June 2022

IMPORTANT PRESCRIBING INFORMATION

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Subject:	**Distribution of ULTRAVIST® (iopromide) injection with Foreign, non-US Labeling in Response to Iodinated Contrast Media Shortage**

Dear Health Care Provider:

The purpose of this letter is to inform you of important information regarding the distribution of foreign labeled Ultravist® (iopromide) injection in the United States (U.S.). In response to iodinated contrast media shortages, due to supply pressures resulting from COVID-19 lockdowns in China, Bayer has engaged with the United States Food and Drug Administration to import and distribute a limited quantity of Ultravist® (iopromide) stock which was originally intended and labeled for foreign markets.

This imported stock is manufactured at the same site (Bayer AG, Berlin, Germany) that manufactures the Ultravist® (iopromide) intended for the U.S. market; however, it is not labeled with current FDA-approved labeling. A summary of the foreign labeled stock for importation and distribution is provided below.

Product Description	**Iodine (I) Concentration**	**Package size**	**Leaflet Language**	**Exp. Date**	**Batch Number**	**NDC**
Ultravist 370 (iopromide) injection	370 mg I/mL	1X100 ml Bottle	Spanish	02.28.2025	KT0C160 KT0C3BJ	50419-348-10
Ultravist 370 (iopromide) injection	370 mg I/mL	10X200 ml Bottle	English / Afrikaans	01.31.2023	KT0A4KA	50419-348-21

Ultravist 300 (iopromide) injection	300 mg I/mL	1X200 ml Bottle	Spanish	03.31.2025	KT0C95T	50419-347-20
Ultravist 370 (iopromide) injection	370 mg I/mL	1X200 ml Bottle	Spanish	03.31.2025	KT0C7P0	50419-348-20
Ultravist 370 (iopromide) injection	370 mg I/mL	10X100 ml Bottle	English / French	09.30.2023	KT07TL3	50419-348-12
Ultravist 300 (iopromide) injection	300 mg I/mL	1X50 ml Bottle	Arabic / French	01.31.2024	KT09P6C	50419-347-05
Ultravist 370 (iopromide) injection	370 mg I/mL	10X50 ml Bottle	English	11.30.2023	KT09JPA	50419-348-05
					KT0A22A	
Ultravist 370 (iopromide) injection	370 mg I/mL	10X100 ml Bottle	English	02.29.2024	KT0A1S5	50419-348-13
Ultravist 370 (iopromide) injection	370 mg I/mL	1X100 ml Bottle	Arabic / French	02.28.2025	KT0C0V1	50419-348-11

The package inserts of the foreign Ultravist stock may differ from the U.S. Package Insert for Ultravist® (iopromide). As such, please refer to the full U.S. Prescribing Information (USPI) for Ultravist® (iopromide) to ensure you follow the USPI. It is important to note that Ultravist® (iopromide) injection is **approved only for intra-arterial and intravenous administration**. Ultravist® (iopromide) is NOT for intrathecal use (see section 4 of the USPI, Contraindications). A side-by-side comparison of the approved U.S. vial labeling and foreign vial/carton labeling is also provided at the end of this letter.

The contact details on the foreign stock will be for Bayer affiliates outside of the U.S. You can contact Bayer HealthCare Pharmaceuticals, Inc. directly at 1-888-842-2937 if you have questions about the information contained in this letter or the safe and effective use of Ultravist® (iopromide). The Ultravist® barcode may not register accurately on U.S. barcode scanning systems. Institutions should manually input the product into their systems, and confirm that their systems do not provide incorrect information when the product is scanned. Alternative procedures should be followed to assure that the correct drug product is being used and administered to individual patients.

Reporting Adverse Events

Health care providers and patients are encouraged to report adverse events in patients receiving Ultravist® (iopromide) at 1-888-842-2937 or https://safetrack-public.bayer.com.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report **Online**: www.fda.gov/medwatch/report.htm
- **Regular Mail or Fax**: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178 (1-800-332-0178)

Gené van den Ende

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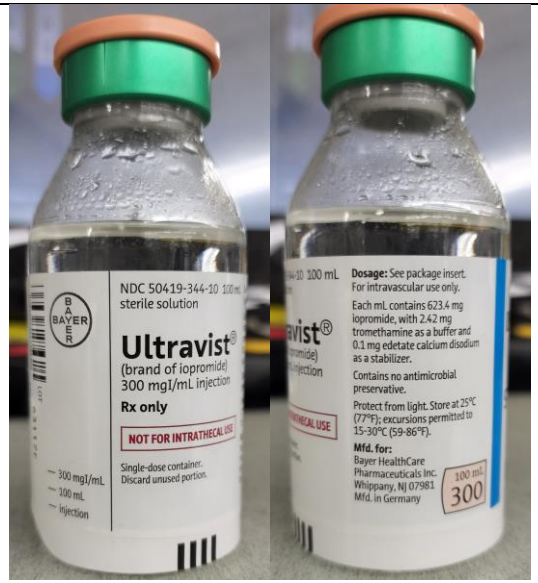
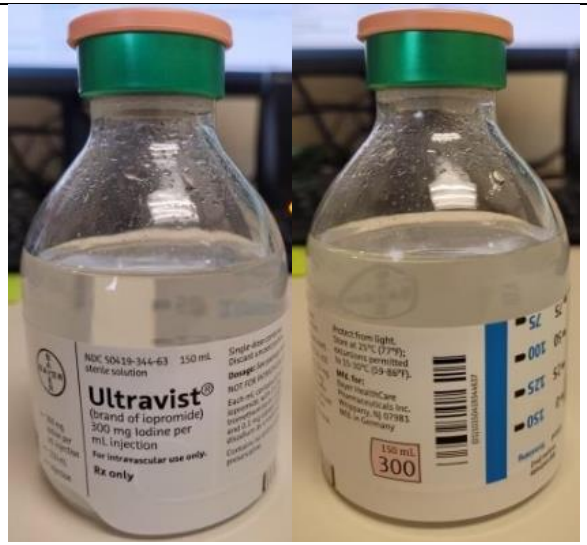
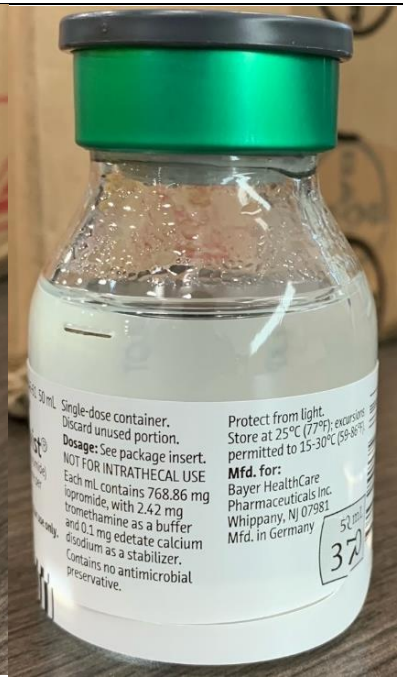
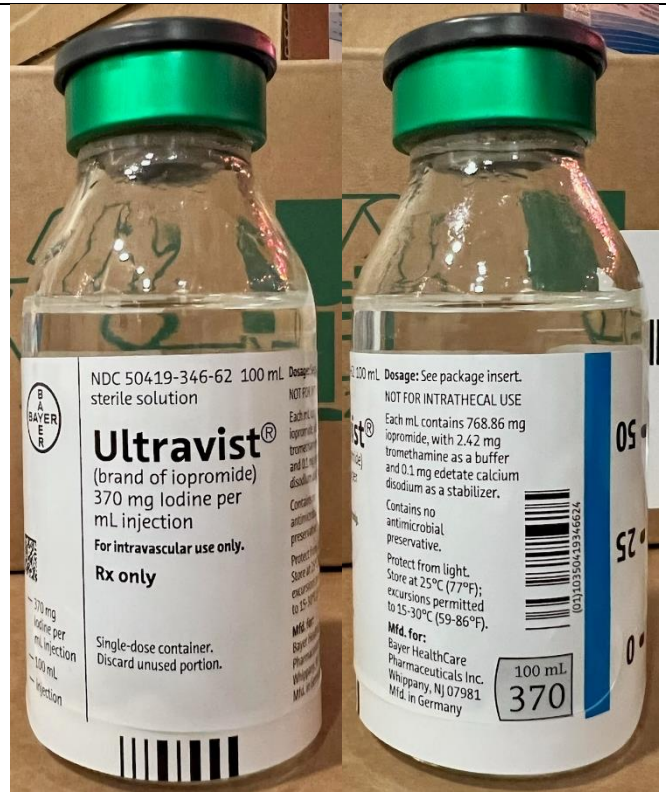
Head Americas Medical Affairs Radiology
Bayer U.S. LLC

Attachment to Important Prescribing Information Letter Regarding Distribution of Ultravist (iopromide) Injection with Foreign, non-US Labeling in Response to Iodinated Contrast Media Shortage

Ultravist (iopromide) Injection Label Product Comparison Table

Primary Packaging Image			
	NDC 50419-344-60 NDC 50419-344-05	NDC 50419-344-61 NDC 50419-344-10	NDC 50419-344-63 NDC 50419-344-15
Description	Ultravist 300 mg iodine/mL 50mL bottle	Ultravist 300 mg iodine/mL 100mL bottle	Ultravist 300 mg iodine/mL 150mL bottle
Manufactured For:	United States	United States	United States

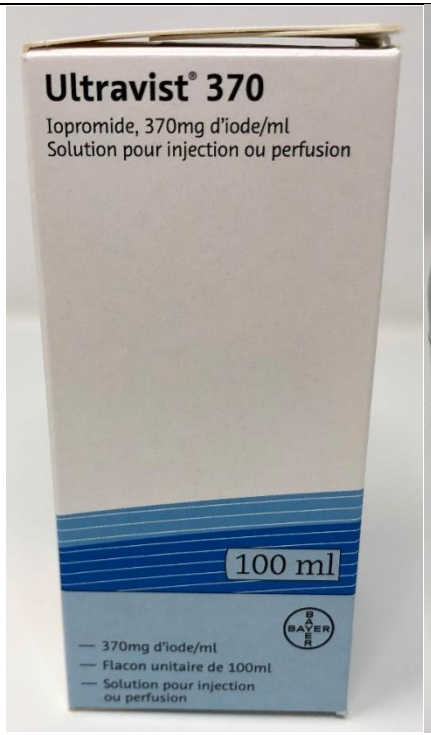
Ultravist (iopromide) Injection Label Product Comparison Table

Primary Packaging Image	 	
	NDC 50419-346-61 NDC 50419-346-05	NDC 50419-346-62 NDC 50419-346-10
Description	Ultravist 370 mg iodine/mL 50mL bottle	Ultravist 370 mg iodine/mL 100mL bottle
Manufactured For:	United States	United States

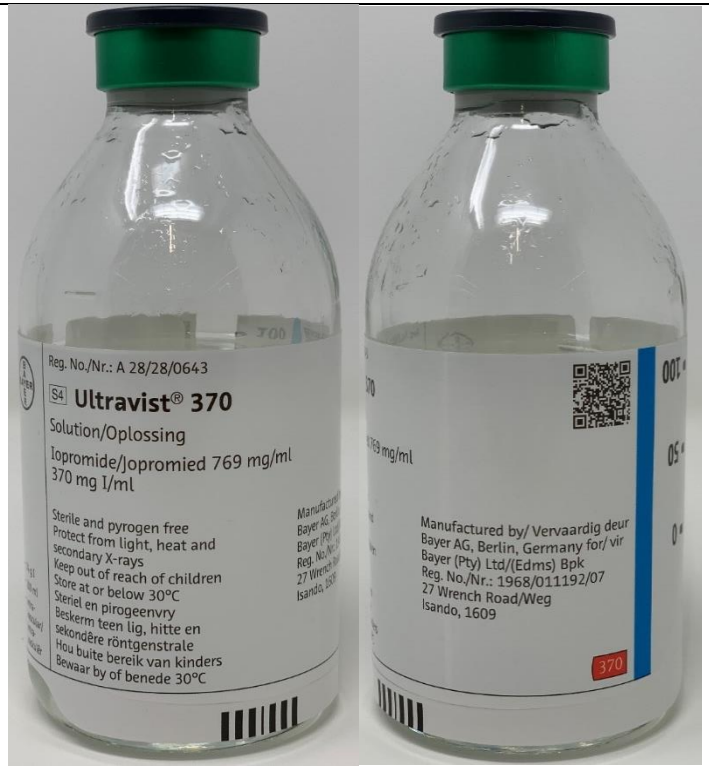
Ultravist (iopromide) Injection Label Product Comparison Table

Primary Packaging Image		
	NDC 50419-347-20	NDC 50419-348-20
Description	Ultravist 300 mg iodine/mL 200mL bottle	Ultravist 370 mg iodine/mL 200mL bottle
Manufactured For:	Mexico	Mexico

Ultravist (iopromide) Injection Label Product Comparison Table

Primary Packaging Image	 	 
	NDC 50419-347-05	NDC 50419-348-11
Description	Ultravist 300 mg iodine/mL 50mL bottle	Ultravist 370 mg iodine/mL 100mL bottle
Manufactured For:	Algeria	Algeria

Ultravist (iopromide) Injection Label Product Comparison Table

Primary Packaging Image		
	NDC 50419-348-10	NDC 50419-348-21
Description	Ultravist 370 mg iodine/mL 100mL bottle	Ultravist 370 mg iodine/mL 200mL bottle
Manufactured For:	Chile	South Africa

Ultravist (iopromide) Injection Label Product Comparison Table

Primary Packaging Image			
	NDC 50419-348-12	NDC 50419-348-05	NDC 50419-348-13
Description	Ultravist 370 mg iodine/mL 100mL bottle	Ultravist 370 mg iodine/mL 50mL bottle	Ultravist 370 mg iodine/mL 100mL bottle
Manufactured For:	Middle Africa	Middle East	Middle East

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