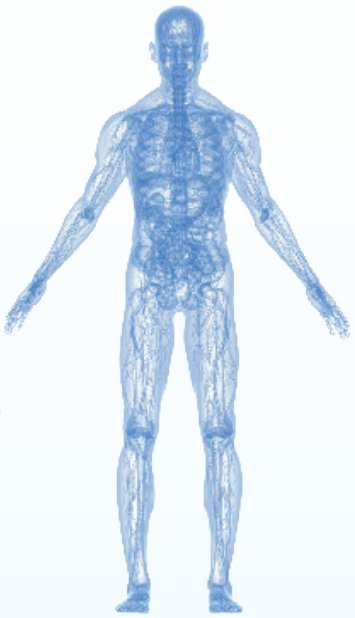
there's more to see...

# Unilux® (Iopamidol)

## Non-ionic, low-osmolar CT contrast media for intravenous or intra-arterial use

This medicinal product is for diagnostic use only, in adults, adolescents and children from childbirth onwards



### Unilux® 300 mg I/ml Solution for injection

Therapeutic indications:
X-Ray contrast media for:
- angiography
  (venography, arteriography, phlebography of the extremities)
- digital subtraction angiography (DSA)
- contrast enhancement in computed tomography (CT)
- urography
- retrograde contrast media investigations
- imaging of all body cavities
  (e.g. arthrography, hysterosalpingography, fistulography)

### Unilux® 370 mg I/ml Solution for injection

Therapeutic indications:
X-Ray contrast media for:
- angiography
  (venography, arteriography, phlebography of the extremities)
- digital subtraction angiography (DSA)
- contrast enhancement in computed tomography (CT)
- urography
- retrograde contrast media investigations
- imaging of all body cavities
  (e.g. arthrography, hysterosalpingography, fistulography)
- intraoperative cholangiography

Qualitative and quantitative composition

Active substance: Iopamidol

Unilux® 300 mg I/ml: 1 ml of solution for injection contains 612 mg Iopamidol corresponding to 300 mg Iodine

Unilux® 370 mg I/ml: 1 ml of solution for injection contains 755 mg Iopamidol corresponding to 370 mg Iodine

Excipients: Trometamol, Hydrochloric acid for pH adjustment, Sodium calcium edetate, Water for injections.

Nature and contents of container

Unilux® 300 mg I/ml and Unilux® 370 mg I/ml are available in:
50 ml, 75 ml, 100 ml, 200 ml and 500 ml glass vials or bottles; single packs, multi packs of 10 units (5 units for 500 ml). (Not all pack sizes may be marketed)

Marketing Authorisation Holder
Sanochemia Pharmazeutika AG
Boltzmanngasse 11
1090 Vienna, Austria

SANOCHEMIA Pharmazeutika AG
The Specialty Pharma Company

Contact: www.sanochemia.at • email: office@sanochemia.at • phone: +43-1-3191456-0

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According to the SmPC approved in Austria ("Country of Origin").

Note:
For further information please refer to your local SmPC

NAME OF THE MEDICINAL PRODUCT
Unilux 300 mg iodine/ml, solution for injection
Unilux 370 mg iodine/ml, solution for injection

QUALITATIVE AND QUANTITATIVE COMPOSITION
Unilux 300 mg iodine/ml:
1 ml contains:
Iopamidol 612 mg
Iodine concentration 300 mg/ml
Excipient:
sodium, contained in 0.39 mg/ml sodium calcium edetate

Unilux 370 mg iodine/ml:
1 ml contains:
Iopamidol 755 mg
Iodine concentration 370 mg/ml
Excipient:
sodium, contained in 0.48 mg/ml sodium calcium edetate

THERAPEUTIC INDICATIONS
This medicinal product is for diagnostic use only.

The recommended uses and dosages are for adult (for children, please refer to full local SmPC).

Unilux 300 mg iodine/ml:

- angiography (venography, arteriography, phlebography of the extremities): angiography of the large vessels (1 - 1.2 ml / kg bw), peripheral arteriography (30 - 50 ml), visualization of the cerebral vessels (5 - 10 ml), phlebography (30 - 50 ml)
- digital subtraction angiography (DSA): intra-arterially, intravenous (40 ml)
- contrast enhancement in computed tomography (CT): cranial CT (1 - 2 ml / kg bw), whole-body CT
- urography: intravenous (1 ml / kg bw), retrograde
- retrograde contrast media investigations
- imaging of all body cavities (e.g. arthrography, hysterosalpingography, fistulography)

Unilux 300 is used in adults, adolescents and children from childbirth onwards.

Unilux 370 mg iodine/ml:

- angiography (venography, arteriography, phlebography of the extremities): angiography of large vessels (0.8 - 1.2 ml / kg bw), peripheral arteriography, coronary angiography and laevo-cardiography (8 - 15 ml), left ventriculography (50 - 70 ml), phlebography
- digital subtraction angiography (DSA): intra-arterially, intravenous (40 ml)
- contrast enhancement in computed tomography (CT): cranial CT (1 - 1.5 ml / kg bw), whole-body CT
- urography: intravenous (0.8 ml / kg bw), retrograde
- retrograde contrast media investigations
- imaging of all body cavities (e.g. arthrography, hysterosalpingography, fistulography)
- intraoperative cholangiography

Unilux 370 is used in adults, adolescents and children from childbirth onwards.

DOSAGE AND METHOD OF ADMINISTRATION
General information
The volume and concentration of the administered contrast medium largely depend on the patient's age and weight, cardiac output, renal function, the patient's general condition, the organ/vascular region under investigation, the examination technique selected and technical equipment.

As a rule, the same iodine concentration and the same volume are used as with other conventional iodinated X-ray contrast media.

As with all contrast media, the lowest dose needed to achieve adequate imaging should be used.

In case of doubt, preference should be given to a higher concentration rather than a larger volume.

If diagnostic clarification requires several high individual doses, there should be an interval of 10 - 15 minutes prior to re-administering the contrast medium, even in patients who are adequately hydrated.

CONTRAINDICATIONS

- hypersensitivity to the active substance and/or iodine or to any of the excipients of the product listed in section 6.1. of the SmPC
- manifest hyperthyroidism.
- hysterosalpingography must not be performed in the presence of acute inflammatory processes in the pelvic cavity.
- manifest tetany.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties
Pharmacotherapeutic group: water-soluble, nephrotropic, low osmolar X-ray contrast media.
ATC code: V08AB04

PHARMACEUTICAL PARTICULARS
List of excipients
Trometamol, hydrochloric acid for pH adjustment, sodium calcium edetate, water for injections.

MARKETING AUTHORISATION HOLDER
Sanochemia Pharmazeutika AG
Boltzmanngasse 11
1090 Vienna
Austria

Medicinal product subject to medical prescription.