


PRODUCT LIST



Our sales network extends globally
to provide you with our **high quality products**
wherever you may be.

Finished Products

IOPAMIDOL INJECTION	6
GADOBUTROL PREFILLED INJECTION	7
GADOTERATE MEGLUMINE PREFILLED INJECTION	8
FATTIODOL INJECTION	9

Raw Materials

IOPAMIDOL	12
GADOBUTROL	13
GADOTERIDOL	14
GADOXETATE(EOB-DTPA)	15
DOTA	16



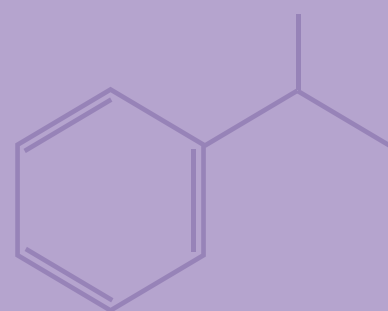
Finished Products

IOPAMIDOL INJECTION

GADOBUTROL PREFILLED INJECTION

GADOTERATE MEGLUMINE PREFILLED INJECTION

FATTIODOL INJECTION



lifescience

Brand Name : Pamiray Injection

Pamiray Injection is a new nonionic, water soluble X-ray contrast medium with favorable physicochemical and biologic properties compared with existing radiopaque agent.

Ingredient

Pamiray 300 Injection contains iopamidol 0.612 g per ml (300 mg as iodine)
Pamiray 370 Injection contains iopamidol 0.7552 g per ml (370 mg as iodine).

Indications

1. X-ray contrast media for neuroradiology (ventriculography, basilarography, myelography)
2. Angiography (arteriography, venography)
3. Urography
4. Computer tomography (CAT Scanning)

Dosage and administration

For further information, please see the insert.

Shelf Life

3 years

Storage

1 ~ 30°C

How Supplied

Pamiray 300 Injection : 50, 100mL x 1 vial / Box
Pamiray 370 Injection : 50, 100mL x 1 vial / Box



Iopamidol Injection

Brand Name : Gadovision Prefilled Injection

Gadovision Prefilled Injection is a paramagnetic macrocyclic contrast agent administered for MRI. This solution for injection is provided in a prefilled syringe to enhance the convenience for medical professionals and patients.

Ingredient

Each mL contains Gadobutrol 604.72 mg

Indications

1. Contrast enhancement in cranial and spinal MRI
2. Contrast enhancement in magnetic resonance angiography (CE-MRA)
3. Contrast enhanced MRI of liver or kidneys in patients with high suspicion or evidence of having focal lesions to classify these lesions as benign or malignant
 - * It facilitates visualisation of abnormal structures or lesions and helps in the differentiation between healthy and pathological tissue.

Dosage and administration

For further information, please see the insert.

Shelf Life

3 years

Storage

1 ~ 30°C

How Supplied

5 mL x 5 prefilled syringes
7.5 mL x 5 prefilled syringes
10 mL x 5 prefilled syringes
15 mL x 5 prefilled syringes



Gadobutrol Prefilled Injection

Brand Name : Uniray Prefilled Injection

Uniray Prefilled Injection is a gadolinium-based contrast agent indicated for intravenous use with magnetic resonance imaging (MRI). This solution for injection is provided in a prefilled syringe to enhance the convenience for medical professionals and patients.

Ingredient

100 mL contains Gadolinium oxide 9.062 g, DOTA 20.246 g, and Meglumine 9.76 g (as Gadoterate Meglumine 37.69 g)

Indications

Use with Magnetic Resonance Imaging (MRI) in the cranial nerve and spine
Use with Magnetic Resonance Imaging (MRI) in the body (including MR angiography)

Dosage and administration

For further information, please see the insert.

Shelf Life

3 years

Storage

1 ~ 30°C

How Supplied

10 mL x 5 prefilled syringes
15 mL x 5 prefilled syringes
20 mL x 5 prefilled syringes



Gadoterate Meglumine Prefilled Injection

Brand Name : Fattiodol Injection

Fattiodol, ethiodized oil injection, is a sterile injectable radio-opaque diagnostic agent for use in hysterosalpingography and lymphography. Each milliliter contains 480 mg of Iodine organically combined with ethyl esters of fatty acids of poppy-seed oil. The precise structure of Fattiodol is unknown at this time.

Fattiodol is a sterile, clear, pale yellow to amber colored oil.

Ingredient

Ethyl esters of iodized fatty acids of poppy seed oil (12.8g/10ml)

Indications

1. Lymphography and ptyalography
2. Use as a radio-opaque medium for TACE (Transarterial chemoembolization) of hepatoma

Dosage and administration

1. Lymphography and ptyalography
Dosage should be the minimum required amount according to the patients' status, screening range and etc. Range of the drug is about 0.1 ~ 0.2mL per minute.
The standard amount of one lymphography case is like follows.
Radiography for one arm : 2~4mL
Radiography for both arms : 5~6mL
Radiography for one leg : 5~7mL
Radiography for both legs : 10~12mL
2. TACE (Transarterial chemoembolization) of hepatocellular carcinoma
According to the size of tumor, generally dosage is not more than 15mL

Shelf Life

36 months

Storage

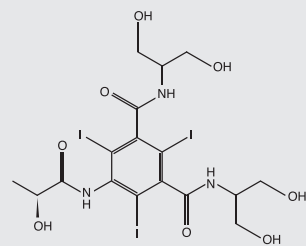
Store at room temperature, protect from light

How Supplied

10 mL x 10 ampoules / Box
10 mL x 1 ampoule / Box



Fattiodol Injection



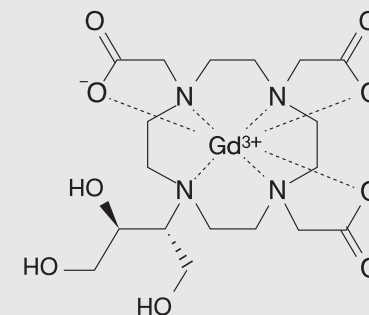
Items

Specifications (USP)

Description	White or almost white powder Complies with USP
Specific optical rotation	-4.6° to -5.2°(t=20°C;λ=436nm)
Assay	98.0 -101.0%
Free aromatic amine	≤ 0.02%
Free iodine	The toluene layer shows no red color.
Limit of free iodide	≤ 0.001%
Heavy metals	≤ 0.001%
Free acid or alkali	NMT 1.37ml of 0.01N sodium hydroxide or NMT 0.75ml of 0.01N Hydrochloric acid.
Related compounds	≤ 0.25%
Loss on drying	≤ 0.5%
Residue on ignition	≤ 0.1%
Packing	Double PE bags, Preserve in well-closed, light-resistant containers.
Packing Size	10Kg(Other pack sizes may be available on request)
Residual solvent Ethanol	NMT 5000ppm

Chemical Name	(S)-N,N'-bis[2-Hydroxy-1-(hydroxymethyl)ethyl]-2,4,6-triiodo-5-lactamidoisophthalamide
Molecular Formula	C ₁₇ H ₂₂ I ₃ N ₃ O ₈
Molecular Weight	777.09
Therapeutic Function	X-Ray Contrast media

Iopamidol



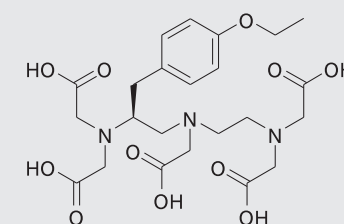
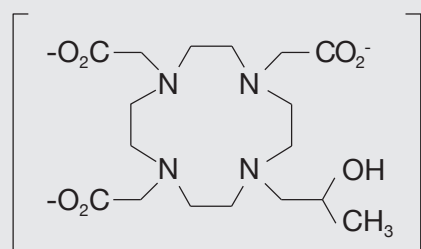
Items

Specifications (In-house)

Description	White or almost white crystalline powder, freely soluble in water
Identification	Concordant with the reference standard spectrum
Specific optical rotation	+0.05° ~ - 0.05° (as anhydrous basis)
Impurity	
Clarity of solution	Clear and no foreign matter is detected
Ethanol	Not more than 2,000 ppm
Related substances	Butrol : Not more than 0.05% Other related substances : Not more than 0.05% Total related substances : Not more than 0.30%
Free gadolinium	Not more than 0.01% (as anhydrous basis)
Heavy metals	Not more than 20 ppm
Bacterial endotoxins	Less than 1.3 EU/g
Water	Not more than 7.0 %
Content of gadolinium	255 ~ 265 mg/g
Assay	98.0~102.0% (as anhydrous basis)

Chemical Name	Gadolinium(III) 2,2'-[10-((2R,3S)-1,3,4-trihydroxybutan-2-yl)-1,4,7,10-tetraazacyclododecane-1,4,7-triyl]triacetate
Molecular Formula	C ₁₈ H ₃₁ GdN ₄ O ₉
Molecular Weight	604.72
Therapeutic Function	MRI Contrast media

Gadobutrol

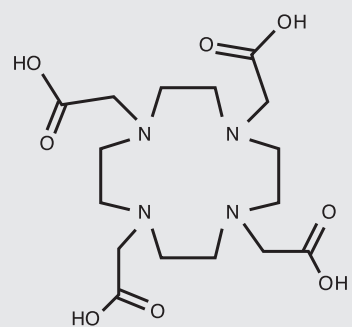


Items	Specification(JP)
Character	A white powder
Identification	Concordant with the reference standard spectrum
A : IR	Concordant with the reference standard spectrum
B : UV	7g/50mL in water
Test	
• pH	5.8 ~ 6.8
• Water	8 ~ 13%
• Purity	
1) transparency and color	transparent and no color
2) Heavy metals	Not more than 10 ppm
3) Related substance 1	
'- related compound A	Not more than 0.01%
4) Related substance 2	
'- Gadoteridol related compound (RRT 0.3)	Not more than 0.05%
'- Gadoteridol related compound (RRT 1.1)	Not more than 0.05%
'- Related compound (Except gadoteridol Related compound of RRT of 0.3, 1.1)	Not more than 0.20%
5) Related substance 3	
Free gadolinium(III)	Not more than 0.01%
Isomer ratio	Not more than 2.5%
Assay	97.0% ~ 101.0%(Anhydrous basis)
Chemical Name	(±)-[10-(2-hydroxypropyl)-1,4,7,10-tetraazacyclo-dodecane-1,4,7-triacetato(3-)]gadolinium Gadolinium, [10-(2-hydroxypropyl)-1,4,7,10-tetraazacyclododecane-1,4,7-triacetato(3-)-N1,N4,N7,N10,O1,O4,O7,O10]-
Molecular Formula	C ₁₇ H ₂₉ GdN ₄ O ₇
Molecular Weight	558.7
Therapeutic Function	MRI Contrast media

Items	Specifications (In-house)
Description	White or almost white powder
Identification	Concordant with the reference standard spectrum
Ionic compounds	
Total Impurity	Not more than 0.4%
Sulfate salt	Not more than 0.1%
Individual impurity	Not more than 0.1%
Related compounds	
Total impurity	Not more than 1.25%
HOB-DTPA	Not more than 0.3%
Individual impurity	Not more than 0.1%
Heavy metals (Pb)	Not more than 0.002%
Enantiomeric purity	Not less than 99%
Residue on ignition	Not more than 0.1%
Bacterial endotoxins	Less than 6.0 EU/g
Water	Not more than 15 %
Assay	97.5 ~ 102.0%
Chemical Name	(4S)-4-[4-Ethoxybenzyl]-3,6,9-tris(carboxylmethyl)-3,6,9-triazaundecanoic acid
Molecular Formula	C ₂₃ H ₃₃ N ₃ O ₁₁
Molecular Weight	527.53
Therapeutic Function	MRI Contrast media

Gadoteridol

Gadoxetate (EOB-DTPA)



Items

Specifications (In-house)

Description	Odorless, white powder										
Identification	The principal spot from the sample solution and the spot from the standard solution show the same color (reddish brown) and same Rf value (0.33)										
Purity	<table border="0"> <tr> <td>Clarity</td> <td>Transparent</td> </tr> <tr> <td>Chloride</td> <td>NMT 200ppm</td> </tr> <tr> <td>Sodium</td> <td>NMT 100ppm</td> </tr> <tr> <td>Potassium</td> <td>NMT 100ppm</td> </tr> <tr> <td>Water</td> <td>NMT 10.0%</td> </tr> </table>	Clarity	Transparent	Chloride	NMT 200ppm	Sodium	NMT 100ppm	Potassium	NMT 100ppm	Water	NMT 10.0%
Clarity	Transparent										
Chloride	NMT 200ppm										
Sodium	NMT 100ppm										
Potassium	NMT 100ppm										
Water	NMT 10.0%										
Assay	98.0–102.0% (anhydrous basis)										

Chemical Name	1,4,7,10-tetraazacyclododecane N,N',N'',N'''-tetraacetic acid
Molecular Formula	C ₁₆ H ₂₈ O ₈ N ₄
Molecular Weight	404.4
Therapeutic Function	MRI Contrast media

DOTA

