SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

IOMIDOL 300 mg I/ mL , solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Iopamidol USP.....612 mg

Iodine content.....300 mg

For 1 mL of solution

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Injectable solution

Clear, colorless to pale yellow, slightly viscous solution.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Radiological contrast product to be used for angiography, left ventriculography, coronary angiography, and urography.

4.2. Posology and method of administration

Posology

Treatment plan:

Procedure	Dosage
Peripheral arteriography Veinography	Adults 10 – 50 ml* Children * * Adults 20 – 50 ml Children * *
Angiocardiography and left ventriculography Left ventriculography	Adults 30 – 80 ml Children * *
Coronary arteriography	Adults 4 - 8ml per artery.
Retrograde aortography	Adults 30 – 80 ml Children * *
Selective renal arteriography Hepatic Celiac Superior mesenteric Inferior mesenteric	Adults 30 – 70 ml 40–70 ml 25–70 ml 5 – 30 ml Children * *
Selective visceral angiography Intravenous injection Left ventriculography Selective coronary angiography using intra-arterial DSA	Adults 30 – 70 ml Children's 40-70 ml Adults 25 – 70 ml Children 5 – 30 ml Adults 2 – 5 ml
Intravenous urography	Adults 40 – 80 ml In cases of severe renal insufficiency, the usual high-dose methods should be used (up to 1.5 ml/kg). Children 1 - 2.5ml/kg or * *

* Repeat if necessary * * Depending on size and age

Elderly: posology for adults.

The dosage must be adjusted according to the examination, the patient's age, body weight, cardiac output, renal function, general condition, and the technique used. Generally, the same concentration and volume of iodine are used with other common iodinated radiological contrast agents. As with all contrast agents, the lowest dose

necessary to achieve adequate visualization should be used.

Method of administration

- Intraventricular
- Intra-arterial
- Intravenous

No other medicine or contrast product should be mixed with the iopamidol injectable solution.

Peripheral arteriography and phlebography (veinography) : percutaneous injection into the appropriate blood vessel is used for visualization of peripheral arteries and veins.

Enhanced computed tomography : Contrast enhancement for brain scans can be achieved between one and three minutes after IV injection. Iomidol injection is also used for whole-body scintigraphy examinations after IV administration by bolus, drip infusion, or a combination of both methods.

Urography : the contrast agent is injected intravenously and rapidly eliminated by the kidneys. In patients with severe renal impairment, high-dose urography should be used.

4.3. Contraindications

Iopamidol is strictly contraindicated in patients with overt hyperthyroidism .

Hypersensitivity to the active substance iopamidol and/or iodine or to any of the excipients listed in section 6.1.

4.4. Special warnings and precautions for use

Diagnostic procedures involving the use of a contrast agent must be performed under the direction of personnel who have received the required training and have a thorough knowledge of the particular procedure to be performed.

Appropriate facilities must be available to deal with any complications of the procedure, as well as for the emergency treatment of a serious reaction to the contrast agent itself.

During the examination, an intravenous line must be available for emergency treatment in case of a reaction.

After administration of the contrast agent, competent personnel, medications and equipment for emergency resuscitation must be available for at least 30 minutes.

Caution is necessary during the injection of the contrast agent to avoid extravasation.

Local tissue irritation may occur in the event of perivascular infiltration of the contrast agent.

In patients with known or past epilepsy, anticonvulsant therapy should be maintained before and after myelographic procedures. In some cases, anticonvulsant therapy may be increased during the 48 hours preceding the examination. If a seizure occurs during the procedure, intravenous administration of diazepam or phenolbarbital is recommended. Iopamidol injection should be used with caution in patients with hypercalcemia and cerebrovascular disease.

The risk associated with a particular investigation may be increased by conditions such as advanced arteriosclerosis and hypertension.

The administration of iodinated contrast agents may worsen the symptoms of myasthenia gravis.

General anesthesia may be indicated in certain patients. However, a higher incidence of adverse effects has been reported in these patients, probably due to the hypotensive effect of anesthesia.

Like all other contrast agents, this product may cause anaphylaxis or other allergic reactions including nausea, vomiting, dyspnea, erythema, urticaria, and hypotension. Occasional severe reactions with fatal outcomes have been reported.

A history of allergy, asthma, or adverse reactions during previous similar examinations indicates the need for increased caution; the benefit must clearly outweigh the risk in these patients. Pretreatment with antihistamines or corticosteroids to prevent or minimize possible allergic reactions in these patients may be considered.

The risk of bronchospasm-inducing reactions in asthmatic patients is higher after the administration of contrast agents, particularly in patients taking beta-blockers.

In patients with suspected or confirmed hypersensitivity to contrast media, sensitivity testing is not recommended, as severe or fatal reactions to contrast media are not predictable from these tests.

The patient should also be informed that allergic reactions may develop up to several days after the procedure; in this case, a doctor should be consulted immediately.

Particular attention should be paid to patients with moderate to severe renal impairment (reflected by elevated blood urea). Substantial deterioration of renal function is minimized if the patient is well hydrated. Renal function parameters, especially urine output, should be monitored post-procedure in these patients. Pre-existing renal insufficiency may predispose to acute renal dysfunction following contrast administration.

In patients with impaired renal function, the administration of potentially nephrotoxic drugs should be avoided until the contrast agent is completely excreted. In these patients, renal function parameters should be monitored post-procedure. Any further administration of contrast agent should be postponed until renal function has returned to its pre-existing level. In these patients, maintaining hydration is important to minimize further deterioration of renal function. Patients undergoing dialysis may receive contrast agents such as iopamidol , which can be easily removed by dialysis.

Patients with severe hepatic, renal, or combined hepatorenal insufficiency should not be examined unless absolutely necessary. A repeat examination should be postponed for 5 to 7 days.

The presence of kidney damage in diabetic patients is one of the predisposing factors for renal failure after the administration of contrast agents. This can precipitate lactic acidosis in patients taking metformin. Patients must be adequately hydrated before and after radiographic procedures. Patients with severe liver or myocardial dysfunction, myelomatosis, diabetes, polyuria or oliguria, hyperuricemia, infants, elderly patients, and patients with severe systemic disease should not be exposed to dehydration.

Fluid intake should not be restricted and any abnormalities in fluid or electrolyte balance should be corrected before using this hypertonic solution.

Patients with Waldenström's paraproteinemia, multiple myeloma, or severe hepatic and renal insufficiency are also at greater risk: in these cases, adequate hydration is recommended after administration of the contrast agent.

Contrast agents can exacerbate sickle cell disease in individuals homozygous for sickle cell disease when administered intravenously or intra-arterially. To prevent crises in patients with sickle cell disease, adequate hydration must be ensured, and a minimal volume of low-concentration contrast agent should be used.

Patients with congestive heart failure should be observed for several hours after the procedure to detect delayed hemodynamic disturbances, which may be associated with a transient increase in circulating osmotic load.

In patients undergoing angiocardiography procedures, particular attention must be paid to the condition of the right heart and pulmonary circulation. Right heart failure and pulmonary hypertension can precipitate bradycardia and systemic hypotension upon injection of the organic iodine solution. Right heart angiography should only be performed when absolutely necessary.

Ventricular arrhythmias may occur infrequently during intracardiac and/or coronary arteriography.

Caution should be exercised when performing examinations with iodinated contrast media in patients with or suspected of having hyperthyroidism or autonomously functioning thyroid nodule(s), as thyrotoxic crises have been reported following the administration of iodinated contrast media.

Iomidol should be used with caution in patients with hyperthyroidism. Hyperthyroidism may recur in patients previously treated for Graves' disease.

In patients undergoing thyroid examination with a radioactive iodine-based tracer, consideration should be given that iodine uptake in the thyroid gland will be reduced for several days (up to two weeks) after administration of an iodinated contrast agent that is eliminated by the kidneys.

Patients with pheochromocytoma may develop a severe hypertensive crisis following intravascular administration of iopamidol. Premedication with alpha-receptor blockers is recommended.

During angiographic procedures, the possibility of dislodging the plaque or damaging or perforating the vessel wall must be considered during catheter manipulation and contrast agent injection. Test injections are recommended to ensure correct catheter placement.

In aortic arch examinations, the catheter tip must be positioned carefully to avoid hypotension, bradycardia, and CNS damage due to excessive pressure transmitted by the injector pump to the brachiocephalic branches of the aorta.

Angiography should be avoided whenever possible in patients with homocystinuria due to an increased risk of thrombosis and embolism. In patients undergoing peripheral angiography, there must be a pulse in the artery into which the radiological contrast agent will be injected. In patients with thromboangiitis obliterans or ascending infections associated with severe ischemia, angiography should be performed, if indicated, with particular caution.

In patients undergoing venography , particular caution is required in patients with suspected phlebitis, severe ischemia, local infections, or complete venous occlusion.

Serious neurological events have been observed following direct injection of contrast agents into cerebral arteries or vessels supplying the spinal cord, or in angiocardiography due to accidental filling of the carotid arteries.

IOMIDOL should be administered with caution in elderly patients, patients with symptomatic cerebrovascular disease , recent stroke or frequent transient ischemic attack (TIA), impaired blood-brain barrier permeability, increased intracranial pressure, suspected intracranial tumor, abscess or hematoma/hemorrhage, history of seizure disorders, chronic alcoholism or multiple sclerosis.

Patients with these conditions have an increased risk of neurological complications.

Vasospasm and subsequent cerebral ischemic phenomena may be caused by intra-arterial injections of contrast agents.

Intrathecal administration :

A precise risk/benefit assessment is necessary if, based on the clinical history, there is a history of epilepsy or in the presence of blood in the cerebrospinal fluid or in the presence of a local or systemic infection where bacteremia is likely.

The contrast agent should be removed as much as possible in case of blockage of the cerebrospinal fluid.

Pediatric population :

Infants (under 1 year old), and especially newborns, are particularly sensitive to electrolyte imbalances and hemodynamic changes. Care should be taken regarding the dosage used, the details of the procedure, and the patient's condition.

When examining young children or babies, do not restrict fluid intake before administering a hypertonic contrast solution. Any existing fluid and electrolyte imbalances should also be corrected.

In pediatric roentgenology , great care should be taken when injecting contrast medium into the right heart chambers of cyanotic newborns with pulmonary hypertension and impaired cardiac function.

In newborns, and especially in premature infants, it is recommended to monitor thyroid function tests (TSH and T4) 7-10 days and 1 month after administration of iodinated contrast agents, due to the risk of hypothyroidism due to iodine overload.

Geriatrics :

Elderly patients are particularly susceptible to adverse reactions due to reduced physiological function, especially when high doses of contrast agents are used. Myocardial ischemia, major arrhythmias, and premature ventricular complexes are more likely to occur in these patients. The likelihood of acute renal failure is also higher in these patients.

Women of childbearing age :

Radiological examinations of women should, if possible, be performed during the pre-ovulatory phase of the menstrual cycle and should be avoided during pregnancy. Appropriate investigations and measures must be taken when women of childbearing age are exposed to any radiological examination, with or without contrast medium.

4.5. Interactions with other medicinal products and other forms of interaction

Associations not recommended

To prevent the occurrence of lactic acidosis in diabetic patients under treatment with oral antidiabetic drugs of the biguanide class, biguanides should be stopped 48 hours before administration of the contrast agent and restarted only after it has been demonstrated that renal function has returned to pre-examination values.

Associations to consider

Cardiac and/or hypertensive patients undergoing treatment with diuretics, angiotensin-converting enzyme (ACE) inhibitors and/or beta-blockers are at higher risk of adverse effects when iodinated contrast agents are administered.

Arterial thrombosis has been reported when iopamidol was administered after papaverine.

The administration of vasopressors strongly potentiates the neurological effects of intra-arterial contrast agents.

Renal toxicity has been reported in patients with hepatic dysfunction who received oral cholecystographic agents followed by intravascular contrast agents. Therefore, the administration of intravascular contrast agents should be postponed in patients who have recently received a cholecystographic contrast agent .

In patients receiving beta-blockers, there is a high risk of more severe anaphylactoid reactions.

Following administration of iopamidol , atypical adverse reactions, for example erythema, fever and flu-like symptoms, have been reported in patients treated with interleukin-2.

Interference with diagnostic tests

Contrast agents can interfere with laboratory tests for bilirubin, protein, or inorganic substances (e.g., iron, copper, calcium, and phosphate). These substances should not be measured on the same day as the contrast agent administration.

After administration of iopamidol , the thyroid tissue's ability to absorb iodine is reduced for 2 to 6 weeks. Use of this product may interfere with thyroid function tests.

4.6. Fertility, pregnancy and breastfeeding

Radiological examination of women should, if possible, be carried out during the pre-ovulation phase of the menstrual cycle .

Pregnancy

Radiological examinations should be avoided during pregnancy; furthermore, since IOMIDOL has not been shown to be safe for pregnant women, it should only be administered if the procedure is considered essential by the physician. In addition to fetal radiation exposure, the risk/benefit balance of iodine-containing contrast agents must also take into account the sensitivity of the fetal thyroid to iodine.

Breastfeeding

Iodine-containing radiological contrast agents are excreted in breast milk in small amounts. Based on animal studies, IOMIDOL is not toxic to animals after oral administration. Based on current experience, harm to the breastfed infant is unlikely. Discontinuation of breastfeeding is not necessary.

4.7. Effects on the ability to drive vehicles and use machinery

There is no known effect on the ability to drive and use machines. However, due to the risk of early reactions, it is not recommended to drive or operate machinery within one hour of the last intravascular injection.

4.8. Undesirable effects

The use of iodinated contrast agents can cause undesirable side effects. These are generally mild to moderate and transient in nature. However, serious and life-threatening reactions, sometimes leading to death, have been reported.

Anaphylaxis (anaphylactoid/hypersensitivity reactions) may manifest as: mild localized or more diffuse angioedema, tongue swelling, laryngospasm or laryngeal edema, dysphagia, pharyngitis and throat tightness, pharyngolaryngeal pain, cough, conjunctivitis, rhinitis, sneezing, a feeling of warmth, increased sweating, asthenia, dizziness, pallor, dyspnea, wheezing, bronchospasm, and moderate hypotension. Skin reactions may occur in the form of various types of rashes, diffuse erythema, diffuse vesicles, urticaria, and pruritus. These reactions, which occur regardless of the dose administered and the route of administration, may represent the first signs of an impending shock. Administration of the contrast agent must be stopped immediately and—if necessary—specific treatment should be initiated via intravenous access.

Following intravascular administration, reactions usually occur within minutes of the dose. However, delayed reactions, generally involving the skin, may occur, most often within 2 to 3 days, and more rarely within 7 days, after administration of the contrast agent.

Following intrathecal administration, most side effects occur with a delay of a few hours due to the slow absorption from the administration site and distribution throughout the body. Reactions generally occur within 24 hours of injection.

More severe reactions involving the cardiovascular system, such as vasodilation with pronounced hypotension, tachycardia, dyspnea, agitation, cyanosis, and loss of consciousness progressing to respiratory and/or cardiac arrest, can be fatal. These events can occur rapidly and require aggressive and comprehensive cardiopulmonary resuscitation.

Primary circulatory collapse may be the only presentation and/or the initial presentation without respiratory symptoms or without other signs or symptoms described above.

Intravascular administration :

Adult subjects: The number of adult patients who participated in clinical trials with intravascular administration of Iopamidol was 2,548, including 1,597 with intra-arterial administration and 951 with intravenous administration.

System/organ	Side effects	
	Clinical trials	Post-marketing

				monitoring
	Common (≥1/100 to <1/10)	**Unusual (≥ 1/1,000 to <1/100)**	**Rare (≥ 1/10,000 to <1/1,000)**	**Frequency unknown**
Blood and lymphatic system disorders				Thrombocytopenia
Immune system disorders				Anaphylaxis, anaphylactic reactions
Psychiatric disorders			Confusional state	
Nervous system disorders	headaches	Dizziness, altered taste	Paresthesia	Coma, Transient ischemic attack, Syncope, Depression of consciousness or loss of consciousness, Seizure,
Visual disturbances				Vision problems Conjunctivitis, photophobia Transient blindness
Heart problems		Cardiac dysrhythmias such as extrasystoles, atrial fibrillation, ventricular tachycardia and ventricular fibrillation*.	Bradycardia	Ischemic myocardial infarction, Heart failure, Cardiopulmonary arrest, Tachycardia
Vascular disorders		Hypotension, Hypertension, Hot Flashes		Circulatory collapse or shock
Respiratory, thoracic and mediastinal disorders			Pulmonary edema, Asthma, Bronchospasms	Respiratory arrest, respiratory failure, acute respiratory distress syndrome, respiratory distress, apnea, laryngeal edema, dyspnea
Gastrointestinal disorders	Nausea	Vomiting, diarrhea, abdominal pain, dry mouth		Excessive salivary secretion, Enlarged salivary glands
Skin and subcutaneous tissue disorders		Skin rash, hives, itching, erythema, increased sweating.		Facial edema, mucocutaneous syndrome **
Musculoskeletal and connective tissue disorders		Back pain	Muscle spasms	Musculoskeletal pain , muscle weakness
Kidney and		Acute renal		

urinary problems		failure		
General issues and conditions of the administration site	Sensation of warmth	Chest pain, Pain at the injection site***, Fever, Feeling cold		Stiffness, pain, discomfort
Investigations		Elevated blood creatinine		Changes in the electrocardiogram, particularly ST segment depression

* Cardiac reactions may occur as a result of the risks associated with the coronary catheterization procedure: these complications include coronary thrombosis and embolism.

** As with other iodinated contrast agents, very rare cases of mucocutaneous syndromes, including Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome) and erythema multiforme, have been reported following the administration of Iopamidol

*** Pain and swelling at the injection site may occur. In most cases, these are due to extravasation of the contrast agent. These reactions are generally transient and result in complete healing. However, inflammation and even skin necrosis have been observed in very rare cases. In some isolated cases, extravasation has led to the development of compartment syndrome.

Pediatric population

The safety profile of Iopamidol is similar in children and adults.

Administration into the body cavity

The majority of reactions occur a few hours after administration of the contrast agent due to the slow absorption from the administration site and distribution in the body.

An increase in blood amylase is common after ERCP. Very rare cases of pancreatitis have been described. Reactions reported in cases of arthrography and fistulography generally represent irritative manifestations superimposed on existing tissue inflammation.

Systemic hypersensitivity is rare, usually mild, and manifests as skin reactions. However, the possibility of severe anaphylactoid reactions cannot be ruled out.

Reporting suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals report any adverse effects suspected unwanted substance via the FRILAB declaration form available under the tab pharmacovigilance information from the website : www.frilab.ch

4.9. Overdose

Dosages exceeding the specific dose in the leaflet are not recommended, as they could lead to adverse effects that may be life-threatening.

If necessary, hemodialysis can be used to remove iopamidol from the body. Treatment of overdose aims to support all vital functions and to rapidly initiate symptomatic treatment.

Intravascular

In case of accidental intravascular overdose in humans, water and electrolyte losses must be compensated by infusion. Renal function should be monitored for at least three days.

Intrathecal

Signs of intrathecal overdose may include: ascending hyperreflexia or tonic -clonic spasms , which may progress to generalized seizures and, in severe cases of central involvement, hyperthermia, stupor and respiratory depression.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic properties

Pharmacotherapeutic class: Iodine contrast agents code ATC : V08AB04

Iopamidol is a contrast agent belonging to the new generation of non-ionic compounds whose solubility is due to the presence of hydrophilic substitutes in the molecule. This results in a solution with low osmolality compared to ionic

media.

Iopamidol has proven effective as a radiological contrast agent in neuroradiology, angiography, venography , arthrography, urography, cerebral angiography and left ventriculography and coronary angiography.

Efficiency and clinical security

Its toxicity, particularly on the heart and CNS, is lower than that of ionic contrast agents.

5.2. Pharmacokinetic properties

The pharmacokinetics of iopamidol are consistent with an open two-compartment pharmacokinetic model with first-order elimination.

Distribution

The distribution volume is equivalent to the extracellular fluid

Elimination

Elimination occurs almost entirely via the kidneys. Less than 1% of the administered dose was recovered in the feces up to 72 hours after administration. Elimination is rapid; up to half of the administered dose can be recovered in the urine within the first two hours following administration. There is no evidence of biotransformation.

Binding to serum proteins is negligible.

5.3. Preclinical safety data

Animal toxicology studies do not allow us to predict any adverse effects other than those documented during the use of iopamidol in humans.

6. PHARMACEUTICAL PARTICULARS

6.1. List of the excipients

Trometamine , calcium disodium edetate , hydrochloric acid and water for injection.

6.2. Incompatibilities

Without object.

6.3. Shelf life

2 years.

6.4. Special precautions for storage

Store at controlled room temperature between 20°C and 25°C, excursion permitted to 15-30°C.

Do not freeze. Protect from light and secondary X-rays. Keep out of reach of children.

6.5. Nature and contents of container

100 mL in a bottle (glass); box of 1

50 mL in a bottle (glass); box of 1

6.6. Special precautions for disposal and handling

Any unused medicinal product or waste material should be disposed of in accordance with local regulations.

7. OPERATORS AND MANUFACTURERS

Operator of the export marketing authorization

FRILAB SA

17, rue des Pierres du Niton

1207 Geneva SWITZERLAND

Manufacturer

LIVEALTH BIOPHARM PVT LTD

Administrative site :

Regd . Off.- 77, Ratne Jyot Industrial Premises , Irla Gaothan, Vile Parle (West)

Mumbai – 400056, Maharashtra

India

Manufacturing site :

D-82, MIDC Area, Cross road No. 4-A

Hingna , Nagpur – 440028 Maharashtra

India

8. DATE OF REVISION OF THE TEXT

February 2026.

9. DOSIMETRY

Not applicable.

CONDITIONS FOR PRESCRIPTION AND DISPENSING

List I