



תאריך: ינואר 2020

רופא /ה, רוקח/ת נכבד/ה,

חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

## Abitren Teva 75mg/3 ml

Solution for I.M Injection

### אביטרן טבע 75 מ"ג / 3 מ"ל

תמיסה להזרקה לתוך השריר

כל אמפולה של 3 מ"ל מכילה: Diclofenac sodium 75 mg

#### עדכונים בעלון לרופא

#### התוויה כפי שאושרה בתעודת הרישום:

Treatment of:

- Exacerbations of inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, ankylosing spondylitis, osteoarthritis, spondylarthritis, non-articular rheumatism.
- Treatment of painful conditions due to inflammation of non-rheumatic origin.
- Renal colic and biliary colic.
- Post-traumatic and post-operative pain, inflammation and swelling.

ברצוננו להודיע שהעלון לרופא עודכן, בפירוט שלהלן כלולים העדכונים העיקריים בלבד (תוספות מסומנות באדום):



#### 4.4 Special warnings and precautions for use

##### General

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As with other nonsteroidal anti-inflammatory drugs including diclofenac, allergic reactions, including anaphylactic/anaphylactoid reactions can also occur without earlier exposure to the drug (see section 4.8 Undesirable effects). **Hypersensitivity reactions can also progress to Kounis syndrome, a serious allergic reaction that can result in myocardial infarction. Presenting symptoms of such reactions can include chest pain occurring in association with an allergic reaction to diclofenac.**

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##### Gastrointestinal effects:

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**NSAIDs, including diclofenac, may be associated with increased risk of gastrointestinal anastomotic leak. Close medical surveillance and caution are recommended when using diclofenac after gastro-intestinal surgery.**

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##### Cardiovascular and cerebrovascular effects:

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**Patients should remain alert for the signs and symptoms of serious arteriothrombotic events (e.g. chest pain, shortness of breath, weakness, slurring of speech), which can occur without warnings. Patients should be instructed to see a physician immediately in case of such an event.**

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##### Undesirable effects

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Cardiac disorders	
Uncommon*	Myocardial infarction, cardiac failure, palpitations, chest pain.
Not known	Kounis syndrome

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