SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. INITIALS	1a. COUNTRY	2. DATE OF BIRTH			2a. AGE	3. SEX	4-6. REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION
		Day	Month	Year			Day	Month	Year	
PRIVACY					70 Year(s)	M	13	Apr	2025	☐ PATIENT DIED

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [Low Level Term]
ATRIAL FIBRILLATION [Atrial fibrillation] (10003658 v28.0) - Serious - Not recovered - 13-Apr-2025/UNK

☐ LIFE THREATENING
☐ HOSPITALIZATION
☐ DISABILITY OR INCAPACITY
☐ CONGENITAL ANOMALY/BIRTH DEFECT
■ OTHER MEDICALLY IMPORTANT CONDITION
☐ REQUIRED INTERVENTION (MEDICAL DEVICE)

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name)

#1 [Suspect] Omacor Capsule (Omega-3-acid ethyl esters 90)

20. DID REACTION ABATE AFTER STOPPING DRUG?
☐ YES ☐ NO ☐ NA

15. DAILY DOSE(S)	16. ROUTE(S) OF ADMINISTRATION
#1 1000 milligram	#1 Oral use

17. INDICATION(S) FOR USE

#1 HYPERTRIGLYCERIDEMIA [Hypertriglyceridemia] (10020870 v28.0)

21. DID REACTION REAPPEAR AFTER REINTRODUCTION ?
☐ YES ☐ NO ☐ NA

18. THERAPY DATES (from/to)	19. THERAPY DURATION
#1 24-Jul-2023	#1

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUGS(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)
#1 Solferol 1,000 IU Soft Capsules (COLECALCIFEROL) ; 25-Jul-2023; 1000 international unit .
#2 altavitaD3 (CHOLECALCIFEROL) ; 25-Jul-2023; 1000 international unit .
#3 ASPIRIN (GENERIC) (ACETYLSALICYLIC ACID) ; 01-Sep-2013; 75 milligram .

Continue on next page(s)

23. OTHER RELEVANT HISTORY (e.g. diagnostics, allergics, pregnancy with last month of period, etc.)

From / To Dates	Description
# 1	[Hypertension] (10020772 v28.0)
# 2	[Rheumatoid arthritis] (10039073 v28.0)

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER
BASF AS
P.O.Box 420
NO-1327 Lysaker NO

26. REMARKS
Version : 11

24b. MFR CONTROL NO.
IE-BASF-2025011702

25b. NAME AND ADDRESS OF REPORTER
PRIVACY

24c. DATE RECEIVED BY MANUFACTURER
06-May-2025

24d. REPORT SOURCE
☐ STUDY ☐ LITERATURE ■ AUTHORITY
■ HEALTH PROFESSIONAL ☐ OTHER

DATE OF THIS REPORT
07-May-2025

25a. REPORT TYPE
■ INITIAL ☐ FOLLOW UP :

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case description : This case was downloaded from Eurdravigilance on 6-May-2025 and contains no narrative.

Other case identifiers:
Eudravigilance number: IE-HPRA-2025-120480
Date initially received: 06-May-2025
Date received by BASF AS: 06-May-2025
Duplicate numbers : HMARR-000001307 (Boots), IE-HPRA-2025-120480 (HPRA).

14-19. Drugs

#	Name	Dosage Information	Lot/Batch	Route of Admin.	Indication	Therapy dates	Therapy duration
1	[Suspect] Omacor Capsule (Omega-3-acid ethyl esters 90)	1000 milligram	UNK	Oral use	HYPERTRIGLYCERIDEMIA [Hypertriglyceridemia] (10020870 v28.0)	24-Jul-2023	

22. CONCOMITANT DRUGS(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)

#	Name	Dosage Information	Lot/Batch	Route of Admin.	Indication	Therapy dates	Therapy duration
1	Solferol 1,000 IU Soft Capsules (COLECALCIFEROL)	1000 international unit	UNK	Oral use	VITAMIN D DEFICIENCY [Vitamin D deficiency] (10047626 v28.0)	25-Jul-2023	
2	altavitaD3 (CHOLECALCIFEROL)	1000 international unit	UNK	Oral use	VITAMIN D DEFICIENCY [Vitamin D deficiency] (10047626 v28.0)	25-Jul-2023	
3	ASPIRIN (GENERIC) (ACETYLSALICYLIC ACID)	75 milligram	UNK		[Drug use for unknown indication] (10057097 v28.0)	01-Sep-2013	
4	ATORVASTATIN (GENERIC) (ATORVASTATIN-CALCIUM)	400 milligram	UNK		HYPERCHOLESTEROLEMIA [Hypercholesterolemia] (10020604 v28.0)	21-Nov-2022	
5	Benepali (ETANERCEPT)	50 milligram every 1 week(s)	UNK	Subcutaneous use	RHEUMATOID ARTHRITIS [Rheumatoid arthritis] (10039073 v28.0)	23-Sep-2019	

23. OTHER RELEVANT HISTORY continued

3 [Hypercholesterolemia] (10020604 v28.0)

4 [Vitamin D deficiency] (10047626 v28.0)