

Safety Alert

March 2022

A new warning about Thyroid Dysfunction of Iopromide in Pediatric Patients 0 to 3 Years of Age

EDA performs label update to include the following:

Warnings and Precautions

Thyroid Dysfunction in Pediatric Patients 0 to 3 Years of Age

Thyroid dysfunction characterized by hypothyroidism or transient thyroid suppression has been reported after both single exposure and multiple exposures to iodinated contrast media. Among patients 0 to 3 years of age exposed to iodinated contrast media, thyroid dysfunction has been reported in 1% to 15% depending on the age of the patient and the dose of the iodinated contrast agent.

Younger age, very low birth weight, prematurity, and the presence of other conditions, such as, admission to neonatal or pediatric intensive care units, and cardiac conditions are associated with an increased risk. Pediatric patients with cardiac conditions may be at the greatest risk given that they often require high doses of contrast during invasive cardiac procedures, such as catheterization and computed tomography (CT).

Pediatric patients 0 to 3 years of age warrant closer monitoring because an underactive thyroid during early life may be harmful for motor, hearing, and cognitive development and may require transient T4 replacement therapy. Evaluate thyroid function in all pediatric patients 0 to 3 years of age within 3 weeks following exposure to iodinated contrast media, especially in term and preterm neonates. If thyroid dysfunction is detected, treat and monitor thyroid function as clinically needed.

The safety and effectiveness of Iopromide in pediatric patients younger than 2 years of age have not been established, and Iopromide is not approved for use in pediatric patients younger than 2 years of age.

Use in Specific Populations

Pediatric Use

Thyroid function tests indicative of thyroid dysfunction, characterized by hypothyroidism or transient thyroid suppression have been reported following iodinated contrast media administration in pediatric patients, including term and preterm neonates; Some patients were treated for hypothyroidism. Monitor pediatric patients 0 to 3 years of age closely, particularly those with one or more potential risk factors, for thyroid dysfunction

Background on the safety concerns

INDICATIONS AND USAGE

Iopromide Injection is an iodinated contrast agent indicated for:

1.1 Intra-Arterial Procedures*

- 300 mg Iodine per mL for cerebral arteriography and peripheral arteriography
- 370 mg Iodine per mL for coronary arteriography and left ventriculography, visceral angiography, and aortography

1.2 Intravenous Procedures*

- 300 mg Iodine per mL for excretory urography
- 300 mg Iodine per mL and 370 mg Iodine per mL for contrast Computed Tomography (CT) of the head and body

Pediatric Dosing

The recommended dose in children over 2 years of age for the following evaluations is:

- Intra-arterial:

Cardiac chambers and related arteries (370 mg Iodine per mL):

Inject 1 to 2 milliliters per kilogram (mL/kg). Do not exceed 4 mL/kg as total dose.

- Intravenous:

Contrast Computerized Tomography or Excretory Urography (300 mg Iodine per mL):

Inject 1 to 2 mL/kg. Do not exceed 3 mL/kg as total dose.

References:

FDA ([Click here](#))