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Zecuity (Sumatriptan Iontophoretic Transdermal System)

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The following adverse reactions are discussed in more detail in other sections of the prescribing information:

-]**WARNINGS AND PRECAUTIONS** Allergic Contact Dermatitis [see
-]**WARNINGS AND PRECAUTIONS** Myocardial ischemia, myocardial infarction, and Prinzmetal's angina [see
-]**WARNINGS AND PRECAUTIONS** Arrhythmias [see
-]**WARNINGS AND PRECAUTIONS** Chest, throat, neck, and/or jaw pain/tightness/pressure [see
-] **WARNINGS AND PRECAUTIONS**Cerebrovascular events [see
-]**WARNINGS AND PRECAUTIONS** Other vasospasm reactions [see
-]**WARNINGS AND PRECAUTIONS** Medication overuse headache [see
-]**WARNINGS AND PRECAUTIONS** Serotonin syndrome [see
-]**WARNINGS AND PRECAUTIONS** Increase in blood pressure [see
-]**WARNINGS AND PRECAUTIONS** Anaphylactic/anaphylactoid reactions [see

Clinical Trials 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 with rates in the clinical trials of another drug and may not reflect the rates observed in practice.

In two long-term, open-label studies in which patients were allowed to treat multiple migraine attacks for up to 1 year, 15% (99 out of 662) withdrew from the study because of adverse reaction. The most common adverse reactions leading to withdrawal from the study were contact dermatitis (4%) and application site pain (4%).

The most common adverse reactions (? 5%) in a controlled single dose study were application site pain, paresthesia, pruritus, warmth, and discomfort.

Controlled single dose acute migraine study

Table 1 lists adverse reactions that occurred at a frequency of 2% or greater in a controlled clinical study of ZECUITY in patients with acute migraine (Study 1)]. In that study, patients randomized to the control group used the same activated iontophoretic transdermal delivery system (TDS) as patients **Clinical Studies**[see randomized to ZECUITY, with the only difference being the absence of sumatriptan in the drug reservoir. Therefore, patients in the control group were exposed to same TDS-related risks as patients in the ZECUITY group, minus the risks related to sumatriptan. Only reactions that occurred at a frequency of 2% or more in patients treated with ZECUITY or control are included in Table 1.

Table 1: Adverse Reactions Reported by at least 2% of Patients in Study 1

Percent of Subjects Reporting		Adverse Reaction
Control (n = 235)	ZECUITY (n = 234)	
17%	26%	Application site pain
16%	9%	Application site paresthesia
7%	8%	Application site pruritus
3%	6%	Application site warmth
6%	6%	Application site discomfort
2%	4%	Application site irritation
1%	3%	Application site discoloration

The incidence of “atypical sensations” adverse events (paresthesia, sensation warm/cold) and “pain and other pressure sensations” (chest pain/tightness/pressure/heaviness or neck/throat/jaw pain, tightness, pressure or heaviness) was 2% each in ZECUITY-treated patients, vs. 0% in the control group.

Application site bruising was reported in 2 ZECUITY-treated patients (0.9%) vs. no patient in the control group.

Subgroup analyses of age (? 41 years, > 41 years), race (Caucasian, non-Caucasian) and body mass index (BMI) (? 25.7 mg/kg2, > 25.7 mg/kg2) showed no difference between subgroups for adverse events.

Skin Irritation Examination

In Study 1, patients performed their own examination of the TDS application site at 4, 12, and 24 hours post TDS activation, and daily thereafter until resolution. Skin irritation examination scores are summarized in Table 2. The median time to “no redness” was 2.6 days for Zecuitycompared with 0.3 day in the control group.

Table 2: Subject Self-examination Skin Irritation Scoring

Control (n = 235)	ZECUITY (n = 234)		-Time point
73%	39%	No or minimal redness	4 hours
24%	55%	Moderate redness	
1%	4%	Intense redness	
2%	2%	Intense redness with blisters/broken skin	
90%	69%	No or minimal redness	12 hours
9%	27%	Moderate redness	
0%	2%	Intense redness	
1%	2%	Intense redness with blisters/broken skin	
93%	79%	No or minimal redness	24 hours
6%	19%	Moderate redness	
0%	1%	Intense redness	
1%	1%	Intense redness with blisters/broken skin	

Application site reactions across clinical studies (Controlled single dose acute migraine study and long term safety studies)

In the controlled and uncontrolled clinical studies combined (n = 796 unique ZECUITY-treated subjects), the frequency of application site reactions of clinical interest is presented in Table 3.

Table 3: Application Site Reactions

Percent of Subjects Reporting (N = 796)	Event
5%	Discoloration
4%	Contact Dermatitis
4%	Irritation
3%	Vesicles
2%	Bruising
0.4%	Erosion