Skip to main content

Cosentyx (Secukinumab Injection)

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

The following adverse reactions are discussed in greater detail elsewhere in the labeling:

- **WARNINGS AND PRECAUTIONS**Infections [see]
- **WARNINGS AND PRECAUTIONS** Exacerbations of Crohn's Disease [see]
- **WARNINGS AND PRECAUTIONS** Hypersensitivity 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 to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

A total of 3430 plaque psoriasis subjects were treated with COSENTYX in controlled and uncontrolled clinical trials. Of these, 1641 subjects were exposed for at least 1 year.

Four placebo-controlled phase 3 trials in plaque psoriasis subjects were pooled to evaluate the safety of COSENTYX in comparison to placebo up to 12 weeks after treatment initiation, in Trials 1, 2, 3 and 4. In total, 2077 subjects were evaluated (691 to COSENTYX 300 mg group, 692 to COSENTYX 150 mg group, and 694 to placebo group) [see **Clinical Studies**].

Table 1 summarizes the adverse reactions that occurred at a rate of at least 1% and at a higher rate in the COSENTYX groups than the placebo group during the 12-week placebo-controlled period of the placebo-controlled trials.

Table 1 : Adverse Reactions Reported by Greater Than 1% of Subjects with Plaque Psoriasis Through Week 12 in Trials 1, 2, 3 and 4

Placebo (N=694) n (%)	COSENTYX 150 mg (N=692) n (%)	COSENTYX 300 mg (N=691) n (%)	Adverse Reactions
60 (8.6)	85 (12.3)	79 (11.4)	Nasopharyngitis
10 (1.4)	18 (2.6)	28 (4.1)	Diarrhea
5 (0.7)	22 (3.2)	17 (2.5)	Upper respiratory tract infection
5 (0.7)	10 (1.4)	10 (1.4)	Rhinitis
2 (0.3)	1 (0.1)	9 (1.3)	Oral herpes
0 (0)	7 (1.0)	8 (1.2)	Pharyngitis
1 (0.1)	8 (1.2)	4 (0.6)	Urticaria
1 (0.1)	2 (0.3)	8 (1.2)	Rhinorrhea

Adverse reactions that occurred at rates less than 1% in the placebo-controlled period of Trials 1, 2, 3, and 4 through week 12 included: sinusitis, tinea pedis, conjunctivitis, tonsillitis, oral candidiasis, impetigo, otitis media, otitis externa, inflammatory bowel disease, increased liver transaminases and neutropenia.

Infections

In the placebo-controlled period of the clinical trials in plaque psoriasis (a total of 1382 subjects treated with COSENTYX and 694 subjects treated with placebo up to 12 weeks), infections were reported in 28.7% of subjects treated with COSENTYX compared with 18.9% of subjects treated with placebo. Serious infections occurred in 0.14% of patients treated with COSENTYX and in 0.3% of patients treated with placebo [see **WARNINGS AND PRECAUTIONS**].

Over the entire treatment period (a total of 3430 plaque psoriasis subjects treated with COSENTYX for up to 52 weeks for the majority of subjects), infections were reported in 47.5% of subjects treated with COSENTYX (0.9 per patient-year of follow-up). Serious infections were reported in 1.2% of subjects treated with COSENTYX (0.015 per patient-year of follow-up).

Phase 3 data showed an increasing trend for some types of infection with increasing serum concentration of secukinumab. Candida infections, herpes viral

infections, staphylococcal skin infections, and infections requiring treatment increased as serum concentration of secukinumab increased.

Neutropenia was observed in clinical trials. Most cases of secukinumab-associated neutropenia were transient and reversible. No serious infections were associated with cases of neutropenia.

Exacerbation of Crohn's Disease

Exacerbations of Crohn's disease, in some cases serious, were observed in clinical trials in both COSENTYX and placebo treated patients. In the psoriasis program, with 3430 patients exposed to COSENTYX there were 3 cases of exacerbation of Crohn's disease [see **WARNINGS AND PRECAUTIONS**].

Hypersensitivity Reactions

Anaphylaxis and cases of urticaria occurred in COSENTYX-treated patients in clinical trials [see **WARNINGS AND PRECAUTIONS**].

Immunogenicity

-As with all therapeutic proteins, there is the potential for immunogenicity. The immunogenicity of COSENTYX was evaluated using an electrochemiluminescence based bridging immunoassay. Less than 1% of subjects treated with COSENTYX developed antibodies to secukinumab in up to 52 weeks of treatment. However, this assay has limitations in detecting anti-secukinumab antibodies in the presence of secukinumab; therefore the incidence of antibody development might not have been reliably determined. Of the subjects who developed antidrug antibodies, approximately one-half had antibodies that were classified as neutralizing. Neutralizing antibodies were not associated with loss of efficacy.

The detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. Additionally, the observed incidence of antibody (including neutralizing antibody) positivity in an assay may be influenced by several factors including assay methodology, sample handling, timing of sample collection, concomitant medications, and underlying disease. For these reasons, comparison of incidence of antibodies to COSENTYX with the incidences of antibodies to other products may be misleading.