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Adcirca (Tadalafil Tablets)

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

The following serious adverse reactions are discussed elsewhere in the labeling:

- **WARNINGS AND PRECAUTIONS** Hypotension [see]
- **PATIENT INFORMATION** and **WARNINGS AND PRECAUTIONS** Visual Loss [see]
- **WARNINGS AND PRECAUTIONS** Hearing loss [see]
- **WARNINGS AND PRECAUTIONS** Priapism [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 to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Tadalafil was administered to 398 patients with PAH during clinical trials worldwide. In trials of ADCIRCA, a total of 311 and 251 subjects have been treated for at least 182 days and 360 days, respectively. The overall rates of discontinuation because of an adverse event (AE) in the placebo-controlled trial were 9% for ADCIRCA 40 mg and 15% for placebo. The rates of discontinuation because of AEs, other than those related to worsening of PAH, in patients treated with ADCIRCA 40 mg was 4% compared to 5% in placebo-treated patients.

In the placebo-controlled study, the most common AEs were generally transient and mild to moderate in intensity. Table 1 presents treatment-emergent adverse events reported by ? 9% of patients in the ADCIRCA 40 mg group and occurring more frequently than with placebo.

TABLE 1: Treatment-Emergent Adverse Events Reported by ? 9% of Patients in ADCIRCA and More Frequent than Placebo by 2%

ADCIRCA 40 mg (%) (N=79)	ADCIRCA 20 mg (%) (N=82)	Placebo (%) (N=82)	EVENT
42	32	15	Headache
14	9	4	Myalgia
13	2	7	Nasopharyngitis
13	6	2	Flushing
13	7	6	Respiratory Tract Infection (Upper and Lower)
11	5	2	Pain in Extremity
11	10	6	Nausea
10	12	6	Back Pain
10	13	2	Dyspepsia
9	0	1	Nasal Congestion (Including sinus congestion)

Postmarketing Experience

The following adverse reactions have been identified during post-approval use of tadalafil. These events have been chosen for inclusion either because of their seriousness, reporting frequency, lack of clear alternative causation, or a combination of these factors. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to estimate reliably their frequency or establish a causal relationship to drug exposure. The list does not include adverse events that are reported from clinical trials and that are listed elsewhere in this section.

Cardiovascular and cerebrovascular — Serious cardiovascular events, including myocardial infarction, sudden cardiac death, stroke, chest pain, palpitations, and tachycardia, have been reported postmarketing in temporal association with the use of tadalafil. Most, but not all, of these patients had preexisting cardiovascular risk factors. Many of these events were reported to occur during or shortly after sexual activity, and a few were reported to occur shortly after the use of tadalafil without sexual activity. Others were reported to have occurred hours to days after the use of tadalafil and sexual activity. It is not possible to determine whether these events are related directly to tadalafil, to sexual activity, to the patient's underlying cardiovascular disease, to a combination of these factors, or to other factors

].**WARNINGS AND PRECAUTIONS**[see

Hypersensitivity reactions including urticaria, Stevens–Johnson syndrome, and exfoliative dermatitis **Body as a whole —**

Migraine, seizure and seizure recurrence, and transient global amnesia **Nervous —**

Visual field defect, retinal vein occlusion, and retinal artery occlusion **Ophthalmologic —**

Cases of sudden decrease or loss of hearing have been reported postmarketing in temporal association with the use of PDE5 inhibitors, including **Otologic —** tadalafil. In some of the cases, medical conditions and other factors were reported that may have also played a role in the otologic adverse events. In many cases, medical follow-up information was limited. It is not possible to determine whether these reported events are related directly to the use of tadalafil, to the patient's].**PATIENT INFORMATION** and **WARNINGS AND PRECAUTIONS**underlying risk factors for hearing loss, a combination of these factors, or to other factors [see

].**WARNINGS AND PRECAUTIONS** Priapism [see **Urogenital —**