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Factive (Gemifloxacin Mesylate)

Zuletzt aktualisiert: 30. November 2017

In clinical studies, 8119 patients received daily oral doses of 320 mg FACTIVE. In addition, 1797 healthy volunteers and 81 patients with renal or hepatic impairment received single or repeat doses of gemifloxacin in clinical pharmacology studies. The majority of adverse reactions experienced by patients in clinical trials were considered to be of mild to moderate severity.

FACTIVE was discontinued because of an adverse event (determined by the investigator to be possibly or probably related to drug) in 2.0% of patients, primarily due to rash (0.8%), nausea (0.3%), diarrhea (0.3%), urticaria (0.2%) and vomiting (0.2%). Comparator antibiotics were discontinued because of an adverse event at an overall comparable rate of 2.1%, primarily due to diarrhea (0.5%), nausea (0.4%), vomiting (0.3%), rash (0.3%), abdominal pain (0.2%) and vertigo (0.2%).

The most commonly reported adverse events with a frequency of ?2% for patients receiving 320 mg FACTIVE versus comparator drug (beta-lactam antibiotics, macrolides or other fluoroquinolones) are as follows: diarrhea 5.0% vs. 6.2%; rash 3.5% vs. 1.1%; nausea 3.7% vs. 4.5%; headache 4.2% vs. 5.2%; abdominal pain 2.2% vs. 2.2%; vomiting 1.6% vs. 2.0%; and dizziness 1.7% vs. 2.6%.

Adverse Events with a Frequency of Less than 1%

Additional drug-related adverse events (possibly or probably related) in the 8119 patients, with a frequency of >0.1% to ?1% included: abdominal pain, anorexia, constipation, dermatitis, dizziness, dry mouth, dyspepsia, fatigue, flatulence, fungal infection, gastritis, genital moniliasis, genital pruritus, hyperglycemia, increased alkaline phosphatase, increased ALT, increased AST, increased creatine phosphokinase, insomnia, leukopenia, pruritus, somnolence, taste perversion, thrombocythemia, urticaria, vaginitis, and vomiting.

Other adverse events reported from clinical trials which have potential clinical significance and which were considered to have a suspected relationship to the drug, that occurred in ?0.1% of patients were: abnormal urine, abnormal vision, anemia, arthralgia, asthenia, back pain, bilirubinemia, dyspnea, eczema, eosinophilia, facial edema, flushing, gastroenteritis, granulocytopenia, hot flashes, increased GGT, increased non-protein nitrogen, leg cramps, moniliasis, myalgia, nervousness, non-specified gastrointestinal disorder, pain, pharyngitis, photosensitivity/phototoxicity reactions, pneumonia, thrombocytopenia, tremor, vertigo. .)**PRECAUTIONS**(See

In clinical trials of acute bacterial exacerbation of chronic bronchitis (ABECB) and community acquired pneumonia (CAP), the incidences of rash were as follows (Table 3):

Table 3: Incidence of Rash by Clinical Indication in Patients Treated with FACTIVE

CAP (7 days) N = 643		CAP (5 days) N = 256		ABECB (5 days) N = 2284		
%	n/N	%	n/N	%	n/N	
4	26/643	0.4	1/256	1.2	27/2284	Totals
9.1	8/88	2.7	1/37		NA*	Females, <40 years
2.3	5/214	0	0/73	1.5	16/1040	Females, ?40 years
5	5/101	0	0/65		NA*	Males, <40 years
3.3	8/240	0	0/81	0.9	11/1203	Males, ?40 years

* insufficient number of patients in this category for a meaningful analysis (See **PRECAUTIONS**).

Laboratory Changes

The percentages of patients who received multiple doses of FACTIVE and had a laboratory abnormality are listed below. It is not known whether these abnormalities were related to FACTIVE or an underlying condition.

Clinical Chemistry

increased ALT (1.7%), increased AST (1.3%), increased creatine phosphokinase (0.7%), increased alkaline phosphatase (0.4%), increased total bilirubin (0.4%), increased potassium (0.3%), decreased sodium (0.2%), increased blood urea nitrogen (0.3%), decreased albumin (0.3%), increased serum creatinine (0.2%), decreased calcium (0.1%), decreased total protein (0.1%), decreased potassium (0.1%), increased sodium (0.1%), increased lactate dehydrogenase (<0.1%) and increased calcium (<0.1%).

CPK elevations were noted infrequently: 0.7% in FACTIVE patients vs. 0.7% in the comparator patients.

Hematology

increased platelets (1.0%), decreased neutrophils (0.5%), increased neutrophils (0.5%), decreased hematocrit (0.3%), decreased hemoglobin (0.2%), decreased platelets (0.2%), decreased red blood cells (0.1%), increased hematocrit (0.1%), increased hemoglobin (0.1%), and increased red blood cells (0.1%).

In clinical studies, approximately 7% of the FACTIVE treated patients had elevated ALT values immediately prior to entry into the study. Of these patients, approximately 15% showed a further elevation of their ALT at the on-therapy visit and 9% showed a further elevation at the end of therapy visit. None of these patients demonstrated evidence of hepatocellular jaundice. For the pooled comparators, approximately 6% of patients had elevated ALT values immediately prior to entry into the study. Of these patients, approximately 7% showed a further elevation of their ALT at the on-therapy visit and 4% showed a further elevation at the end of therapy visit.

In a clinical trial where 638 patients received either a single 640 mg dose of gemifloxacin or 250 mg BID of ciprofloxacin for 3 days, there was an increased incidence of ALT elevations in the gemifloxacin arm (3.9%) vs. the comparator arm (1.0%). In this study, two patients experienced ALT elevations of 8 to 10 times the upper limit of normal. These elevations were asymptomatic and reversible.

Post-Marketing Adverse Reactions

The majority of the post-marketing adverse events reported were cutaneous and most of these were rash. Some of these cutaneous adverse events were considered serious. The majority of the rashes occurred in women and in patients under 40 years of age. The following are additional adverse reactions reported during the post-marketing use of FACTIVE. Since these reactions are reported voluntarily from a population of uncertain size, it is impossible to reliably estimate their frequency or establish a causal relationship to FACTIVE exposure:

- peripheral neuropathy that may be irreversible;
- anaphylactic reaction, erythema multiforme, skin exfoliation, facial swelling;
- exacerbation of myasthenia gravis;
- hemorrhage, increased international normalized ratio (INR), retinal hemorrhage;
- peripheral edema;
- renal failure;
- .);**PRECAUTIONS** prolonged QT, supraventricular tachycardia, syncope, transient ischemic attack; photosensitivity/phototoxicity reaction (See
- antibiotic-associated colitis;
- tendon rupture.