

Individual Case Safety Report Narrative

Case narrative, postmarketing safety report | Marked-up specimen

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A case narrative rewritten from the order information arrived into the order the patient experienced.

ORIGINAL, WITH EDITS MARKED

SPECIMEN, PREPARED BY EDITFAST FOR ILLUSTRATION. NOT A REAL RECORD.

CASE NARRATIVE (draft) - Calder Therapeutics (fictitious) - Product: sertivane tablets

Case received 14/03/26 from pharmacist. Pt reported SOB and CP². Hx of HTN.¹ Reporter did not provide pt identifier at intake.⁴

F/U 20/03/26: pharmacist confirms pt is 62 yo F, adm. to hosp. 12/03/26, d/c 15/03/26³. Drug started 02/03/26, 10 mg BID. Conmeds: amlodipine.

F/U 02/04/26: pt recovered, no sequelae reported.⁵ Pharmacy fax of 14/03/26 on file.

WHAT CHANGED, AND WHY

#	Was	Now	Reason
1	Case received 14/03/26 from pharmacist. Pt reported SOB and CP. Hx of HTN.	The patient is a 62-year-old woman with a history of hypertension.	The draft opens on the day the report arrived. The guidance asks for the chronology of the patient's experience, which begins with the history and the medication rather than with the phone call.
2	SOB and CP	shortness of breath and chest pain	Abbreviations are to be avoided outside laboratory parameters and units. A narrative that has to stand alone cannot rely on a reader supplying them.
3	adm. to hosp. 12/03/26, d/c 15/03/26	admitted to the hospital on March 12, 2026, and discharged on March 15, 2026	Neither abbreviation is expanded anywhere in the narrative. An all-numeric date is read as March 12 in one country and as December 3 in another, and the narrative gives the reader no key.
4	Reporter did not provide pt identifier at intake.	Patient identifier CT-2026-0417 appears on the pharmacy fax dated March 14, 2026, which is the source document for this case.	The narrative recorded an absence at intake and was never revised when the source document arrived. The value was on the fax already on file.
5	F/U 02/04/26: pt recovered, no sequelae reported.	In a second follow-up on April 2, 2026 the pharmacist reported that the patient had recovered with no sequelae.	The guidance asks that new information in follow-up reports be clearly identified. A label of F/U with a date does not say who supplied what.