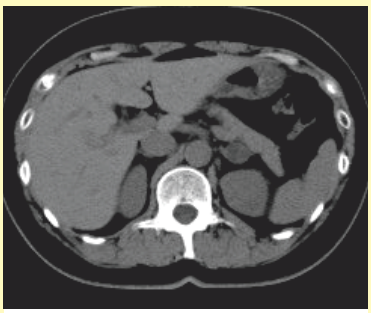
UNIPROMID

IOPROMIDE INJECTION USP

Low Osmolar Non-Ionic Water Soluble Iodinated Contrast Media

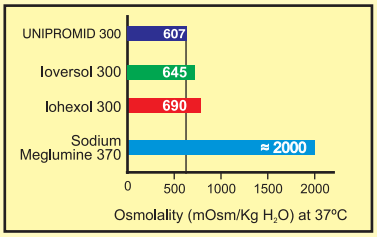
FOR INTRAVENOUS AND INTRA - ARTERIAL USE NOT FOR INTRATHECAL USE.

- Contrast agent for Intravascular administration opacifies vessels.
- Permitting radiographic Visualization of Internal Structures until significant hemodilutions occurs.
- Low Incidences of Adverse Reactions.
- Usage Convenience.



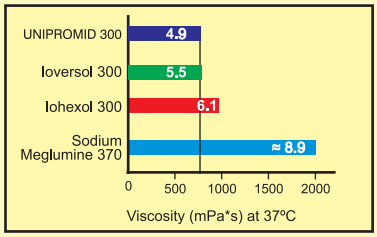
CT of abdomen without contrast. Note the lack of distinction between abdominal organs.

Comparative Osmolality

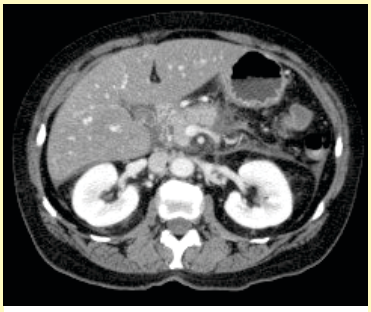


Lesser the Osmotic Pressure exerted by a contrast medium, better is the tolerance. High Osmolality is associated not only with pain and discomfort in injection but also with effects on the Haemodynamic System.

Comparative Viscosity



Lesser Viscosity in a contrast medium leads to lesser Haemodynamic changes. Low Viscosity ensures not only less pain and heat sensation but also ease of administration resulting in better patient compliance.



CT scan of abdomen with intravenous contrast. Notice how much better you can see the kidneys and blood vessels.

COMPOSITION	UNIPROMID 300	UNIPROMID 370
Iopromide	62.34%	76.88%
Iodine Concentration	300 mg/ml	370 mg/ml
pH	7.25 ± 0.75	7.25 ± 0.75
Viscosity (mPa*s)		
@ 37°C	4.9	10
@ 20°C	9.2	22
Osmolality (mOsm/g H_2O)		
@ 37°C	0.607	0.774

Painless ... Smooth ... Reliable

Indication	Concentration	Vessel / Volume
Guideline for intra-arterial administration Adults:		
Cerebral Arterigraphy	300 mg I/ml	Carotid arteries : 3 - 12 ml Vertebral arteries : 4 - 12 ml Aortic arch injection (4-vessel): 20 - 50 ml Not exceed 150 ml of cumulative dose.
Peripheral Arteriography	300 mg I/ml	Subclavian or femoral artery: 5 - 40 ml. Aortic bi function: 25 - 50 ml Not to exceed 250 ml of cumulative dose.
Coronary Arteriography and Left Ventriculography	370 mg I/ml	Right or left coronary artery: 5 - 40 ml left ventricle: 30 - 60 ml Not to exceed 225 ml of cumulative dose.
Visceral angiography	370 mg I/ml	Use volume and infusion rate proportional to blood flow and related to vascular and pathological characteristics of the specific vessels being studied. Not to exceed 225 ml cumulative dose.
Guideline for intravenous administration: Adults:		
Excretory Urography	300 mg I/ml	300 mg/kg, IV (with normal renal function) Not to exceed 100 ml cumulative dose
Contrast computed tomography Head Body (bolus Injection) Body (bolus Infusion)	300 mg I/ml	 50-200 ml 50-200 ml 100-200 ml Not to exceed 200 ml cumulative dose.
Contrast computed tomography Head Body (bolus Injection) Body (bolus Infusion)	370 mg I/ml	 41-162 ml 41-162 ml 81-162 ml Not to exceed 162 ml cumulative dose.
For pediatric patients:		
Cardiac chambers and related arteries	370 mg I/ml	< 2 years: Safety and efficacy not established. >2 years: Inject 1 to 2 ml/kg intra-arterial. Not to exceed cumulative dose of 4 ml/kg.
Contrast computerized tomography	300 mg I/ml	< 2 years: Safety and efficacy not established. >2 years: Inject 1 to 2 ml/kg IV. Not to exceed cumulative dose of 3 ml/kg.
Excretory Urography	300 mg I/ml	< 2 years: Safety and efficacy not established. >2 years: Inject 1 to 2 ml/kg IV. Not to exceed cumulative dose of 3 ml/kg.

DOSAGE AND ADMINISTRATION:

General:

It is desirable that solution of radiopaque diagnostic agents for intravascular use be at body temperature when injected. In the event that crystallization of the medium has occured, place the vial in hot (60° - 100°C) water for about five minutes, then shake gently to obtain a clear solution. Cool to body temperature before use. Discard vial without use if solids persist. Patients should be well hydrated prior to and following UNIPROMID administration.

CONTRAINDICATIONS:

Do not administer Iopromide Injection intrathecally. Inadvertent intrathecal administration may cause death, convulsions, cerebral hemorrhage, coma, paralysis, arachnoiditis, acute renal failure, cardiac arrest, seizures, rhabdomyolysis, hyperthermia, and brain edema.

Preparatory dehydration (for example, prolonged fasting and the administration of a laxative) before UNIPROMID Injection is contraindicated in pediatric patients because of risk of acute renal failure.

HOW SUPPLIED: Single dose vials of 50 ml and 100 ml.

STORAGE: UNIPROMID should be stored according to instruction on the label, protected from light and store at controlled room temperature.

Discard the unused portion.

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