

All correspondence should be addressed to the Director General



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LET\_LSE/PMS/0016/05/26

# ZAMBIA MEDICINES REGULATORY AUTHORITY

## PUBLIC NOTICE

Date: 12<sup>th</sup> May 2026

To: Distributors, Retailers, Radiologists and other Healthcare Professionals, General Public

### **Medical Product Alert N°1/2026 Substandard ACCUPAQUE (Iohexol), OMNIPAQUE (Iohexol) and VISIPAQUE (Iodixanol) in all WHO regions**

The Zambia Medicines Regulatory Authority (ZAMRA) is a statutory body established under an Act of Parliament, the Medicines and Allied Substances Act No. 3 of 2013 of the laws of Zambia. The main mandate of ZAMRA is to regulate, and control the manufacture, importation, storage, distribution, supply, sale and use of medicines and allied substances for human and animal use for public health protection.

Based on the above, ZAMRA wishes to alert healthcare professionals, pharmaceutical outlets and members of the public that it has been notified by the World Health Organisation (WHO) of a Class I quality defect affecting specific batches of iodinated contrast media (Iohexol or Iodixanol) marketed under the brand names ACCUPAQUE, OMNIPAQUE and VISIPAQUE solutions for injection, **presented in 100 ml polypropylene containers**, manufactured by GE HealthCare Ireland Limited.

The defect involves the presence of **metallic particulate matter**, either adhered to or embedded within the inner surface of polypropylene bottles. In at least one confirmed instance identified by the manufacturer, a free metallic particulate was present within the finished product. **The quality defect only affects batches supplied in 100 ml polypropylene containers. Batches supplied in glass containers are not affected.** The affected batches of these products have been supplied globally to multiple countries. Distribution primarily occurred at hospital level, including facilities performing interventional radiology, cardiology and vascular surgery procedures.

#### **What is Iohexol and Iodixanol**

These products are non-ionic, water-soluble, iodinated contrast agents used to enhance X-ray and CT imaging, making blood vessels and organs visible, thereby aiding in the detection of abnormalities. **These products are strictly for use in healthcare settings only by Radiologists and other trained healthcare professionals.**

#### **Risks**

These products are injectable solutions for intra-arterial and intravenous use. The presence of particulate matter poses a safety risk especially when injected intra-

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**Report Adverse Reactions to:**  
Pharmacovigilance Unit, Lusaka  
Tel: +260 211 432 356  
E-mail: [npvu@zamra.co.zm](mailto:npvu@zamra.co.zm)  
Website: [www.zamra.co.zm](http://www.zamra.co.zm)

arterially and can cause serious adverse events including life-threatening embolic events.

### How to identify these substandard products

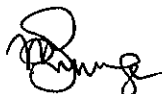
The list of affected products and batches provided by GE Healthcare Ireland Limited is included in Annexes 1 and 2 of this Notice.

### Advise to healthcare providers, pharmaceutical outlets and public

ZAMRA wishes to advise healthcare professionals and health facilities who may be in possession of the affected products, to not use them and return them to the point of purchase for stock replacement. Pharmaceutical outlets and other distribution centres that may have the affected products are advised to refrain from selling or using them and return them to their suppliers for destruction.

If you suffer any adverse drug reaction/event having used any of the affected batches, you are advised to seek immediate medical advice and report the incident to the National Pharmacovigilance Unit at Zambia Medicines Regulatory Authority by phone: +260 211 432 356/+260/956 521 094 or email address at: [npvu@zamra.co.zm](mailto:npvu@zamra.co.zm) or [pharmacy@zamra.co.zm](mailto:pharmacy@zamra.co.zm).

Should the public need further clarification, please do not hesitate to contact the Secretariat.



Makomani Siyanga (Mr)  
**DIRECTOR-GENERAL**

#### Annex 1: Products subject of WHO Medical Product Alert N°1/2026

Product	Accupaque (Iohexol)	Omnipaque (Iohexol)	Visipaque (Iodixanol)
Stated manufacturer	GE Healthcare Ireland Limited		
Affected lot numbers	See Annex 2	See Annex 2	See Annex 2
Expiry date	See Annex 2	See Annex 2	See Annex 2

#### Annex 2 – List of affected products and batches

Product	Batch	Expiry
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
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
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	17298713	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
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

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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
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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
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OMNIPAQUE 755 mg USB 10x100 ml	17247369	06-Aug-28
VISIPAQUE 320 mg USB 1x100 ml	17270129	26-Jul-28
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VISIPAQUE 320 mg USB 10x100 ml	17353211	25-Jul-28
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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
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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