature and date:____

Reviewed by : ____
Signature and date
(Pharmacovigilance Department)

Remarks : ____

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