



אוקטובר 2025

רופא/ה, רוקח/ת נכבד/ה,

חברת טבע מודיעה על העדכונים הבאים בעלון לרופא של התכשיר:

## Abitren® Teva 75 mg/3ml

Solution for I.M. Injection

אביטרן® טבע 75 מ"ג/ג 3 מ"ל

תמיסה להזרקה לתוך השריר

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

### 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.

העלון לרופא עודכן. בפירוט שלהלן כלולים העדכונים העיקריים בלבד. תוספות מידע מסומנות באדום, החמרות מסומנות על רקע צהוב:

#### 4.4 Special warnings and precautions for use

[...]

##### Skin effects:

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolysis and **generalised bullous fixed drug eruption**, have been reported very rarely in association with the use of NSAIDs, including Abitren Teva 75mg/3 ml (see section 4.8 Undesirable effects).

[...]

טבע תעשיות פרמצבטיות בע"מ

רח' התאנה 1, פארק תעשייה חמ"ן ת.ד. 975, שוהם 6085001 | טל: 972-3-6864000 | [www.tevapharm.com](http://www.tevapharm.com)



### Injection site reactions:

Injection site reactions have been reported after the administration of diclofenac intramuscularly, including injection site necrosis, and embolia cutis medicamentosa, also known as Nicolau syndrome (particularly after inadvertent subcutaneous administration), **fixed drug eruption and generalised bullous fixed drug eruption.** Appropriate needle selection and injection technique should be followed during intramuscular administration of diclofenac (see section 4.2).

### 4.8 Undesirable effects

[...]

<u>Skin and subcutaneous tissue disorders</u>	
Common	Rash.
Rare	Urticaria.
Very rare	Bullous eruptions, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), dermatitis exfoliative, loss of hair, photosensitivity reaction, purpura, allergic purpura, pruritus.
<u>Not Known</u>	<u>Fixed drug eruption, generalised bullous fixed drug eruption.</u>

[...]

Adverse drug reactions from post-marketing experience (frequency not known)

Injection site reactions: Embolia cutis medicamentosa (Nicolau syndrome)

Skin and subcutaneous tissue disorders: **Fixed drug eruption and generalised bullous fixed drug eruption.**

[...]

העלון נשלח לפרסום במאגר התרופות שבאתר האינטרנט של משרד הבריאות, [/https://israeldrugs.health.gov.il](https://israeldrugs.health.gov.il), וניתן לקבלו מודפס ע"י פניה לחברת טבע.