



# Summary of investigation results

## lomeprol

## lohexol (for urinary tract, blood vessel, CT)

### Non-proprietary name

- a. lomeprol
- b. lohexol (for urinary tract, blood vessel, CT)

### Brand name (Marketing authorization holder)

- a. lomeron 300 Injection 20 mL, 50 mL, 100 mL, lomeron 350 Injection 20 mL, 50 mL, 100 mL, lomeron 400 Injection 20mL, 50 mL, 100 mL, lomeron 300 Injection Syringe 50 mL, 75 mL, 100mL, lomeron 350 Injection Syringe 50 mL, 75 mL, 100 mL, 135 mL (Bracco-Esai Co., Ltd.)
- b. Omnipaque 140 Injection 50 mL, 220 mL, Omnipaque 240 Injection 20 mL, 50 mL, 100mL, Omnipaque 300 Injection 20 mL, 50 mL, 100mL, 150 mL, Omnipaque 350 Injection 20 mL, 50 mL, 100mL, Omnipaque 240 Injection Syringe 100 mL, Omnipaque 300 Injection Syringe 50 mL, 80 mL, 100 mL, 110 mL, 125 mL, 150 mL, Omnipaque 350 Injection Syringe 45 mL, 70 mL, 100 mL (Daiich Sankyo Co., Ltd.), and the others

### Indications

See Appendix.

### Summary of revision

“Acute generalized exanthematous pustulosis” should be added to the skin disorders subsection in the Clinically Significant Adverse Reactions section.



## **Background of the revision and investigation results**

Cases of acute generalized exanthematous pustulosis have been reported in patients treated with iomeprol as well as with iohexol preparations for urinary tract, blood vessels, and CT in Japan and overseas. Following investigation results based on the opinions of expert advisors and the available evidence, the MHLW/PMDA concluded that revision of the package insert was necessary.

## **The number of reported adverse reactions and fatal cases in the last 3 fiscal years in Japan**

- a. One case involving acute generalized exanthematous pustulosis has been reported (causal relationship with this product could not be ruled out for this patient.) No fatal cases have been reported.
- b. One case involving acute generalized exanthematous pustulosis has been reported (causal relationship with this product could not be ruled out for this patient.) No fatal cases have been reported.

## Appendix

	<b>Nonproprietary Name</b>	<b>Branded name</b>	<b>Indications MAH name</b>
a	lomeprol	lomeron 300 Injection 20 mL lomeron 300 Injection 50 mL lomeron 300 Injection 100 mL	Cerebral blood vessel angiography, thoracic aortography, abdominal angiography, extremities angiography, venography by digital X-ray method, arteriography by digital X-ray method, computer-assisted tomography, and intravenous urography
		lomeron 350 Injection 20 mL lomeron 350 Injection 50 mL lomeron 350 Injection 100 mL	Angio cardiography, thoracic aortography, abdominal angiography, extremities angiography, venography by digital X-ray method, arteriography by digital X-ray method, computer-assisted tomography, and intravenous urography
		lomeron 400 Injection 20 mL lomeron 400 Injection 50 mL lomeron 400 Injection 100 mL	Angio cardiography, thoracic aortography, abdominal angiography, and intravenous urography
		lomeron 300 Injection Syringe 50 mL lomeron 300 Injection Syringe 75 mL, lomeron 300 Injection Syringe 100 mL	Computer-assisted tomography, intravenous urography, cerebral blood vessel angiography, thoracic aortography, abdominal angiography, extremities angiography, venography by digital X-ray method, and arteriography by digital X-ray method

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	<b>Nonproprietary Name</b>	<b>Branded name</b>	<b>Indications MAH name</b>
		lomeron 350 Injection Syringe 50 mL lomeron 350 Injection Syringe 75 mL lomeron 350 Injection Syringe 100 mL lomeron 350 Injection Syringe 135 mL	Computer-assisted tomography, intravenous urography, angiography, thoracic aortography, abdominal angiography, extremities angiography, venography by digital X-ray method, and arteriography by digital X-ray method
b	Iohexol	Omnipaque 140 Injection 50 mL Omnipaque 140 Injection 220 mL	Arteriography by digital X-ray method, and computer-assisted tomography
		Omnipaque 240 Injection 20 mL Omnipaque 240 Injection 50 mL Omnipaque 240 Injection 100mL	Extremities angiography, computer-assisted tomography, and intravenous urography
		Omnipaque 300 Injection 20 mL Omnipaque 300 Injection 50 mL Omnipaque 300 Injection 100mL Omnipaque 300 Injection 150 mL	Cerebral blood vessel angiography, selective angiography, extremities angiography, arteriography by digital X-ray method, venography by digital X-ray method, computer-assisted tomography, and intravenous urography
		Omnipaque 350 Injection 20 mL Omnipaque 350 Injection 50 mL Omnipaque 350 Injection 100mL	Angiocardiology (including pulmonary artery angiography), aortography, selective angiography, extremities angiography, venography by digital X-ray method, computer-assisted tomography, intravenous urography, and angiocardiology of pediatrics (including pulmonary artery angiography)

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	<b>Nonproprietary Name</b>	<b>Branded name</b>	<b>Indications MAH name</b>
		Omnipaque 240 Injection Syringe 100 mL	Extremities angiography, computer-assisted tomography, and intravenous urography
		Omnipaque 300 Injection Syringe 50 mL Omnipaque 300 Injection Syringe 80 mL Omnipaque 300 Injection Syringe 100 mL Omnipaque 300 Injection Syringe 110 mL Omnipaque 300 Injection Syringe 125 mL Omnipaque 300 Injection Syringe 150 mL	Cerebral blood vessel angiography, selective angiography, extremities angiography, arteriography by digital X-ray method, venography by digital X-ray method, computer-assisted tomography, and intravenous urography
		Omnipaque 350 Injection Syringe 45 mL Omnipaque 350 Injection Syringe 70 mL Omnipaque 350 Injection Syringe 100 mL	Angiocardiography (including pulmonary artery angiography), aortography, selective angiography, extremities angiography, venography by digital X-ray method, computer-assisted tomography, intravenous urography, and angiocardiography of pediatrics (including pulmonary artery angiography)

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