

## PRESCRIBING INFORMATION

<b>NAME OF DRUG:</b>	TELEBRIX® 38 ORAL
<b>PROPER NAME:</b>	Meglumine Ioxitalamate and Sodium Ioxitalamate Oral Solution 77%
<b>PHARMACOLOGY CLASSIFICATION:</b>	Oral Radiopaque Contrast Medium for Dilution

Liebel-Flarsheim Canada Inc.  
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Control No. 203737

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## **NAME OF DRUG**

Telebrix® 38 Oral  
(Meglumine Ioxitalamate and Sodium Ioxitalamate Oral Solution 77% w/v)

## **THERAPEUTIC CLASSIFICATION**

Oral Radiopaque Contrast Medium for Dilution

## **ACTION**

When diluted to a 2% solution as directed, Telebrix® 38 Oral is an oral contrast medium for use as a bowel opacifier during CT scanning of the abdomen and pelvis. A bowel lumen which is adequately opacified with contrast medium facilitates interpretation of the anatomy of the image and permits differentiation of bowel loops from soft tissue masses.

## **INDICATION**

Telebrix® 38 Oral is indicated as a bowel opacifier during CT scanning of the abdomen and pelvis.

## **CONTRAINDICATIONS**

- Hypersensitivity to ioxitalamate acid salts or to any of the excipients
- Severe oliguria or anuria
- History of major immediate or delayed skin reaction (see ADVERSE REACTIONS section) to Telebrix® 38 Oral administration
- If a broncho-esophageal fistula or a risk of aspiration is suspected, hyperosmolar monomeric ionic contrast agents are contraindicated because of the risk of intra-alveolar edema
- Manifest thyrotoxicosis

## **WARNINGS**

**This medicinal product must not be injected.**

Allergic reaction is possible regardless of the administration route and dose.

Administration by oral route generally leads to very limited systemic diffusion; if the gastrointestinal mucosa is normal, only 5% maximum of the dose administered is found in the urine, the remainder being eliminated with the feces. However, if the gastrointestinal mucosa is altered, absorption is increased; it becomes total and rapid in the event of perforation, with passage into the peritoneal cavity. The medicinal product is then eliminated with the urine. The

occurrence of any dose-dependent systemic effects therefore depends on the condition of the gastrointestinal mucosa.

### **Hypersensitivity**

Any iodinated contrast medium can cause minor or major hypersensitivity reactions that may be life-threatening. They may be immediate (less than 60 minutes) or delayed (up to 7 days). They are often unpredictable.

The risk of a major reaction requires the immediate availability of the means necessary for emergency resuscitation.

Several mechanisms have been reported:

- Direct toxicity affecting the vascular endothelium and tissue proteins
- Pharmacological action altering the concentration of certain endogenous factors (histamine, complement fractions, inflammation mediators), more frequent with hyperosmolar products
- Immediate IgE-type allergy dependent on the contrast medium (anaphylaxis)
- Cell-mediated allergic reactions (late onset cutaneous reactions)

Patients having previously suffered a reaction during administration of an iodinated contrast medium are at increased risk of experiencing a renewed reaction during administration of the same, or another iodinated contrast medium, and are therefore considered to be high risk subjects.

### **Iodinated Contrast Media and the Thyroid (see also section PRECAUTIONS, Dysthyroidism)**

Prior to administration of an iodinated contrast medium, it must be ensured that the patient is not to undergo a scintigraphic or biological exploration of the thyroid, or administration of radioactive iodine treatment.

Administration of iodinated contrast media, regardless of the route, can interfere with hormone assays and iodine fixation by the thyroid or thyroid cancer metastases until normalization of urine iodine levels. Since thyroid tests are altered, they should be performed prior to radiological examinations. If tests are necessary in the weeks following the administration of an iodinated contrast medium, thyroid hormones (thyroxine, triiodothyronine) should be assayed directly.

### **Thyroid dysfunction**

Telebrix, like all other iodinated contrast media, may induce changes in thyroid function in some patients. Transient hyperthyroidism or hypothyroidism has been reported following iodinated contrast media administration to adult and pediatric patients. Decreased levels of thyroxine (T4) and triiodothyronine (T3) and increased level of TSH were reported after exposure to ICM in infants, especially preterm infants,

which remained for up to a few weeks or even more than a month (see ADVERSE REACTIONS). Some patients were treated for hypothyroidism (see PRECAUTIONS – Special populations – Pediatrics - Infants).

## **PRECAUTIONS**

### **General**

Diagnostic procedures which involve the use of iodinated contrast agents should be carried out under the direction of radiologists skilled and experienced in the particular procedure to be performed.

The possibility of an idiosyncratic reaction occurring in patients who have previously received a contrast medium without ill effect should always be considered.

### **Intolerance to Iodinated Contrast Media**

Prior to the examination:

- Identify subjects at risk via specific questioning concerning history. A positive history of bronchial asthma or allergy, a family history of allergy, or a previous reaction or hypersensitivity to a contrast agent implies a greater than usual risk. Such a history may be more accurate than pre-testing in predicting the potential for reaction, although not necessarily the severity or type of reaction in the individual case. A positive history of this type does not absolutely contraindicate the use of a contrast agent, when a diagnostic procedure is deemed essential, but does call for extreme caution.

Corticosteroids and H1-antihistamines were suggested as pre-medication in patients at the highest risk of hypersensitivity. However, they do not prevent serious or fatal anaphylactic shock to occur. Pre-medication with antihistamines or corticosteroids as a means of avoiding or at least decreasing possible allergic reactions in such patients should be considered.

During the examination, the following must be ensured:

- Medical supervision
- Maintenance of a venous access
- Drugs and equipment for resuscitation readily available

After the examination:

- Further to administration of a contrast medium, the patient must remain under observation for at least 30 minutes, as most adverse effects occur within this time.
- The patient must be warned that late onset reactions may occur (up to 7 days later) (see section ADVERSE REACTIONS).

### **Renal Failure**

Iodinated contrast media may temporarily alter renal function or aggravate existing renal failure. The preventive measures to be taken are as follows:

- Identify high risk patients: dehydrated subjects, patients with renal impairment, diabetes, severe cardiac insufficiency, monoclonal gammopathy (e.g. multiple myeloma, Waldenström's disease), recent myocardial infarction, intra-aortic balloon pump, low hematocrit level, hyperuricemia, a history of renal failure following administration of iodinated contrast media, elderly subjects, in particular those with atheromatous disease or multiple morbidities.
- Initiate appropriate hydration by fluid and sodium solution where required.
- Avoid combinations of nephrotoxic medicines (if such combinations are necessary, reinforce renal biological monitoring). The medicinal products in question are notably angiotensin converting enzyme (ACE) inhibitors, aminoglycosides, organoplatins, high-dose methotrexate, pentamidine, foscarnet and certain antivirals (aciclovir, ganciclovir, valaciclovir, adefovir, cidofovir, and tenofovir), vancomycin, amphotericin B, nonsteroidal anti-inflammatory drugs, diuretics, immunosuppressants such as cyclosporin or tacrolimus, ifosfamide.
- The interval between two X-ray examinations involving administration of an iodinated contrast medium should consider prolonged elimination in case of renal function impairment and should be as long as clinically acceptable, in particular in at-risk patients. For those patients it is preferable to allow at least for a 48- to 72-hour interval. In case of renal impairment following the first examination, any further examination should be deferred until initial renal function has been restored.

Hemodialysis patients may receive iodinated contrast media, as these products are dialysable. The hemodialysis department must first be consulted.

### **Liver Failure**

Special attention must be paid when a patient suffers both from liver failure and renal failure, as this situation increases the risk of contrast medium retention.

### **Asthma**

Asthma must be stabilised prior to administration of an iodinated contrast medium. Special attention must be paid in cases of asthma attacks occurring up to 8 days prior to the examination, due to the increased risk of bronchospasm.

### **Dysthyroidism**

Following administration of an iodinated contrast medium, in particular in patients with goiter or with a history of dysthyroidism, the risk of hyperthyroidism or induction of hypothyroidism exists. Hypothyroidism may also occur in newborns that have received, or whose mother has received an iodinated contrast medium. Their thyroid function should be therefore evaluated and monitored.

### **Severe Cardiovascular Disorders**

In the event of existing or early stage heart failure, coronary artery disease, pulmonary arterial hypertension or valvular heart disease, the risk of pulmonary edema, myocardial ischemia and arrhythmia or severe hemodynamic disorders is increased following administration of an iodinated contrast medium.

### **Central Nervous System Disorders**

The benefit/risk ratio must be estimated on a case per case basis due to the risk of worsening of neurological symptoms in patients presenting with transient ischemic attack, acute cerebral infarction, recent intracranial hemorrhage, and cerebral edema, idiopathic or secondary epilepsy (tumor, scar).

### **Pheochromocytoma**

Patients suffering from pheochromocytoma may experience hypertensive crisis following intravascular administration of a contrast medium and may require appropriate treatment prior to the procedure.

### **Myasthenia**

Administration of a contrast medium may worsen myasthenia symptoms.

### **Exacerbation of Side Effects**

Side effects related to administration of iodinated contrast media may be enhanced by pronounced states of excitation, anxiety and pain. Appropriate treatment, and possibly sedation, may be necessary.

### **Interaction with Other Medicinal Products**

#### **Radiopharmaceuticals (see also section WARNINGS, Hypersensitivity)**

A risk of hyperthyroidism or induction of hypothyroidism exists in at-risk patients. Iodinated contrast media disturb radioactive iodine uptake by thyroid tissue during several weeks and this may lead to poor fixation in the thyroid scintigraphy and reduced effectiveness of iodine 131 treatment. Where renal scintigraphy performed by injection of renal tubular secreted radiopharmaceuticals is planned, it is recommended to carry out this procedure prior to administration of the iodinated contrast medium.

#### **Beta-blockers, Vasoactive Substances, Angiotensin Converting Enzyme Inhibitors, Angiotensin Receptor Antagonists**

These medicinal products reduce the efficacy of the cardiovascular compensation mechanisms that occur in hemodynamic disorders. Hypersensitivity reactions can be aggravated in patients on beta-blockers, and particularly in the presence of bronchial asthma. These patients may be refractory to standard treatment of hypersensitivity reactions with beta-agonists. The physician must be aware of this before administering the iodinated contrast agent and appropriate intensive care equipment must be available.

#### **Diuretics**

Due to the risk of dehydration induced by diuretics, fluid and electrolyte rehydration is initially necessary for minimising the risk of acute kidney failure. Because of its hyperosmolar properties, Telebrix® 38 Oral can have an additive diuretic effect.

#### Interleukin-2

Enhanced reaction to contrast media during treatment with interleukin-2 (intravenous route) may occur: rash, flushing, erythema, fever or flu-like symptoms, or more rarely hypotension, oliguria or even kidney failure.

Potentially Nephrotoxic Agents (see also section PRECAUTIONS, Renal failure)

#### Fibrinolytic Agents

Contrast media have been shown to impair the effects of fibrinolytic agents *in vitro*, in a concentration-dependent manner. Because of this enzyme inhibition, which varies according to the fibrinolytic agent, iodinated contrast media should not be used concurrently.

#### Others Forms of Interaction

High concentrations of iodinated contrast media in plasma and urine may interfere with *in vitro* bilirubin, protein and inorganic substance assay (iron, copper, calcium and phosphate); it is therefore recommended not to perform any assay of these substances during the 24 hours following the procedure.

Thyroid function, thyroid tests (see section WARNINGS, Iodinated Contrast Media and the Thyroid, and section PRECAUTIONS, Dysthyroidism).

#### Use During Pregnancy

Since radiation exposure during pregnancy should be generally avoided, regardless of whether a contrast agent is used or not, the benefit of X-ray examination has to be considered carefully. The product should be used during pregnancy only if the benefit to the mother clearly outweighs the risk to the fetus.

#### Embryotoxicity

Studies conducted in animals have not shown any teratogenic effects. In the absence of teratogenic effects in animals, no malformation in humans is expected. To date, the substances causing malformations in humans have been found to be teratogenic in animals in well-conducted studies in two species.

#### Fetotoxicity

Occasional iodine overload following administration of the contrast medium in the mother may lead to fetal dysthyroidism if the examination is carried out after 14 weeks of amenorrhea. The thyroid function of neonates exposed *in utero* should be evaluated and monitored.

However, reversibility of this effect and the expected maternal benefit indicate that occasional administration of an iodinated contrast medium should not be delayed where the indication for radiological examination in pregnant women is carefully assessed.

## **Special populations**

### Pediatrics

Infants : Decreased levels of thyroxine (T4) and triiodothyronine (T3) and increased level of TSH were reported after exposure to ICM in infants, especially preterm infants, which remained for up to a few weeks or more than a month (see ADVERSE REACTIONS). Hypothyroidism in infants may be harmful for growth and development, including mental development and may require treatment. Thyroid function in infants exposed to ICM should therefore be evaluated and monitored until thyroid function is normalized.

### Nursing Mothers

Small quantities of iodinated contrast media are excreted in breast milk. Occasional administration in mothers therefore bears a low risk of causing adverse effects in infants.

It is not known whether Telebrix® 38 Oral is excreted in human milk. Because of possible adverse effects in the nursing infant, breastfeeding should be substituted by bottle feeding for at least 24 hours following administration of Telebrix® 38 Oral.

### **Effects on Ability to Drive and Use Machines:**

No studies on the effects on the ability to drive and use machines have been performed. Due to the pharmacological properties of Telebrix® 38 Oral itself, an effect on the ability to drive and use machines is unlikely.

## **ADVERSE REACTIONS**

Since post-marketing, the most commonly reported adverse reactions following the administration of Telebrix® 38 Oral are hypersensitivity (including anaphylactic reaction, anaphylactoid reaction and anaphylactic shock), urticaria, rash (including erythema and maculopapular rash) and injection site reactions (such as edema, pain and inflammation).

The hypersensitivity reactions are usually immediate (during the administration or over the hour following the start of the administration) or sometimes delayed (one hour to several days after the administration), and usually appear as skin reactions.

Immediate reactions comprise one or several, successive or concomitant effects, usually including skin reactions, respiratory and/or cardiovascular disorders, which may be the first signs of shock, which can rarely be fatal.



**Post-Market Adverse Drug Reactions:**

Endocrine disorders: Thyroid function tests indicative of hypothyroidism or transient thyroid suppression have been uncommonly reported following iodinated contrast media administration to adult and pediatric patients, including infants. Some patients were treated for hypothyroidism.

**Tabulated list of adverse reactions reported with Telebrix® 38 Oral following enteral administration:**

<b>System Organ Class</b>	<b>Frequency: Adverse reaction</b>
Immune system disorders	Frequency not known: Anaphylactic shock, anaphylactic reaction, anaphylactoid reaction, hypersensitivity
Endocrine disorders	Frequency not known: Thyrotoxic crisis*, hyperthyroidism*, thyroid disorder**
Nervous system disorders	Frequency not known: Syncope, somnolence, dizziness
Eye disorders	Frequency not known: Eyelid edema
Cardiac disorders	Frequency not known: Cardiac arrest, tachycardia, cyanosis
Vascular disorders	Frequency not known: Shock, hypertension, hypotension
Respiratory, thoracic and mediastinal disorders	Frequency not known: Laryngeal edema, aspiration <sup>1</sup> pneumonia, pulmonary edema, dyspnea, cough, sneezing
Gastrointestinal disorders	Frequency not known: Ileus, enterocolitis, diarrhea***, nausea, vomiting, abdominal pain
Skin and subcutaneous tissue disorders	Frequency not known: <i>Immediate:</i> Angioedema, urticaria, pruritus, erythema, hyperhidrosis <i>Delayed:</i> Rash, rash maculopapular
General disorders and administration site conditions	Frequency not known: Edema, face edema, hot sensation, pain, chills
Investigations	Frequency not known: Serum creatinine increased

<sup>1</sup> in patients with swallowing impairment, oral route

\* Thyrotoxicosis may occur in patients with asymptomatic or uncontrolled hyperthyroidism as well as in patients with autonomous thyroid nodules (take special care with elderly patients). The occurrence of symptoms may be delayed (for several months) after the administration.

\*\* Thyroid disorder may be the exacerbation of goiter. Temporary hypothyroidism may also occur in newborns (premature infants) whose mother has received an iodinated contrast medium.

\*\*\* Diarrhea may lead to dehydration, especially in children. Restoration of water and electrolyte balance is recommended in dehydrated patients.

**The following adverse reactions were reported with any form of Telebrix following non-enteral administration and/or with other iodinated contrast media:**

<b>System Organ Class</b>	<b>Frequency: Adverse reaction</b>
Psychiatric disorders	Confusional state, agitation, hallucination, anxiety

Nervous system disorders	Coma, brain edema, loss of consciousness, convulsion, paresis/paralysis, paraesthesia, tremor, amnesia, speech disorder, headache, dysgeusia
Eye disorders	Visual impairment, photophobia, transient blindness
Ear and labyrinth disorders	Vertigo, hearing impairment
Cardiac disorders	Myocardial infarction, angina pectoris, arrhythmia, bradycardia
Vascular disorders	Thrombophlebitis <sup>1</sup> , pallor, flushing
Respiratory, thoracic and mediastinal disorders	Respiratory arrest, respiratory failure, laryngospasm, bronchospasm, throat tightness
Gastrointestinal disorders	Parotid gland enlargement, salivary hypersecretion, pancreatitis <sup>2</sup>
Reproductive system and breast disorders	Pelvic pain <sup>3</sup>
Skin and subcutaneous tissue disorders	Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme, dermatitis bullous, eczema
Musculoskeletal disorders	Muscle spasms, arthralgia <sup>4</sup>
Renal disorders	Acute renal failure, anuria
General disorders	Malaise, pyrexia, injection site extravasation, injection site necrosis <sup>5</sup> , injection site pain, injection site inflammation, injection site edema
Investigations	Abnormal electroencephalogram, blood amylase increased

<sup>1</sup> following intravascular administration

<sup>2</sup> following endoscopic retrograde cholangiopancreatography (ERCP)

<sup>3</sup> in the event of hystero-graphy

<sup>4</sup> in the event of arthrography

<sup>5</sup> in the event of extravasation

### Adverse Reactions in Children

The expected nature of the undesirable effects connected with Telebrix® 38 Oral is the same as that of the effects reported in adults. Their frequency cannot be estimated from the available data.

### **SYMPTOMS AND TREATMENT OF OVERDOSAGE**

Overdose increases the risk of nephropathy and can result in diarrhea, dehydration, electrolyte imbalance, hemodynamic and cardiovascular disorders so treatment of an overdose should be directed towards the support of all vital functions and prompt institution of specific therapy. Renal function must be monitored during at least three days. Hemodialysis may be carried out if necessary.

As much as possible of the contrast medium should be removed from the stomach by gastric suction and lavage. With very high doses, fluid and electrolyte losses must be compensated by appropriate rehydration.

#### WARNING

For management of a suspected drug overdose, contact your regional poison control centre.

## DOSAGE AND ADMINISTRATION

Telebrix® 38 Oral has to be diluted to a 2% w/v salt solution before use. This can be accomplished, for example, by adding 12 mL of Telebrix® 38 Oral to 450 mL of water (see Directions for Dilution in STABILITY AND STORAGE RECOMMENDATIONS).

The diluted solution is used orally for opacification of the bowel lumen in individual patients in the following doses, taken in small aliquots over a period of time. The dose must be adapted according to the patient's age, type of examination and volume of the organ to be examined.

### Adults

**For opacification of the colon:** 450 mL of the diluted solution may be given several hours before the examination and 450 mL at least one half hour before.

**For small bowel opacification:** 450 mL is given several hours before the examination followed by 450 mL at least one half hour before and 150 mL immediately before the examination. The maximum total dose is 1050 mL.

Since a decline in physiological functions is common in the elderly, the clinical condition of the patient should be carefully monitored. For elderly and also patients with severe renal insufficiency or diabetes, Telebrix® 38 Oral should be administered with caution (see PRECAUTIONS section), in well hydrated patients at the minimum effective dose.

### Children

As with all other hyperosmolar contrast media, the use of this preparation should be carefully considered in children. The administered dose should be reduced to the minimum. The oral dose of the diluted solution, for children 1 to 12 years of age, will be limited to 8 mL/kg or 400 mL total dose, whichever is less. For opacification of the colon, one half of the dose may be ingested several hours before the examination and the other half at least one half hour before the examination.

## PHARMACEUTICAL INFORMATION

Trade Name: Telebrix® 38 Oral

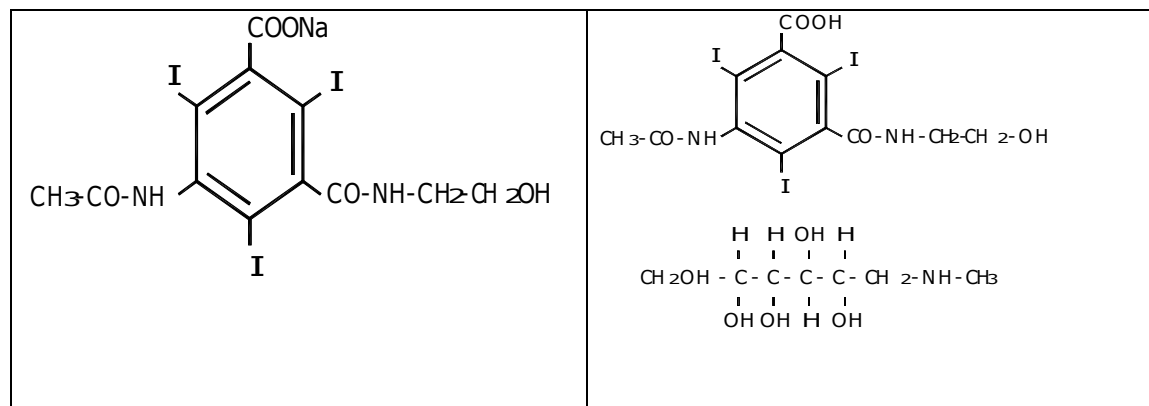
Proper Name: Meglumine Ioxitalamate and Sodium Ioxitalamate 77%

Chemical Name: (1) Monosodium 5-acetamido-N-(2-hydroxyethyl)-2,4,6-triiodoisophthalamate (salt)  
and  
(2) 1-deoxy-1(methylamino)-D-glucitol  
5-acetamido-N-(2hydroxyethyl)-2,  
4,6-triiodiosophthalamate (salt)

Structural Formula:

(1) Sodium Ioxitalamate

(2) Meglumine ioxitalamate



Molecular Weight: (1) 666  
(2) 839.45

### Description

Ioxitalamic acid is a white powder slightly soluble in water.

### Composition

Telebrix® 38 Oral is an aqueous solution for oral use subsequent to dilution. It contains 513 mg/mL of meglumine ioxitalamate and 255 mg/mL of sodium ioxitalamate, equivalent to a combined content of 38% w/v organically bound iodine. It also contains 0.5 mg/mL of monobasic sodium phosphate as a buffer and 0.086 mg/mL of edetate calcium disodium as a stabilizer. The pH is approximately 7.0.

## STABILITY AND STORAGE RECOMMENDATIONS

Store at 15°C to 30°C. Do not freeze. If product is frozen or if crystallization of the salt has occurred, examine the container for physical damage. If no damage has occurred, the container should be brought to room temperature. Intermittent shaking may be necessary to completely redissolve the crystals. Before use, examine the product to ensure that all solids are redissolved. This preparation is sensitive to light and must be protected from strong daylight or direct exposure to the sun.

### Directions for Dilution

Telebrix® 38 Oral may be diluted with tap water. 12 mL of Telebrix® 38 Oral is added to 450 mL of water. This will produce 462 mL of a 2% salt solution. This solution has been found to be stable for 2 weeks at room temperature (15°C to 30°C). **However, the normal procedure is to prepare the solution immediately prior to use. In rare cases the reconstituted solution can be stored for up to 48 hours at room temperature before use. Discard unused portion.**

### Availability of Dosage Forms

Telebrix® 38 Oral is available as a solution for dilution in 30 mL and 120 mL bottles.

## PHARMACOLOGY

Administration by oral route generally leads to very limited systemic diffusion; if the gastrointestinal mucosa is normal, only 5% maximum of the dose administered is found in the urine, the remainder being eliminated with the feces.

## TOXICOLOGY

### Acute toxicity

#### Acute toxicity of Telebrix® 38 Oral in Mice

Species	Number	Route	Result (g/kg of the salt)
Swiss Mice	10M 10F	IV IV	LD50 = 23 g/kg
Swiss Mice	50	IP	LD50 = 22 g/kg
Mice		Oral	Diarrhea and prostration at 30 to 40 g/kg

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## PATIENT MEDICATION INFORMATION

### TELEBRIX<sup>®</sup> 38 ORAL

#### Meglumine Ioxitalamate and Sodium Ioxitalamate Oral Solution 77%

Read this carefully before you start taking Telebrix 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 Telebrix.

#### **What is Telebrix 38 Oral used for?**

Telebrix 38 Oral:

- is for diagnostic use only and is used to help identify an illness.
- makes contrast in the abdomen that is useful during a CT scan of the abdomen and pelvis.
- is used in children and adults.

#### **How does Telebrix 38 Oral work?**

Telebrix 38 Oral creates contrast in the abdomen. This makes it easier for your doctor to interpret the results of your CT scan and make a diagnosis

#### **What are the ingredients in Telebrix 38 Oral?**

Medicinal ingredients: Ioxitalamic Acid.

Non-medicinal ingredients: Disodium Calcium Edetate USP, Meglumine USP, Monobasic Sodium Phosphate USP and Sodium Hydroxide EP.

#### **Telebrix 38 Oral comes in the following dosage forms:**

30 and 120 mL bottle

#### **Do not use Telebrix 38 Oral if:**

- You are hypersensitive to this drug or to any ingredient in the formulation or component of the container.
- You have severe issues with the production of urine (oliguria or anuria).
- You have a history of immediate or delayed major skin reaction to Telebrix.
- You have an abnormal broncho-esophageal connection.
- You manifest thyrotoxicosis (which means having too much thyroid hormone in your body).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Telebrix 38 Oral. Talk about any health conditions or problems you may have, including if you:**

- have had a previous allergic reaction to a contrast agent.
- had to take another contrast agent like Telebrix 38 Oral in the last few days.

- have a history of bronchial asthma and if you had an asthma attack within the last 8 days.
- have kidney problems or a history of kidney problems.
- have diabetes
- have severe heart problems, including:
  - a recent heart attack
  - an intra-aortic balloon pump
  - heart failure
  - artery disease
  - damage to or defect in one of the four heart valves (valvular heart disease)
  - a type of blood pressure that affects your lungs and the right side of your heart (pulmonary arterial hypertension)
- have multiple myeloma (cancer of the plasma blood cells)
- have both liver failure and kidney failure.
- have an enlarged thyroid gland (goiter) or problems with your thyroid gland (dysthyroidism).
- had a transient ischemic attack (similar to a stroke), a stroke, bleeding or swelling in your brain or epilepsy.
- have a rare tumour on your adrenal gland (pheochromocytoma).
- have myasthenia gravis.
- are pregnant or could be pregnant. If you may need to take Telebrix 38 Oral during your pregnancy, your doctor will discuss the benefits and risks of giving it to you.
- are breast-feeding. It is not known if Telebrix 38 Oral is excreted in breast milk. You should bottle feed your baby for at least 24 hours after taking Telebrix 38 Oral.

**Other warnings you should know about:**

**Thyroid function**

Contrast media containing iodine, such as Telebrix, 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 you or 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 Telebrix<sup>®</sup> 38 Oral**

- Radiopharmaceuticals (used for diagnosis of medical conditions).
- Beta-blockers (used to lower blood pressure)
- Vasoactive substances (drugs used to increase or decrease blood pressure)
- Angiotensin receptor antagonists (used to treat high blood pressure and heart failure).
- Diuretics (used to help your body excrete more fluids as urine).
- Interleukin-2 (used to treat cancer).
- Drugs that may be toxic to the kidneys
- Fibrinolytic Agents (used to dissolve blood clots).

**How to take Telebrix 38 Oral ?**

Telebrix 38 Oral will always be used in a hospital or similar setting. It will only be administered to you under the supervision of a health professional skilled and experienced in the particular procedure to be performed.

**Usual dose:**

Your doctor will determine the amount of **Telebrix 38 Oral** to be used. The dose administered will depend on your weight, your age and the procedure. You will have to take Telebrix 38 Oral twice:

- several hours before your CT scan and
- at least 30 minutes before your CT scan

**Overdose:**

If you think you have been given too much **Telebrix 38 Oral**, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**What are possible side effects from using Telebrix 38 Oral?**

These are not all the possible side effects you may feel when taking Telebrix 38 Oral. If you experience any side effects not listed here, contact your healthcare professional.

Common side effects may include:

- Hypersensitivity, allergic reaction, rash, injection site reactions.

Other side effects may include:

- Somnolence, dizziness.
- Swollen eyelids.
- Swelling, severe itching, erythema, excessive sweating, edema, pain, chills.

<b>Serious side effects and what to do about them</b>		
Symptom/ Effect	Talk to your healthcare professional	
	Only if severe	In all cases
<p><b>UNCOMMON</b></p> <ul style="list-style-type: none"> <li>• Lack of a sufficient amount of the thyroid hormone (known as hypothyroidism)</li> <li>• Over- or under-function of the thyroid hormone.</li> <li>• Temporary loss of consciousness.</li> <li>• Cardiac arrest, rapid heartbeat, bluish discoloration of the skin (cyanosis).</li> <li>• High or low blood pressure.</li> <li>• Swelling in the throat, swelling in the lungs, difficult or labor breathing, cough, sneezing.</li> <li>• Painful obstruction of a part of the intestine (ileus), inflammation of the small intestine and the colon, diarrhea, nausea, vomiting, abdominal pain.</li> <li>• Symptom that shows that your kidneys are not working well known as serum creatinine increased.</li> </ul>		✓

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 (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) 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:**

Store at 15°C to 30°C. Protect from light and freezing. Keep out of reach and sight of children.

**If you want more information about Telebrix 38 Oral:**

- 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](#) or by calling 1-844-208-7620.

This leaflet was prepared by Liebel-Flarsheim Canada Inc.

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CANADA

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