Adverse Reaction Report Form

For suspected side effects, lack of effect, medication errors, overdose or quality problems with any Draxer product. Healthcare professionals, Draxer staff, patients and carers may all use this form. You do not need to be certain that the product caused the reaction.

How to send it. Fill this form on your phone or computer, save it, and email it to draxersafety@gmail.com or send it by WhatsApp to +233 55 711 6113. Serious reactions (see C6) should reach us within 24 hours so that Draxer can report to the FDA within the 7-day limit.
Minimum for a first report: an identifiable patient (A), a suspected product (B), a reaction (C) and a reporter (E). Send what you have; we will follow up for the rest.

A. Patient

A1 Initials | **A2** Age (years) or date of birth | **A3** Weight (kg) | **A4** Health facility / pharmacy

A5 Folder or ID number | **A6** Patient or carer phone | **A7** Patient or carer email (optional)

A8 Sex: ☐ Female ☐ Male

A9 Pregnancy: ☐ Not applicable ☐ Pregnant ☐ Breastfeeding ☐ Unknown

A10 Relevant medical history and known allergies

B. Suspected product(s)

Enter the Draxer product as B1. If a second medicine is also suspected, use B2.

	Product (brand name)	Active ingredient and strength	Batch / lot no.	Expiry	Dose and frequency	Route
B1						
B2						

	Date started	Date stopped	Reason for use (indication)	Bought from (pharmacy / online)
B1				
B2				

C. Adverse reaction

C1 Description of the reaction (what happened, how severe, signs, test results)

C2 Date reaction started | **C3** Date reaction stopped | **C4** Treatment given for the reaction

C5 Reaction still ongoing? ☐ Yes ☐ No

C6 Seriousness (tick all that apply): ☐ Not serious ☐ Death ☐ Life-threatening ☐ Hospitalised / stay prolonged ☐ Persistent or significant disability ☐ Congenital anomaly ☐ Other medically important

C7 Outcome: ☐ Recovered ☐ Recovering ☐ Not recovered ☐ Recovered, after-effects ☐ Fatal ☐ Unknown

C8 Product stopped (dechallenge): ☐ Yes, improved ☐ Yes, no change ☐ Not stopped ☐ Unknown

C9 Product restarted (rechallenge): ☐ Yes, recurred ☐ Yes, no recurrence ☐ Not restarted ☐ Unknown

C10 Type of report: ☐ Side effect ☐ Lack of effect ☐ Medication error ☐ Overdose ☐ Product quality problem ☐ Exposure in pregnancy or breastfeeding

D. Other medicines taken in the last three months

Include supplements, herbal and traditional remedies. Write "none" in D1 if there are none.

	Name and strength	Dose and frequency	Route	Date started	Date stopped	Reason for use
D1						
D2						
D3						
D4						

E. Reporter

E1 I am a: ☐ Pharmacist ☐ Doctor ☐ Nurse / midwife ☐ Other health worker ☐ Draxer staff member ☐ Patient ☐ Carer / relative

E2 Full name

E3 Profession and facility

E4 Phone

E5 Email

E6 Postal address

E7 Date of report

E8 Signature (type your name)

E9 May Draxer contact you for follow-up? ☐ Yes ☐ No

E10 Has this reaction also been reported to the FDA Ghana? ☐ Yes ☐ No ☐ Not sure

Draxer Therapeutics Ltd uses this information to monitor the safety of its products and will share it with the Food and Drugs Authority, Ghana, where required. Personal data is handled under the Data Protection Act, 2012 (Act 843). The identities of the reporter and the patient are not disclosed outside the FDA.

F. For Draxer Patient Safety Office use only

F1 Draxer reference (DRX-)

F2 Date received (Day 0)

F3 Received by

F4 Received via (web, email, WhatsApp, phone, paper)

F5 Serious? (Y / N)

F6 Expected? (Y / N)

F7 Reported to FDA on

F8 FDA / E2B case number

F9 Follow-up required? (Y / N, date)

F10 Case closed on

F11 QPPV signature