

**READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE
PATIENT MEDICATION INFORMATION**

ULTRAVIST®

iopromide injection

ULTRAVIST® 240

(iopromide injection 50% w/v, 240mg I/ml)

ULTRAVIST® 300

(iopromide injection 62% w/v, 300mg I/ml)

ULTRAVIST® 370

(iopromide injection 77% w/v, 370mg I/ml)

For Professional Use Only

Read this carefully before you start taking **ULTRAVIST** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **ULTRAVIST**.

What is ULTRAVIST used for?

- ULTRAVIST is a contrast medium for radiographic (X-ray) or computed tomography (CT) examinations.
- ULTRAVIST is for diagnostic use only.

How does ULTRAVIST work?

ULTRAVIST contains iodine. X-rays are unable to pass through contrast media because they are absorbed by the iodine. The areas of your body where ULTRAVIST is distributed after it is injected into your bloodstream, or joint, or a body cavity, become visible during the X-ray or CT examination. Depending on the mode of administration and the administered strength, ULTRAVIST provides visualization of the veins and arteries, detection of abnormalities in the urinary system, kidney, brain, spine, heart, joints and body cavities.

What are the ingredients in ULTRAVIST?

Medicinal ingredients: iopromide

Non-medicinal ingredients: calcium disodium edetate (EDTA), hydrochloric acid and tromethamine.

ULTRAVIST comes in the following dosage forms:

ULTRAVIST is an aqueous solution for injection into a vein or body cavity. It is supplied in three strengths. ULTRAVIST 240 provides 499 mg of iopromide per mL (equal to 240 mg of organically bound iodine per mL). ULTRAVIST 300 provides 623 mg of iopromide per mL (equal to 300 mg of organically bound iodine per mL). ULTRAVIST 370 provides 769 mg of iopromide per mL (equal to 370 mg of organically bound iodine per mL).

ULTRAVIST is packaged in vials.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take ULTRAVIST. Talk about any health conditions or problems you may have, including if you:

- You have had a previous reaction to contrast media
- You suffer or have suffered from an allergy (eg, seafood allergy, hay fever, hives) or bronchial asthma
- You are allergic (hypersensitive) to iopromide or to any of the other ingredients of ULTRAVIST
- Your kidneys do not work properly
- You have disturbances of both kidney and liver function
- You are taking medicine that affects your kidney function
- You have had a kidney transplant
- You suffer from dehydration
- You have diabetes
- You have heart disease or circulatory disease
- You suffer from a vascular condition in which you have clotting of some small blood vessels in the hands or feet (Buerger's disease or thromboangiitis obliterans)
- You have high blood pressure (hypertension)
- You have a special kind of high blood pressure caused by a rare tumour of the adrenal gland which sits near the kidney (pheochromocytoma)
- You have, or you are suspected to have a thyroid gland that is overactive, or you have a thyroid nodule, or you have a swelling of the neck caused by enlargement of the thyroid gland (bland nodular goiter)
- You have a circulatory problem in the brain (for example, cerebral arteriosclerosis or cerebral artery spasm)
- You suffer from brain conditions with seizures or from other diseases of the nervous system
- You suffer from a condition where you have increased intracranial pressure or a disrupted blood-brain barrier
- You suffer from cancer of the blood cells (multiple myeloma)
- You suffer from an overproduction of special proteins (paraproteinemia)
- You suffer from a harmful accumulation of homocysteine in the body (homocystinuria)
- You have sickle cell disease
- You have a breathing condition where too much air collects deep in the lungs (pulmonary emphysema)
- You suffer from a condition in which the muscles become weak and tire easily (myasthenia gravis)
- You are pregnant or think you might be pregnant (even if you are not sure)
- You are breast-feeding or intend to breast-feed, since breast-feeding should be stopped for 48 hours following ULTRAVIST administration
- You are planning to have a special procedure to allow your doctor to visualize your gallbladder (oral cholecystography)
- Before you receive ULTRAVIST, your doctor will screen you for the function of your kidneys in order to decide whether the intended examination is possible or not.

Other warnings you should know about:

Thyroid Function

Contrast media containing iodine, such as ULTRAVIST, may change thyroid activity in some patients, both in adults and infants. This may cause:

- hypothyroidism (i.e. too little thyroid hormones in the blood)
- or
- hyperthyroidism (i.e. too much thyroid hormones in the blood)

Thyroid Function in infants

Contrast media containing iodine may cause hypothyroidism in infants, especially infants born too soon that:

- can continue for several weeks to a month after treatment
- can harm growth and development
- can harm mental growth
- may require treatment
- can cause symptoms such as:
 - fatigue, shortness of breath, low heart rate
 - reduced appetite, feeling cold, weight gain
 - muscle stiffness

Contact your doctor if these symptoms happen to your infant.

Your doctor may order blood tests for your infant after treatment to follow thyroid hormone levels in the blood.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with ULTRAVIST:

- beta-blockers (medicines used to treat high blood pressure or other heart conditions)
- biguanides (eg, metformin - a medicine used to treat diabetes)
- interleukin
- radioactive substances for the thyroid gland
- Your doctor will advise you how to take these medicines before the examination.
- Some medical tests (eg, thyroid function tests, blood tests for clotting [coagulation] or blood clot breakdown [fibrinolysis] or tests for complement proteins [involved in immunity and inflammation]) may be affected by the use of ULTRAVIST. Tell your doctor if you have any of these tests scheduled.

How to take ULTRAVIST:

ULTRAVIST will be given to you by a healthcare professional who is experienced in the use of radiopharmaceuticals.

Usual dose:

- Your doctor will make sure that you receive enough fluid before your examination.
- You may be given an enema or laxative on the evening before your CT or X-ray examination.

- The actual dose (volume) of ULTRAVIST that is right for you will be worked out by your health professional and will depend on your age, body weight and the type of examination that is being done. The speed at which ULTRAVIST is injected, and the length of time until the X-rays or CT are taken will also depend of the type of X-ray or CT being done.

Overdose:

If you think you have taken too much ULTRAVIST, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

Overdosing is unlikely. If it does happen, your doctor will treat any symptoms that follow.

What are possible side effects from using ULTRAVIST?

These are not all the possible side effects you may feel when taking ULTRAVIST. If you experience any side effects not listed here, contact your healthcare professional.

Like all medicines, ULTRAVIST can cause side effects, although not everybody gets them.

The most common side effect of ULTRAVIST is having a sensation of warmth.

Common side effects observed in clinical trials (between 1 and 10 in every 100 patients are likely to get these):

- sensation of warmth (severe)
- sensation of pain (slight to moderate)
- feeling sick (nausea), vomiting, diarrhea

Uncommon side effects observed in clinical trials (between 1 and 10 in every 1 000 patients are likely to get these):

- severe sensation of pain
- restlessness/anxiety
- pins and needles of the arm or face (paresthesia)
- sensation of whirling/dizziness (vertigo)
- taste sensation (dysgeusia)
- headache
- shoulder pain
- numbness
- sore throat

Side effects reported from postmarketing experience:

- palpitations,
- hearing disorders, hearing disturbances
- discomfort in bright light (photophobia), pressure over the eyes
- stomach (abdominal) pain
- swelling of salivary glands, throat irritation
- change in body temperature. chills, shivers, sweating
- feeling unwell (malaise)
- paleness (pallor)
- tight muscles (hypertonia)
- decreased sensation (hypoesthesia)
- tremor
- agitation
- runny nose (rhinitis)

Serious side effects and what to do about them		
Symptom/ Effect	Talk to your healthcare professional	
	Only if severe	In all cases
UNCOMMON		
Collapse (including vasovagal reactions)		✓
Low blood pressure (hypotension), high blood pressure (hypertension)	✓	
Serious allergy-like (anaphylactoid) reactions, sometimes fatal, with symptoms such as shock, swelling of the throat, face, tongue, lips (laryngeal/pharyngeal/tongue/face edema, angioedema, Quincke's edema, Laryngeal spasm, mucosal swelling), difficulty swallowing (dysphagia), difficulty in breathing (respiratory symptoms, bronchospasm, dyspnea, asthma), hives (urticaria), coughing, sneezing, redness of the eyes (conjunctivitis). Blurred/disturbed vision, tearing (lacrimation)		✓
Swelling or pain around the knee	✓	
SIDE EFFECTS FROM POSTMARKETING EXPERIENCE		
Blood clots (thromboembolic events, venous thrombosis)		✓
Blood vessel inflammation (thrombophlebitis, vasculitis (severe))		✓
Chest pain/ discomfort (myocardial ischemia/ infarction)		✓
Heart stopped (cardiac arrest)		✓
Inflammation and tissue injury at injection site, in case of extravasation	✓	
Lips turning blue (cyanosis)		✓
Memory loss (amnesia)		✓
Paresis/paralysis		✓
Possible heart rhythm disturbance (rapid or slow heart beat)	✓	
Redness of the skin (erythema and/or vasodilation), itching (pruritus), rash	✓	
Seizure (convulsion)		✓
Stevens Johnson's or Lyell syndrome with symptoms such as redness, pain swelling or blistering of the skin		✓
Stroke, with symptoms including but not limited to sudden onset headache and/or weakness, difficulty speaking, blurred vision, sleepiness (somnolence), confusion		✓
Temporary loss of vision (transient cortical blindness)		✓

Serious side effects and what to do about them		
Taking foreign material into lungs (aspiration)	✓	
Pressure in muscle and related tissue with symptoms such as pain, hardness, swelling, and “pins and needles” feeling, related to the condition known as compartment syndrome where a significant volume of the contrast agent has escaped into the tissues, and can be life-threatening		✓

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

ULTRAVIST should be stored between 15°C and 30°C and protected from light.

If you want more information about ULTRAVIST:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the manufacturer’s website <http://www.bayer.ca> or by calling Bayer Medical Information at 1-800-265-7382 or canada.medinfo@bayer.com.

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