

ספטמבר, 2023

## Iopamiro 300, 370, Solution for Injection

צוות רפואי נכבד,

חברת דקסל בע"מ מבקשת להודיעכם על עדכון בעלון לרופא של התכשירים יופמירו 300, 370. בהודעה זו מפורטים העדכונים המהווים החמרה במידע הבטיחותי בלבד. למידע מלא, יש לעיין בעלון. העלון לרופא נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלו מודפס ע"י פנייה לבעל הרישום: דקסל בע"מ, רח' דקסל 1, אור עקיבא 3060000, ישראל, טל': 04-6364000.

### הרכב התכשיר:

Each ml of solution contains iopamidol 612.4 mg or 755.3 mg respectively.

### התוויות מאושרות:

X-ray contrast medium in neuroradiology, angiography, urography, ct scanning, arthrography and fistulography.

העלון לרופא עודכן בספטמבר 2023. להלן העדכונים המהווים החמרה במידע הבטיחותי (מסומנים באדום):

#### 4.4 Special warnings and special precautions for use

...

##### Disturbed thyroid function

Thyroid function tests indicative of hypothyroidism or transient thyroid suppression have been reported following iodinated contrast media administration to adult and paediatric patients, including infants. Some patients were treated for hypothyroidism. See also section on Use in Special Populations- *Newborns, children*.

...

##### **Use in Special Populations**

...

Special attention should be paid to paediatric patients below 3 years of age because an incident underactive thyroid during early life may be harmful for motor, hearing, and cognitive development and may require transient T4 replacement therapy. The incidence of hypothyroidism in patients younger than 3 years of age exposed to iodinated contrast media has been reported between 1.3% and 15% depending on the age of the subjects and the dose of the iodinated contrast agent and is more commonly observed in neonates and premature infants. Neonates may also be exposed through the mother during pregnancy. Thyroid function should be evaluated in all paediatric patients younger than 3 years of age

following exposure to iodinated contrast media. If hypothyroidism is detected, the need for treatment should be considered and thyroid function should be monitored until normalized.

...

## 4.6 Fertility, pregnancy and lactation

### Pregnancy

...

In neonates who have been exposed to iodinated contrast media in utero, it is recommended to monitor thyroid function (see section 4.4).

...