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Agrylin (Anagrelide)

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

The following adverse reactions are discussed in greater detail in other sections of the labeling:

-] **WARNINGS AND PRECAUTIONS**Cardiovascular Toxicity [see
-]**WARNINGS AND PRECAUTIONS** Bleeding Risk [see
-]**WARNINGS AND PRECAUTIONS** Pulmonary Toxicity [see

Clinical Trial 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.

Clinical Studies in Adult Patients

] diagnosed with myeloproliferative neoplasms of varying etiology (ET: 551; PV: 117; OMPN: **Clinical Trials** In three single-arm clinical studies, 942 patients [see 274) were exposed to anagrelide with a mean duration of approximately 65 weeks. Serious adverse reactions reported in these patients included the following: congestive heart failure, myocardial infarction, cardiomyopathy, cardiomegaly, complete heart block, atrial fibrillation, cerebrovascular accident, pericardial effusion], pleural effusion, pulmonary infiltrates, pulmonary fibrosis, pulmonary hypertension, and pancreatitis. Of the 942 patients **WARNINGS AND PRECAUTIONS**[see treated with anagrelide, 161 (17%) were discontinued from the study because of adverse reactions or abnormal laboratory test results. The most common adverse reactions for treatment discontinuation were headache, diarrhea, edema, palpitations, and abdominal pain.

The most frequently reported adverse reactions to anagrelide (in 5% or greater of 942 patients with myeloproliferative neoplasms) in clinical trials were listed in Table 1.

Table 1 : Adverse Reactions Reported in Clinical Studies in at least 5% of Patients

Adverse reactions	AGRYLIN (N=942) (%)
Cardiac Disorder	
Palpitations	26%
Tachycardia	8%
Chest Pain	8%
General disorders and administration site conditions	
Asthenia	23%
Edema	21%
Pain	15%
Fever	9%
Peripheral edema	9%
Malaise	6%
Gastrointestinal disorders	
Diarrhea	26%
Nausea	17%
Abdominal Pain	16%
Vomiting	10%
Flatulence	10%
Anorexia	8%
Dyspepsia	5%
Respiratory, thoracic and mediastinal disorders	
Dyspnea	12%
Cough	6%
Skin and subcutaneous tissue disorders	
Rash	8%
Pruritus	6%

Musculoskeletal and connective tissue disorders	
6%	Back Pain
Nervous system disorders	
44%	Headache
15%	Dizziness
6%	Paresthesia

Adverse Reactions (frequency 1% to < 5%) Included

Flu symptoms, chills. **General disorders and administration site conditions:**

Arrhythmia, angina pectoris, heart failure, syncope. **Cardiac Disorders:**

Hemorrhage, hypertension, postural hypotension, vasodilatation. **Vascular disorders:**

Constipation, gastrointestinal hemorrhage, gastritis. **Gastrointestinal disorders:**

Anemia, thrombocytopenia, ecchymosis. **Blood and lymphatic system disorders:**

Elevated liver enzymes. **Hepatobiliary disorders:**

Arthralgia, myalgia. **Musculoskeletal and connective tissue disorders:**

Depression, confusion, nervousness. **Psychiatric disorders:**

Somnolence, insomnia, amnesia, migraine headache. **Nervous system disorders:**

Epistaxis, pneumonia. **Respiratory, thoracic and mediastinal disorders:**

Alopecia. **Skin and subcutaneous tissue disorders:**

Abnormal vision, diplopia. **Eye disorders:**

Tinnitus **Ear and labyrinth disorders:**

Hematuria, renal failure. **Renal and urinary disorders:**

Clinical Study in Pediatric Patients

The frequency of adverse events observed in pediatric patients was similar to adult patients. The most common adverse events observed in pediatric patients were fever, epistaxis, headache, and fatigue during the 3-month anagrelide treatment in the study. Episodes of increased pulse and decreased systolic or diastolic blood pressure beyond the normal ranges in the absence of clinical symptoms were observed. Adverse events that had been reported in these pediatric patients prior to the study and were considered to be related to anagrelide treatment based on retrospective review were; palpitations, headache, nausea, vomiting, abdominal pain, back pain, anorexia, fatigue, and muscle cramps.

Postmarketing Experience

The following adverse reactions have been identified during post-marketing use of AGRYLIN. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Cases of torsades de pointes, **WARNINGS AND** ventricular tachycardia, interstitial lung diseases (including allergic alveolitis, eosinophilic pneumonia and interstitial pneumonitis) [see], tubulointerstitial nephritis and clinically significant hepatotoxicity (including symptomatic ALT and AST elevations and elevations greater than three**PRECAUTIONS** times the ULN) have been reported.

Other adverse events in pediatric patients reported in spontaneous reports and literature reviews include anemia, cutaneous photosensitivity and elevated leukocyte count.