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Diclofenac Epolamine Topical Patch (Flector Patch)

??? ??????: 30 ??????/?????? 2017

Clinical Studies Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In controlled trials during the premarketing development of Flector Patch (diclofenac epolamine topical patch) , approximately 600 patients with minor sprains, strains, and contusions have been treated with Flector Patch (diclofenac epolamine topical patch) for up to two weeks.

Adverse Events Leading to Discontinuation of Treatment

In the controlled trials, 3% of patients in both the Flector Patch (diclofenac epolamine topical patch) and placebo patch groups discontinued treatment due to an adverse event. The most common adverse events leading to discontinuation were application site reactions, occurring in 2% of both the Flector Patch (diclofenac epolamine topical patch) and placebo patch groups. Application site reactions leading to dropout included pruritus, dermatitis, and burning.

Common Adverse Events

Localized Reactions

Overall, the most common adverse events associated with Flector Patch (diclofenac epolamine topical patch) treatment were skin reactions at the site of treatment.

Table 1 lists all adverse events, regardless of causality, occurring in ? 1% of patients in controlled trials of Flector Patch (diclofenac epolamine topical patch) . A majority of patients treated with Flector Patch (diclofenac epolamine topical patch) had adverse events with a maximum intensity of "mild" or "moderate."

Table 1. Common Adverse Events (by body system and preferred term) in ? 1% of Patients treated with Flector Patch (diclofenac epolamine topical [1]patch) or Placebo Patch

	Placebo N=564		Diclofenac N=572		
	Percent	N	Percent	N	
Application Site Conditions	12	70	11	64	
Pruritus	8	44	5	31	
Dermatitis	< 1	3	2	9	
Burning	1	8	< 1	2	
[2] Other	3	15	4	22	
Gastrointestinal Disorders	6	33	9	49	
Nausea	2	11	3	17	
Dysgeusia	< 1	3	2	10	
Dyspepsia	1	8	1	7	
Other3	2	11	3	15	
Nervous System Disorders	3	18	2	13	
Headache	2	10	1	7	
Paresthesia	1	8	1	6	
Somnolence	1	6	1	4	
[4] Other	< 1	3	1	4	

[1] The table lists adverse events occurring in - placebo-treated patients because the placebo patch was comprised of the same ingredients as Flector Patch (diclofenac epolamine topical patch) except for diclofenac. Adverse events in the placebo group may therefore reflect effects of the non-active ingredients.
[2] Includes: application site dryness, irritation, erythema, atrophy, discoloration, hyperhidriosis, and vesicles.
[3] Includes: gastritis, vomiting, diarrhea, constipation, upper abdominal pain, and dry mouth.
[4] Includes: hypoaesthesia, dizziness, and hyperkinesias.

Foreign labeling describes that dermal allergic reactions may occur with Flector Patch treatment. Additionally, the treated area may become irritated or develop itching, erythema, edema, vesicles, or abnormal sensation.