CONSUMER INFORMATION

ULTRAVIST®
Iopromide injection

ULTRAVIST® 240
(iopromide injection 50% w/v, 240 mg I/mL)

ULTRAVIST® 300
(iopromide injection 62% w/v, 300 mg I/mL)

ULTRAVIST® 370
(iopromide injection 77% w/v, 370 mg I/mL)

For Professional Use Only
This leaflet is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about ULTRAVIST. Contact your health professional if you have any questions about the drug.

ABOUT THIS MEDICATION

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

What it does:
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.

When it should not be used:
- If you are allergic (hypersensitive) to iopromide or to any of the other ingredients of ULTRAVIST (see below for “What the important nonmedicinal ingredients are”).
- If you have, or if you are suspected to have a thyroid gland that is overactive (manifest hyperthyroidism)

What the medicinal ingredient is:
iopromide

What the important nonmedicinal ingredients are:
Calcium disodium edetate, hydrochloric acid, tromethamine.

What dosage forms it comes in:
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.

WARNINGS AND PRECAUTIONS

BEFORE you are given ULTRAVIST, talk to your doctor if any of the following situations apply to you. Your doctor will decide whether the intended examination is possible or not:
- 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 suffer from 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 (lump 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.

INTERACTIONS WITH THIS MEDICATION
Tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Some medicines may affect the way ULTRAVIST works in your body. These include:
• 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.

PROPER USE OF THIS MEDICATION

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.

ULTRAVIST is injected by a doctor via a needle into a vein or a body cavity. ULTRAVIST will be administered immediately before your examination and may be warmed to body temperature.

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

SIDES EFFECTS AND WHAT TO DO ABOUT THEM
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, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

<table>
<thead>
<tr>
<th>Symptom / Effect</th>
<th>Talk with your doctor</th>
<th>Only if severe</th>
<th>In all cases</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Uncommon</strong></td>
<td></td>
<td></td>
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<tr>
<td>Collapse (including vasovagal reactions)</td>
<td></td>
<td></td>
<td>✓</td>
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<tr>
<td>Low blood pressure (hypotension), high blood pressure (hypertension)</td>
<td>✓</td>
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<tr>
<td>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)</td>
<td></td>
<td></td>
<td>✓</td>
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<tr>
<td>Swelling or pain around the knee</td>
<td>✓</td>
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<tr>
<td><strong>Side effects from postmarketing experience</strong></td>
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<tr>
<td>Blood clots (thromboembolic events, venous thrombosis)</td>
<td>✓</td>
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<td>✓</td>
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<td>Blood vessel inflammation (thrombophlebitis, vasculitis (severe))</td>
<td>✓</td>
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<td>✓</td>
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<td>Chest pain/ discomfort (myocardial ischemia/infarction)</td>
<td>✓</td>
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<td>Heart stopped (cardiac arrest)</td>
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<td>✓</td>
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<td>Inflammation and tissue injury at injection site, in case of extravasation</td>
<td>✓</td>
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<td>✓</td>
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<td>Lips turning blue (cyanosis)</td>
<td>✓</td>
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<td>Memory loss (amnesia)</td>
<td>✓</td>
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<td>✓</td>
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<td>Paresis/paralysis</td>
<td>✓</td>
<td></td>
<td>✓</td>
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<td>Possible heart rhythm disturbance (rapid or slow heart beat)</td>
<td>✓</td>
<td></td>
<td>✓</td>
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<td>Redness of the skin (erythema and/or vasodilation), itching (pruritus), rash</td>
<td>✓</td>
<td></td>
<td>✓</td>
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<tr>
<td>Seizure (convulsion)</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Stevens Johnson’s or Lyell syndrome with symptoms such as redness, pain swelling or blistering of the skin</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

This is not a complete list of side effects. For any unexpected effects during and after receiving ULTRAVIST, contact your health professional.

### HOW TO STORE IT

ULTRAVIST should be stored at temperatures between 15°C and 30°C. Protect from light.
REPORTING SUSPECTED SIDE EFFECTS

Canada Vigilance Program:
You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

Report online at www.healthcanada.gc.ca/medeffect
Call toll-free at 1-866-234-2345
Complete a Canada Vigilance Reporting Form and:
  • Fax toll-free to 1-866-678-6789, or
  • Mail to: Canada Vigilance Program
    Health Canada
    Postal Locator 0701E
    Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, please contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION
For more information, please contact your health professional or pharmacist first, or Bayer Medical Information at 1-800-265-7382 or Canada.medinfo@bayer.com.

This document plus the full Product Monograph, prepared for health professionals can be found at: http://www.bayer.ca or by contacting the manufacturer at the above-mentioned phone number and email address.

This leaflet was prepared by:

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