

医疗产品警报 2026 年第 1 期

在世卫组织所有区域发现不合格的 **ACCUPAQUE**（碘海醇）、 **OMNIPAQUE**（碘海醇）和 **VISIPAQUE**（碘克沙醇）

警报摘要

本世卫组织医疗产品警报涉及多个批次的以 **100 毫升聚丙烯容器**包装的 ACCUPAQUE、OMNIPAQUE 和 VISIPAQUE 注射液。2026 年 3 月，爱尔兰卫生产品监管局（HPRA）向世卫组织通报，由 GE HealthCare Ireland Limited 生产的、以 ACCUPAQUE、OMNIPAQUE 和 VISIPAQUE 品牌销售的特定批次的碘化造影剂（碘海醇或碘克沙醇）存在一级质量缺陷。

该缺陷涉及聚丙烯瓶内表面附着或嵌入的金属颗粒物。在制造商确认的至少一起事件中，成品内存在游离的金属颗粒物。该质量缺陷仅影响 **100 毫升聚丙烯容器**盛放的多个批次的产品。玻璃容器盛放的批次不受影响。受影响批次的产品已供应全球多个国家，主要分销至医院（包括用于进行介入放射学、心脏病手术和血管外科手术的医疗机构）。

如何识别这些不合格产品

GE Healthcare Ireland Limited 提供的受影响产品和批次清单见本警报附件 1 和 2。

风险

这些产品是用于动脉内和静脉内注射的溶液。这些产品中的颗粒物构成安全风险，尤其是动脉内注射时，可导致严重不良事件，包括危及生命的栓塞事件。

污染概率可能较低，但在以下情况下存在较高风险：

- 未严格按照制造商产品说明书目视检查产品；
- 召回通知尚未送达机构；
- 由于无可用的替代造影剂，使用受影响产品。

为防止伤害患者，识别并停止临床使用受影响批次的 Accupaque、Omnipaque 和 Visipaque 很重要。

世卫组织全球伪劣医疗产品监测和监督系统

请访问：<https://www.who.int/health-topics/substandard-and-falsified-medical-products>，或发送电子邮件：rapidalert@who.int

对卫生保健专业人员、监管当局和公众的建议

世卫组织提醒国家监管当局和卫生保健专业人员注意，**100 毫升聚丙烯容器**供应的特定批次的 Accupaque、Omnipaque 和 Visipaque 碘化造影剂中可能有金属颗粒物。

国家监管当局应确认收到制造商通知和市场行动指示，并根据国家指南采取适当的监管和公共卫生行动。

世卫组织敦促卫生保健专业人员对可能与颗粒栓塞相关的不良事件保持警惕。

当固体颗粒意外进入血流并阻塞小血管，导致血流受损和缺血性损伤时，可能会发生[颗粒栓塞相关不良事件](#)。临床上，这可表现为呼吸窘迫、心血管或神经系统事件（如肺栓塞、心肌缺血、卒中）、炎症反应、终末器官损伤，或在严重情况下导致多器官衰竭或死亡。

如果您或您认识的人已使用或可能使用过这些产品，或使用后出现不良事件或意外副作用，请立即向卫生保健专业人员寻求医疗建议。

请通过国家系统和世卫组织全球监测和监督系统报告任何疑似缺陷或临床事件。如果您有这些产品，世卫组织建议您不要使用。

如果您有关于这些产品的任何信息，请通过 rapidalert@who.int 联系世卫组织。

附件 1：世卫组织医疗产品警报 2026 年第 1 期涉及的产品

产品	ACCUPAQUE (碘海醇)	OMNIPAQUE (碘海醇)	VISIPAQUE(碘克沙醇)
标注的制造商	GE Healthcare Ireland Limited		
受影响批号	见附件 2	见附件 2	见附件 2
有效期	见附件 2	见附件 2	见附件 2

附件 2 – 受影响产品和批次清单

产品	批号	有效期
26170256 OMNIPAQUE350 10x100PP	17253643	30-Jul-28
26180630 VISIPAQUE320 10x100PP	17244625	14-Aug-28
ACCUPAQUE 300 mg USB 1x100 ml	17333581	07-Nov-28
ACCUPAQUE 300 mg USB 10x100 ml	17321114	06-Aug-28
ACCUPAQUE 300 mg USB 10x100 ml	17270628	06-Aug-28
ACCUPAQUE 300 mg USB 10x100 ml	17329106	22-Oct-28
ACCUPAQUE 300 mg USB 10x100 ml	17334255	22-Oct-28
ACCUPAQUE 300 mg USB 10x100 ml	17356931	04-Sep-28
ACCUPAQUE 300 mg USB 10x100 ml	17356935	12-Oct-28
ACCUPAQUE 300 mg USB 10x100 ml	17366385	15-Nov-28
ACCUPAQUE 300 mg USB 10x100 ml	17370957	16-Nov-28
ACCUPAQUE 300 mg USB 10x100 ml	17298685	06-Aug-28
ACCUPAQUE 300 mg USB 10x100 ml	17333586	22-Oct-28
ACCUPAQUE 300 mg USB 10x100 ml	17366373	15-Nov-28
ACCUPAQUE 350 mg USB 10x100 ml	17089899	20-Jan-28
ACCUPAQUE 350 mg USB 10x100 ml	17260069	05-Aug-28
ACCUPAQUE 350 mg USB 10x100 ml	17302542	11-Aug-28
ACCUPAQUE 350 mg USB 10x100 ml	17302545	25-Jul-28
ACCUPAQUE 350 mg USB 10x100 ml	17370473	02-Dec-28
ACCUPAQUE 350 mg USB 10x100 ml	17370474	01-Dec-28
ACCUPAQUE 350 mg USB 10x100 ml	17238981	05-Aug-28
ACCUPAQUE 350 mg USB 10x100 ml	17312081	06-Aug-28
ACCUPAQUE 350 mg USB 10x100 ml	17318004	14-Oct-28
ACCUPAQUE 350 mg USB 10x100 ml	17340520	21-Oct-28
OMNIPAQUE 300 mg USB 1x100 ml	17339149	04-Sep-28
OMNIPAQUE 300 mg USB 1x100 ml	17359537	22-Oct-28
OMNIPAQUE 300 mg USB 1x100 ml	17271303	05-Aug-28
OMNIPAQUE 300 mg USB 10x100 ml	17334249	07-Sep-28
OMNIPAQUE 300 mg USB 10x100 ml	17350896	04-Sep-28

世卫组织全球伪劣医疗产品监测和监督系统

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OMNIPAQUE 300 mg USB 10x100 ml	17353261	22-Oct-28
OMNIPAQUE 300 mg USB 10x100 ml	17371056	30-Nov-28
OMNIPAQUE 300 mg USB 10x100 ml	17305242	31-Aug-28
OMNIPAQUE 300 mg USB 10x100 ml	17305243	30-Sep-28
OMNIPAQUE 300 mg USB 10x100 ml	17318263	31-Aug-28
OMNIPAQUE 300 mg USB 10x100 ml	17258864	04-Aug-28
OMNIPAQUE 300 mg USB 10x100 ml	17378212	13-Nov-28
OMNIPAQUE 300 mg USB 10x100 ml	17349041	13-Nov-28
OMNIPAQUE 300 mg USB 10x100 ml	17262273	04-Aug-28
OMNIPAQUE 300 mg USB 10x100 ml	17320901	06-Aug-28
OMNIPAQUE 300 mg USB 10x100 ml	17374661	16-Nov-28
OMNIPAQUE 300 mg USB 10x100 ml	17366313	31-Jan-29
OMNIPAQUE 300 mg USB 10x100 ml	17370931	12-Oct-28
OMNIPAQUE 300 mg USB 10x100 ml	17291358	04-Aug-28
OMNIPAQUE 300 mg USB 10x100 ml	17300760	04-Sep-28
OMNIPAQUE 300 mg USB 10x100 ml	17379399	14-Nov-28
OMNIPAQUE 300 mg USB 10x100 ml	17325312	13-Sep-28
OMNIPAQUE 300 mg USB 10x100 ml	17327161	07-Dec-28
OMNIPAQUE 300 mg USB 10x100 ml	17404129	13-Dec-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17225029	03-Sep-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17265376	03-Oct-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17270885	10-Sep-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17292246	04-Oct-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17301805	18-Oct-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17301807	07-Sep-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17301810	20-Oct-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17304992	05-Oct-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17304993	19-Oct-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17304996	25-Nov-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17321225	08-Sep-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17333589	24-Nov-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17333611	26-Nov-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17333613	23-Nov-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17357000	05-Dec-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17366399	14-Dec-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17376486	14-Dec-28
OMNIPAQUE 300mg/ml USB 10x100 ml	17404114	06-Dec-28
OMNIPAQUE 350 mg USB 1x100 ml	17238983	26-Jul-28
OMNIPAQUE 350 mg USB 1x100 ml	17277327	11-Aug-28
OMNIPAQUE 350 mg USB 1x100 ml	17322643	14-Oct-28
OMNIPAQUE 350 mg USB 1x100 ml	17271306	11-Aug-28
OMNIPAQUE 350 mg USB 1x100 ml	17270328	26-Jul-28
OMNIPAQUE 350 mg USB 1x100 ml	17277326	06-Aug-28
OMNIPAQUE 350 mg USB 1x100 ml	17370479	21-Oct-28
OMNIPAQUE 350 mg USB 1x100 ml	17370480	21-Oct-28
OMNIPAQUE 350 mg USB 1x100 ml	17407025	04-Dec-28
OMNIPAQUE 350 mg USB 1x100 ml	17301796	08-Aug-28

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OMNIPAQUE 350 mg USB 10x100 ml	17277089	11-Aug-28
OMNIPAQUE 350 mg USB 10x100 ml	17351100	07-Sep-28
OMNIPAQUE 350 mg USB 10x100 ml	17320944	25-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17411626	20-Nov-28
OMNIPAQUE 350 mg USB 10x100 ml	17332846	07-Sep-28
OMNIPAQUE 350 mg USB 10x100 ml	17238980	26-Jul-28
OMNIPAQUE 350 mg USB 10x100 ml	17277322	30-Jul-28
OMNIPAQUE 350 mg USB 10x100 ml	17298718	07-Aug-28
OMNIPAQUE 350 mg USB 10x100 ml	17361175	01-Dec-28
OMNIPAQUE 350 mg USB 10x100 ml	17379390	25-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17429790	11-Dec-28
OMNIPAQUE 350 mg USB 10x100 ml	17277208	25-Jul-28
OMNIPAQUE 350 mg USB 10x100 ml	17340558	30-Nov-28
OMNIPAQUE 350 mg USB 10x100 ml	17327354	14-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17324090	01-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17361386	01-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17364400	01-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17364401	01-Nov-28
OMNIPAQUE 350 mg USB 10x100 ml	17275275	30-Sep-28
OMNIPAQUE 350 mg USB 10x100 ml	17227949	31-Jul-28
OMNIPAQUE 350 mg USB 10x100 ml	17340534	31-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17361385	30-Nov-28
OMNIPAQUE 350 mg USB 10x100 ml	17403686	31-Dec-28
OMNIPAQUE 350 mg USB 10x100 ml	17291368	11-Aug-28
OMNIPAQUE 350 mg USB 10x100 ml	17349069	01-Dec-28
OMNIPAQUE 350 mg USB 10x100 ml	17413362	15-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17258866	11-Aug-28
OMNIPAQUE 350 mg USB 10x100 ml	17378255	20-Nov-28
OMNIPAQUE 350 mg USB 10x100 ml	17212392	05-Aug-28
OMNIPAQUE 350 mg USB 10x100 ml	17349047	21-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17294798	06-Sep-28
OMNIPAQUE 350 mg USB 10x100 ml	17358213	14-Nov-28
OMNIPAQUE 350 mg USB 10x100 ml	17396721	03-Jan-29
OMNIPAQUE 350 mg USB 10x100 ml	17340557	11-Aug-28
OMNIPAQUE 350 mg USB 10x100 ml	17367331	24-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17364593	14-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17291310	30-Jul-28
OMNIPAQUE 350 mg USB 10x100 ml	17352078	13-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17388194	21-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17368323	20-Nov-28
OMNIPAQUE 350 mg USB 10x100 ml	17244048	25-Jul-28
OMNIPAQUE 350 mg USB 10x100 ml	17374668	02-Dec-28
OMNIPAQUE 350 mg USB 10x100 ml	17344032	06-Aug-28
OMNIPAQUE 350 mg USB 10x100 ml	17306297	23-Jul-28
OMNIPAQUE 350 mg USB 10x100 ml	17308416	26-Jul-28
OMNIPAQUE 350 mg USB 10x100 ml	17314055	05-Aug-28
OMNIPAQUE 350 mg USB 10x100 ml	17328722	12-Nov-28

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OMNIPAQUE 350 mg USB 10x100 ml	17358222	12-Dec-28
OMNIPAQUE 350 mg USB 10x100 ml	17376107	13-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17409644	10-Nov-28
OMNIPAQUE 350 mg USB 10x100 ml	17433391	17-Dec-28
OMNIPAQUE 350 mg USB 10x100 ml	17277315	31-Aug-28
OMNIPAQUE 350 mg USB 10x100 ml	17312303	31-Jul-28
OMNIPAQUE 350 mg USB 10x100 ml	17323704	31-Aug-28
OMNIPAQUE 350 mg USB 10x100 ml	17370063	30-Sep-28
OMNIPAQUE 350 mg USB 10x100 ml	17407055	31-Dec-28
OMNIPAQUE 350 mg USB 10x100 ml	17425028	31-Dec-28
OMNIPAQUE 350 mg USB 10x100 ml	17359070	17-Sep-28
OMNIPAQUE 350 mg USB 10x100 ml	17402891	30-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17402903	02-Nov-28
OMNIPAQUE 350 mg USB 10x100 ml	17406203	01-Nov-28
OMNIPAQUE 350 mg USB 10x100 ml	17417180	25-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17296065	07-Aug-28
OMNIPAQUE 350 mg USB 10x100 ml	17201254	06-Aug-28
OMNIPAQUE 350 mg USB 10x100 ml	17305630	30-Jul-28
OMNIPAQUE 350 mg USB 10x100 ml	17370936	14-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17383109	15-Oct-28
OMNIPAQUE 350 mg USB 10x100 ml	17239721	30-Aug-28
OMNIPAQUE 350 mg USB 10x100 ml	17241442	06-Sep-28
OMNIPAQUE 350 mg USB 10x100ml	17183380	31-Jul-28
OMNIPAQUE 350 mg USB 10x100ml	17319894	07-Aug-28
OMNIPAQUE 350 mg U 10x100 ml	17253638	07-Aug-28
OMNIPAQUE 350mg/ml USB 10x100 ml	17306628	05-Sep-28
OMNIPAQUE 350mg/ml USB 10x100 ml	17333197	10-Dec-28
OMNIPAQUE 350mg/ml USB 10x100 ml	17333198	17-Nov-28
OMNIPAQUE 350mg/ml USB 10x100 ml	17396945	18-Dec-28
OMNIPAQUE 350mg/ml USB 10x100 ml	17396948	22-Dec-28
OMNIPAQUE 350mg/ml USB 10x100 ml	17396953	11-Jan-29
OMNIPAQUE 350mg/ml USB 10x100 ml	17396956	09-Jan-29
OMNIPAQUE 350mg/ml USB 10x100 ml	17423503	01-Jan-29
OMNIPAQUE 350mg/ml USB 10x100 ml	17423525	03-Jan-29
OMNIPAQUE 350mg/ml USB 10x100 ml	17426429	01-Jan-29
OMNIPAQUE 350mg/ml USB 10x100 ml	17426440	04-Jan-29
OMNIPAQUE 350mg/ml USB 10x100 ml	17431310	11-Jan-29
OMNIPAQUE 647 mg USB 10x100 ml	17296089	06-Aug-28
OMNIPAQUE 647 mg USB 10x100 ml	17322376	22-Oct-28
OMNIPAQUE 647 mg USB 10x100 ml	17363927	13-Nov-28
OMNIPAQUE 755 mg USB 10x100 ml	17247369	06-Aug-28
VISIPAQUE 320 mg USB 1x100 ml	17270129	26-Jul-28
VISIPAQUE 320 mg USB 1x100 ml	17363725	05-Dec-28
VISIPAQUE 320 mg USB 1x100 ml	17385132	13-Dec-28
VISIPAQUE 320 mg USB 1x100 ml	17292643	14-Aug-28
VISIPAQUE 320 mg USB 1x100 ml	17305012	25-Jul-28
VISIPAQUE 320 mg USB 1x100 ml	17271300	25-Jul-28

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VISIPAQUE 320 mg USB 10x100 ml	17305010	13-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17320967	15-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17338638	15-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17306843	25-Jul-28
VISIPAQUE 320 mg USB 10x100 ml	17336632	05-Dec-28
VISIPAQUE 320 mg USB 10x100 ml	17353211	25-Jul-28
VISIPAQUE 320 mg USB 10x100 ml	17247383	14-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17331540	25-Jul-28
VISIPAQUE 320 mg USB 10x100 ml	17299098	22-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17264297	25-Jul-28
VISIPAQUE 320 mg USB 10x100 ml	17325742	22-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17338633	25-Jul-28
VISIPAQUE 320 mg USB 10x100 ml	17314000	25-Jul-28
VISIPAQUE 320 mg USB 10x100 ml	17264301	15-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17264302	01-Jul-28
VISIPAQUE 320 mg USB 10x100 ml	17302277	01-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17323156	01-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17302289	31-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17302290	31-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17321866	31-Jul-28
VISIPAQUE 320 mg USB 10x100 ml	17264005	25-Jul-28
VISIPAQUE 320 mg USB 10x100 ml	17291370	25-Jul-28
VISIPAQUE 320 mg USB 10x100 ml	17349086	05-Dec-28
VISIPAQUE 320 mg USB 10x100 ml	17230467	14-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17350682	22-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17318726	13-Sep-28
VISIPAQUE 320 mg USB 10x100 ml	17330329	22-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17437211	13-Dec-28
VISIPAQUE 320 mg USB 10x100 ml	17264311	13-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17291421	22-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17201256	13-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17230526	15-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17320931	15-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17320932	22-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17320933	19-Sep-28
VISIPAQUE 320 mg USB 10x100 ml	17422210	13-Dec-28
VISIPAQUE 320 mg USB 10x100 ml	17275012	22-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17303283	22-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17341274	22-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17363903	05-Dec-28
VISIPAQUE 320 mg USB 10x100 ml	17291424	22-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17278120	22-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17358219	05-Dec-28
VISIPAQUE 320 mg USB 10x100 ml	17415131	05-Dec-28
VISIPAQUE 320 mg USB 10x100 ml	17300762	25-Jul-28
VISIPAQUE 320 mg USB 10x100 ml	17272574	14-Sep-28
VISIPAQUE 320 mg U 10x100 ml	17312861	15-Aug-28

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VISIPAQUE 320 mg U 10x100 ml	17312864	19-Sep-28
VISIPAQUE 320 mg USB 10x100 ml	17244652	26-Jul-28
VISIPAQUE 320 mg USB 10x100 ml	17303308	15-Aug-28
VISIPAQUE 320 mg USB 10x100 ml	17312888	19-Sep-28
VISIPAQUE 320MG 100 ML USB	17303269	15-Aug-28
VISIPAQUE 320MG 100 ML USB	17312884	22-Aug-28
VISIPAQUE 320MG 100 ML USB	17388227	05-Dec-28
VISIPAQUE 320mg USB 1x100ml 32gl	17393760	14-Aug-28
VISIPAQUE 320mg USB 1x100ml 32gl	17393761	12-Aug-28
VISIPAQUE 320mg USB 1x100ml 32gl	17393764	12-Aug-28
VISIPAQUE 320mg USB 1x100ml 32gl	17393765	21-Aug-28
VISIPAQUE 320mg USB 1x100ml 32gl	17403780	22-Aug-28
VISIPAQUE 320mg USB 1x100ml 32gl	17421451	19-Aug-28
VISIPAQUE 320mg USB 1x100ml 32gl	17425290	20-Sep-28
VISIPAQUE 320mg USB 1x100ml 32gl	17425291	10-Oct-28
VISIPAQUE 320mg USB 1x100ml 32gl	17425292	20-Sep-28
VISIPAQUE 320mg USB 1x100ml 32gl	17428130	19-Sep-28
VISIPAQUE 320mg USB 1x100ml 32gl	17428132	19-Sep-28
VISIPAQUE 320mg USB 1x100ml 32gl	17432322	20-Sep-28
VISIPAQUE 320mg USB 1x100ml 32gl	17444560	09-Oct-28

ⁱ Raju SK, Menon R, Nair S, et al. *Non-thrombotic pulmonary embolism from inorganic particulate matter foreign bodies*. Journal of Forensic and Legal Medicine. 2018. Available at: <https://www.researchgate.net/publication/323426498> (accessed 1 May 2026).