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	KR				71 Year(s)	M	17	Sep	2024	☐ PATIENT DIED

7+13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [Low Level Term]

Itching [Itching] (10023084 v28.0) - Serious - Recovered - 17-Sep-2024/17-Sep-2024

Urticaria [Urticaria] (10046735 v28.0) - Serious - Recovered - 17-Sep-2024/17-Sep-2024

Rash [Rash] (10037844 v28.0) - Serious - Recovered - 17-Sep-2024/17-Sep-2024

Dyspnea [Dyspnea] (10013963 v28.0) - Serious - Recovered - 17-Sep-2024/17-Sep-2024

Neck discomfort [Neck discomfort] (10028831 v28.0) - Serious - Recovered - 17-Sep-2024/17-Sep-2024

Nasal congestion [Nasal congestion] (10028735 v28.0) - Serious - Recovered - 17-Sep-2024/17-Sep-2024

☐ 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 (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 every 1 day(s)	#1 Oral use

17. INDICATION(S) FOR USE

#1 [Anaphylactic shock] (10002199 v28.0)

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

18. THERAPY DATES (from/to)	19. THERAPY DURATION
#1 17-Sep-2024/17-Sep-2024	#1

III. CONCOMITANT DRUG(S) AND HISTORY

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

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

From / To Dates	Description
# 1 17-Sep-2024 / 17-Sep-2024	[Anaphylactic shock] (10002199 v28.0)

IV. MANUFACTURER INFORMATION

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

26. REMARKS
Version : 10

24b. MFR CONTROL NO.
KR-BASF-2025011708

25b. NAME AND ADDRESS OF REPORTER
PRIVACY

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

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

DATE OF THIS REPORT
28-May-2025

25a. REPORT TYPE
■ INITIAL ☐ FOLLOW UP :

ADDITIONAL INFORMATION

7+13. DESCRIBE REACTION(S) continued

Case description : This is a case of Omacor Soft Capsule confirmed in the KAERS Database by the regulatory authority. (KAERS No. 2024001196669)

This case concerns a 71-year-old male patient from Korea who experienced multiple adverse events following the administration of Omacor soft capsule(Omega-3-Acid Ethyl Esters 90). On 17-Sep-2024, the patient took a dose of 1000 mg of Omacor orally but soon developed several symptoms including itching, urticaria, rash, dyspnea, neck discomfort, and nasal congestion. These symptoms were confirmed by a medical professional as medically important events.

The patient's medical history includes a previous episode of anaphylactic shock, which occurred on the same date as the reported adverse events. The patient had been prescribed Omacor for anaphylactic shock, which was discontinued following the adverse reactions. The causality assessment of the adverse events, as evaluated by the reporter, was deemed possible in relation to the suspected drug.

The adverse events were reported as having been resolved on the same day they occurred, with no further complications or recurrence noted.
This case was expedited for reporting due to the seriousness of the reactions and the potential risk to the patient.

Partner's sender's comments: This case was downloaded from KAERS DB on 20th May 2025, including data for the period of July 2024 to December 2024.

Other case identifiers:
Kuhnil number: KR-KUHNIL-KI00123-2025
Date initially received: 20-May-2025
Date received by BASF AS: 23-May-2025
SENDER'S COMMENT :

According to the information from the KAERS Database the patient (71 T woman) had an anaphylactic shock treated with Omacor and then developed a series of symptoms consistent with anaphylactic reactions that may be associated with anaphylactic shock. Omacor is not in good medical practice used for treatment of an acute condition like anaphylactic shock and the narrative is not likely correct. Unfortunately, It has not been possible to obtain further information. A more likely scenario is that the patient started on Omacor and then experienced the anaphylactic shock (event) and the other events. All the events can be causally related to Omacor.

Duplicate numbers : 2024001196669 (KAERS Number), KR-KUHNIL-KI00123-2025 (KUHNIL).

14-19. Drugs

#	Name	Dosage Information	Lot/Batch	Route of Admin.	Indication	Therapy dates	Therapy duration
1	[Suspect] Omacor (Omega-3-acid ethyl esters 90)	1000 milligram every 1 day(s)	UNK	Oral use	[Anaphylactic shock] (10002199 v28.0)	17-Sep-2024/17-Sep-2024	