

## Consumer Medicine Information

### What is in this leaflet

This leaflet answers some common questions about CONRAY. It does not contain all the available information. It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of using CONRAY against the benefits it is expected to have for you.

**If you have any concerns about receiving CONRAY, ask your doctor.**

**Keep this leaflet.**

You may need to read it again.

**In this leaflet:**

1. What is CONRAY and what it is used for
2. Before you are given CONRAY
3. How CONRAY is given
4. While you are using CONRAY
5. Possible side effects
6. Product Description

### 1. What is CONRAY and what it is used for

CONRAY is an injectable contrast medium. It is used to make clearer diagnostic images of the brain and body in adults and children. As a result, it helps to clearly show abnormalities in the brain or body. This medicine is for diagnostic use only.

### 2. Before you are given CONRAY

**When you must not use it**

Do not use CONRAY if you are allergic (hypersensitive):

- to the active substances Meglumine or sodium salt of Iothalamate or
- to any of the other ingredients in CONRAY

**Take special care with CONRAY**

Diagnostic procedures involving the use of contrast agents should be conducted under supervision of a physician with the prerequisite training and a thorough knowledge of the procedure to be performed.

**Before you start to use it**

**Tell your doctor if:**

- you suffer from allergies (e.g. medicinal products, seafood, hay fever, hives) or asthma
- you had any reaction to previous injections of a contrast agent, including a previous history of reaction to iodine-based agents
- your kidneys do not function properly
- CONRAY is planned to be used in your child who is under the age of two years

**Tell your doctor if:**

- you are feeling thirsty and/or you have only had small quantities or nothing to drink before the examination
- you have a cardiac pacemaker or any ferromagnetic implant (vascular clips, etc.) or a metallic stent in your body
- you are taking a special kind of antihypertensive medicine, i.e. a beta-blocker
- you have heart disease

- you suffer from epilepsy or brain lesions
- you are or your child is on a controlled sodium diet
- If any of these apply to you, your doctor will decide whether the intended examination is possible or not.

**Using other medicines**

**Please tell your doctor if you are taking or have recently taken any other medicines including medicines obtained without a prescription from your pharmacy, supermarket or health food shop.**

**Pregnancy and breast feeding**

It is not known whether CONRAY passes into human milk. Tell your doctor if you are pregnant, plan to become pregnant or are breast feeding and ask your doctor for advice before you are given CONRAY.

**Important information about some of the ingredients of CONRAY**

This medicine contains in each mL, 600 mg of iotalamate meglumine, 0.09 mg sodium calcium edetate as a stabiliser and 0.125 mg of monobasic sodium phosphate as a buffer. The solution provides 28.0% (280 mg/mL) organically bound iodine.

### 3. How CONRAY is given

**The usual dose**

Your doctor will decide how much you will be given. This depends on your condition and other factors. Patients should be well hydrated prior to and following the administration of CONRAY.

**If you are given more CONRAY than you should have been (overdose)**

Overdosage may occur. The adverse effects of overdosage are potentially life-threatening and affect mainly the pulmonary and cardiovascular system. The symptoms may include cyanosis, bradycardia, acidosis, pulmonary haemorrhage, convulsions, coma and cardiac arrest. Treatment of an overdose is directed toward the support of all vital functions and prompt institution of symptomatic therapy.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

### 4. While you are using CONRAY

**Things to be careful of**

This medicine may cause dizziness, lightheadedness, tiredness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous. Children should be careful when riding bicycles or climbing trees.

**If you feel lightheaded, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

### 5. Possible side effects

Adverse reactions accompanying the use of iodine-containing intravascular contrast

agents are usually mild and transient, although severe and life-threatening reactions, including fatalities, have occurred. Because of the possibility of severe reactions to both the procedure and the radiopaque medium, appropriate emergency facilities and well trained personnel should be available to treat both types. While some reactions usually occur within a few minutes, some may be delayed. The following adverse reactions have been observed in conjunction with the use of iodine-containing intravascular contrast agents.

The most frequent adverse reactions are nausea, vomiting, facial flush and feeling of body warmth. These are usually of brief duration. Other reactions include the following:

**Allergic reactions:**

- hives with or without itching
- rash
- dry mouth
- sweating
- swelling and fluid retention in the face, legs or feet
- Symptoms relating to the respiratory system include sneezing, nasal stuffiness, coughing, choking, chest tightness and wheezing, which may be initial manifestations of more severe and infrequent reactions including asthmatic attack, bronchospasm or if breathing stops or is markedly reduced.
- Rarely, these allergic type reactions can progress into anaphylaxis with loss of consciousness, coma and severe cardiovascular disturbances.

**Cardiovascular reactions:**

- flushing
- occasional blood clots
- Severe cardiovascular responses include rare cases of hypotensive shock, cardiac arrhythmia, and arrest. These reactions are reversible with prompt and appropriate management; however, fatalities have occurred.

**Technique reactions:**

- numbness
- vascular constriction due to injection rate
- blood clots

**Neurological reactions:**

- spasms
- convulsions
- coma

**Other reactions:**

- headache
- trembling, shaking or chills without a fever
- lightheadedness
- temporary renal shutdown
- kidney disease

**Immediately tell the doctor or nurse/technologist who is giving you the injection, if you feel unwell, especially if you feel any tightness, pain or discomfort in your chest, face or throat, or you have difficulty breathing.**

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## 6. Product Description

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### *Ingredients:*

- The active substance is iotalamate meglumine.
- 1 mL contains 600 mg of iotalamate meglumine.
- The other ingredients are: sodium calcium edetate, monobasic sodium phosphate, and water for injection.

This medicine does not contain lactose, sucrose, gluten, tartrazine, or any other azo dyes.

### *What CONRAY looks like and contents of the pack*

CONRAY vials contain a clear, colourless to pale yellow solution.

CONRAY is supplied in vials fitted with bromobutyl rubber closures and aluminium cap seals.

CONRAY vials are supplied in the following package sizes:

- CONRAY 20 mL glass vials x 10 (AUST R 51541)
- CONRAY 50 mL glass vials x 10 (AUST R 51542).

Not all package sizes may be marketed.

Do not use the solution if it is discoloured or particulate material is present.

### *Sponsor*

For any information about this medicine, please contact the sponsor:

#### **Guerbet Australia Pty Ltd**

166 Epping Road  
Lane Cove, NSW 2066  
Australia

This leaflet was prepared in June 2016.