

DIXANOL



IODIXANOL INJECTION USP

Isotonic - Water Soluble - Iodinated
Non-Ionic Contrast Media

Lower Osmolality.

Solutions of Iodixanol are Hypotonic to blood, sodium chloride & calcium chloride have been added to resulting in isotonic solution with blood.

Fewer & less severe osmolality related disturbances.

Less painful, heat & burning sensation.

Iodixanol injection has approximately one third the osmolality of non ionic media & one sixth of monomeric ionic media.

Osmolality 290 mOsm/kg water (Vp @ 37°C)



Contrast-enhanced CT image of the upper abdomen demonstrated two low attenuation areas (M) confirmed as multiple hepatic metastases from a gastrointestinal stromal tumor.

DIXANOL showed no significant metabolism in humans, did not cross intact blood brain barrier.

COMPOSITION	DIXANOL 150	DIXANOL 270	DIXANOL 320
Iodixanol	30.5%	55%	65.2%
Iodine Concentration	150 mg/ml	270 mg/ml	320 mg/ml
pH	7.25 ± 0.45	7.25 ± 0.45	7.25 ± 0.45
Viscosity (mPa*s)			
@ 37°C	1.7	6.3	11.8
@ 20°C	2.7	12.7	26.6
Osmolality (mOsm/Kg H ₂ O)			
@ 37°C	290	290	290



Painless ... Smooth ... Reliable

DOSAGE AND ADMINISTRATION:

The dosage may vary depending on the type of examination, the age, weight, cardiac output and general condition of the patient and the technique used. Usually approximately the same iodine concentration and volume is used as with other iodinated X-ray contrast media in current use, but adequate diagnostic information has also been obtained in some studies with iodixanol injection with somewhat lower iodine concentration. Adequate hydration should be assured before and after administration as for other contrast media. The product is for intravenous, intra-arterial and intrathecal use.

The following dosages may serve as a guide. The doses given for intra-arterial use are for single injections that may be repeated.

Guideline for Intra-arterial use

Indication	Concentration	Volume
Arteriographies; adults only Selective cerebral selective cerebral i.a DSA	270/320 ⁽¹⁾ mg I/ml 150 mg I/ml	5-10 ml per inj. 5-10 ml per inj.
Aortography Peripheral peripheral i.a. DSA selective visceral i.a. DSA	270/320 mg I/ml 270/320 mg I/ml 150 mg I / ml 270 mg I/ml	40-60 ml per inj. 30-60 ml per inj. 30-60 ml per inj. 10-40 ml per inj.
Cardioangiography, Adults Left ventricle and aortic root inj. Selective coronary arteriography Children	320 mg I/ml 320 mg I/ml 320 mg I/ml	30-60 ml per inj. 4-8 ml per inj. Depending on age, weight and pathology (recommended max total dose 10 ml/kg).

Guideline for Intra - arterial use

Indication	Concentration	Volume	Comments
Urography, Adults Children < 7 kg Children > 7 kg	270/320 mg I/ml 270/320 mg I/ml 270/320 mg I/ml	40-80 ml(2) 2 - 4 ml / kg 2-3 ml/kg	All dose depending on age, weight and pathology(max.50 ml)
Venography; adults only	270 mg I/ml	50-150 ml/leg	—
CT-enhancement CT of the head, adults CT of the body, adults Children, CT of the head and body	270/320 mg I/ml 270/320 mg I/ml 270/320 mg I/ml	50-150 ml 75-150 ml 2-3 ml/kg up to 50ml (in a few cases up to 150 ml may be given)	—

Guideline for Intrathecal use

Indication	Concentration	Volume
Lumbar and thoracic myelography (lumbar injection)	270 mg I/ml Or 320 mg I/ml	10-12 ml(3) 10 ml(3)
Cervical myelography (cervical or lumbar injection)	270 mg I/ml Or 320 mg I/ml	10-12 ml(3) 10 ml(3)

Guideline for Use in body cavities-

Indication	Concentration	Volume	Comments
Athrography, adults only	270 mg I/ml	1-15 ml	The dosage must be adjusted individually to allow optimal visualisation
Hysterosalpingography (HSG), adults only	270 mg I/ml	5-10 ml	The recommended dose may be exceeded several times, for example, there is significant backflow into the vagina (up to 40 ml has been studied)
Endoscopic retrograde cholangiopancreat- ography (ERCP), adults only.	270 mg I/ml	50-150 ml/leg	The recommended dose may be exceeded several times if the contrast medium is injected into the duodenum (up to 140 ml has been studied)

(1) Both strengths are documented, but 270 mg I/ml is recommended in most cases.

(2) In high-dose urography higher doses can be used.

(3) To minimize possible adverse reactions a total dose of 3.2 g iodine should not be exceeded.

PRESENTATION:

DIXANOL 150 : Single dose vial of 50 ml.

DIXANOL 270 : Single dose vial of 50 ml.

DIXANOL 320 : Single dose vial of 50 ml.

STORAGE:

DIXANOL should be stored according to instruction on the label, protected from light and secondary X rays. Preserve in well-closed, light-resistant containers. Store at 25°, excursions permitted between 15°C and 30°C. The product in glass containers of 50 ml and over in size may be stored at 37°C for up to three month prior to use.

Discard the unused portion. Do not use, if it contains particulate matter.

Do not freeze. Do not use if the product is inadvertently frozen.

CONTRAINDICATIONS:

Manifest thyrotoxicosis. History of serious hypersensitivity reaction to **DIXANOL**.