Baxter ADVERSE EVENT REPORTING FORM-PERITONEAL DIALYSIS SOLUTIONS

IMPORTANT: ***ALWAYS REPORT THE BATCH NUMBER OF THE PD SOLUTIONS USED***

REPORTER INFORMATION

Reporter Name: _____ **Date of Report:** _____

Reporter Contact Information: _____

☐ **Healthcare professional (please specify):** ☐ **Physician** ☐ **Nurse** ☐ **Pharmacist**

☐ **Other (please specify):** _____

PATIENT INFORMATION

Patient identification (initials): _____ **Date of birth/Age:** _____ **Gender:** ☐ **Male** ☐ **Female**

Past Medical History:

☐ End Stage Renal Disease	☐ Heart failure
☐ Hypertension (high blood pressure)	☐ Heart attack (Myocardial infarction)
☐ Diabetes	☐ Stroke
☐ Heart disease	☐ Pneumonia
☐ Previous episode of peritonitis	
Other (please specify)	

PRODUCT INFORMATION/PD REGIMEN – ***PLEASE PROVIDE ALL BATCH NUMBERS FOR PRODUCTS USED***

Start date of PD regimen below: _____ **Modality:** ☐ **CAPD** ☐ **APD** ☐ **Unknown**

PD Solution Used	Batch Numbers Used	Date Use of this Batch Number Started	Do you suspect this PD solution caused the event?	Were any of the solutions stopped due to peritonitis?
			☐ Yes ☐ No	☐ Yes ☐ No ☐ Unknown
			☐ Yes ☐ No	☐ Yes ☐ No ☐ Unknown
			☐ Yes ☐ No	☐ Yes ☐ No ☐ Unknown
			☐ Yes ☐ No	☐ Yes ☐ No ☐ Unknown
			☐ Yes ☐ No	☐ Yes ☐ No ☐ Unknown

EVENT INFORMATION

Date of event: _____ ☐ **Sterile Peritonitis** ☐ **Bacterial Peritonitis** ☐ **Fungal Peritonitis** ☐ **Cloudy Effluent**

☐ **Other event, please specify:** _____

Description of the Event(s): _____

_____

_____

If the event was peritonitis:
What was the root cause?

☐ Break in aseptic technique, please specify:
☐ Unknown
☐ Other (please specify):

Baxter

Was the patient hospitalized due to the event? ☐ Yes ☐ No If yes, please specify: From: _____ To: _____

Did the patient improve specifically with discontinuation of PD solution? ☐ Yes ☐ No ☐ Unknown
If yes, please specify PD solution? _____

Was the PD solution reintroduced? ☐ Yes ☐ No ☐ Unknown If yes, please specify PD solution? _____
If yes did the peritonitis recur with reintroduction of the PD solution? ☐ Yes ☐ No ☐ Unknown

What was the severity of event? ☐Mild ☐ Moderate ☐ Severe
Please describe further_____
_____

OUTCOME

☐ Recovered Recovery date:_____	☐ Ongoing and deteriorated
☐ Recovered with sequelae	☐ Fatal
☐ Ongoing and improved	☐ Unknown
☐ Ongoing and unchanged	

RELEVANT TESTS/LABORATORY DATA IF THE EVENT WAS PERITONITIS

Date of sampling: dd/mm/year				
Was the sample taken before starting antibiotics	☐ Yes ☐ No ☐ Unknown		☐ Yes ☐ No ☐Unknown	
		Unit		Unit
Leucocytes count		cells/mm^3		cells/mm^3
Neutrophils		%		%
Lymphocytes Eosinophils		%		%
Monocytes		%		%
Eosinophils		%		%
Basophils		%		%

Date of culture: _____

Culture results: ☐ No Growth ☐ Positive culture, please specify organism_____

Any further relevant labs? ☐ Yes (if yes please attach) ☐ No ☐ Unknown

REMEDIAL TREATMENT

Was the patient treated? ☐ Yes (if yes, please specify) ☐ No ☐ Unknown

Treatment Drug Name	Dose / Unit	Frequency	Admin rate	Start date / time	End Date / Time	Indication

Any further treatment? ☐ Yes (if yes please attach) ☐ No ☐ Unknown

CONCOMITANT MEDICATION

Was your patient on any concomitant medication? ☐ Yes (please attach) ☐ No ☐ Unknown

Additional Comments:
_____
_____
_____
_____