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Gabapentin

Adverse Effects

Cardiovascular

- Common (1% to 10%): Peripheral edema, vasodilation, hypertension
- Rare (less than 0.1%): Atrial fibrillation, heart failure, myocardial infarction, cerebrovascular accident, ventricular extrasystoles, bradycardia, premature atrial contraction, pericardial rub, heart block, pericardial effusion, pericarditis
- Postmarketing reports: Cardiac arrest, chest pain, palpitation, tachycardia

Dermatologic

- Common (1% to 10%): Abrasion, facial edema, purpura, rash, pruritus, acne
- Uncommon (0.1% to 1%): Alopecia, eczema, dry skin, increased sweating, urticaria, hirsutism, seborrhea, cyst, herpes simplex
- Rare (less than 0.1%): Stevens-Johnson syndrome, angioedema, erythema multiforme, drug rash (with eosinophilia and systemic symptoms), herpes zoster, skin discolor, skin papules, photosensitive reaction, psoriasis, desquamation, maceration, skin nodules, subcutaneous nodule, melanosis, skin necrosis, local swelling
- Frequency not reported: DRESS/multiorgan hypersensitivity

Endocrine

Rare (less than 0.1%): Hyperthyroid, hypothyroid, goiter, hypoestrogenism, ovarian failure, epididymitis, cushingoid appearance

Gastrointestinal

- Common (1% to 10%): Diarrhea, dry mouth or throat, constipation, nausea, vomiting, dyspepsia, dental abnormalities, gingivitis, abdominal pain, flatulence
- Uncommon (0.1% to 1%): Glossitis, gum hemorrhage, thirst, stomatitis, increased salivation, gastroenteritis, hemorrhoids, bloody stools, fecal incontinence
- Rare (less than 0.1%): Pancreatitis, dysphagia, eructation, pancreatitis, peptic ulcer, colitis, blisters in mouth, tooth discoloration, perlèche, salivary gland enlarged, lip hemorrhage, esophagitis, hiatal hernia, hematemesis, proctitis, irritable bowel syndrome, rectal hemorrhage, esophageal spasm
- Frequency not reported: Dehydration

General

The most common adverse reactions associated with the use of this drug were dizziness, somnolence, and peripheral edema.

Genitourinary

- Common (1% to 10%): Incontinence, impotence
- Uncommon (0.1% to 1%): Hematuria, dysuria, urinary frequency, cystitis, urinary retention, vaginal hemorrhage, amenorrhea, dysmenorrhea, menorrhagia
- Frequency not reported: Breast hypertrophy, gynecomastia, sexual dysfunction (including changes in libido, ejaculation disorders, and anorgasmia)

Hematologic

- Common (1% to 10%): Leucopenia, purpura
- Uncommon (0.1% to 1%): Anemia, lymphadenopathy
- Rare (less than 0.1%): Thrombocytopenia, thrombophlebitis, leukocytosis, lymphocytosis, increased bleeding time
- Frequency not reported: Blood creatine phosphokinase increased, coagulation defect

Hepatic

Rare (less than 0.1%): Hepatitis, jaundice, elevated liver function tests SGOT (AST), SGPT (ALT), and bilirubin, hepatomegaly, hepatotoxicity

Hypersensitivity

Very rare (less than 0.01%): Hypersensitivity syndrome, a systemic reaction with a variable presentation that can include fever, rash, hepatitis, lymphadenopathy, eosinophilia, and sometimes other signs and symptoms

Metabolic

Common (1% to 10%): Weight gain, hyperglycemia Postmarketing reports: Hyponatremia

Musculoskeletal

Common (1% to 10%): Back pain, arthralgia, myalgia, twitching Uncommon (0.1% to 1%):

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Tendonitis, arthritis, joint stiffness, joint swelling Frequency not reported: Rhabdomyolysis, myoclonus Postmarketing reports: Elevated creatine kinase, rhabdomyolysis

Nervous system

Very common (10% or more): Somnolence (21%), dizziness (17%), ataxia (13%) Common (1% to 10%): Abnormal gait, incoordination, neuralgia, tremor, dysarthria, hyperkinesia, seizures, dysarthria, paresthesia, hypesthesia, coordination abnormal, increased/decreased/absent reflexes, vertigo Uncommon (less than 1%): Hypokinesia Rare (less than 0.1%): Movement disorders (e.g., choreoathetosis, dyskinesia, dystonia), loss of consciousness Frequency not reported: Withdrawal precipitated seizure/status epilepticus Postmarketing reports: Movement disorder

Ocular

Common (1% to 10%): Amblyopia, conjunctivitis, diplopia, nystagmus Uncommon (0.1% to 1%): Cataract, dry eyes, eye pain, visual field defect, photophobia, bilateral or unilateral ptosis, eye hemorrhage, hordeolum, eye twitching Rare (less than 0.1%): Eye itching, abnormal accommodation, eye focusing problem, watery eyes, retinopathy, glaucoma, iritis, corneal disorders, lacrimal dysfunction, degenerative eye changes, blindness, retinal degeneration, miosis, chorioretinitis, strabismus

Oncologic

Uncommon (0.1% to 1%): Breast cancer Rare (less than 0.1%): Non-Hodgkin's lymphoma

Other

Very common (10% or more): Fatigue (11%), fever (11%) Common (1% to 10%): Asthenia, accidental injury, otitis media, tremor, pain Rare (0.01% to 0.1%): Tinnitus Very rare (less than 0.01%): Sudden unexplained death in patients with epilepsy Frequency not reported: Sleepwalking, withdrawal symptoms, hearing loss, earache, tinnitus, inner ear infection, otitis, taste loss, unusual taste, ear fullness, perforated ear drum, sensitivity to noise, eustachian tube dysfunction, otitis externa, odd smell, labyrinthitis

Psychiatric

Common (1% to 10%): Abnormal thinking, amnesia, depression, hostility, confusion, emotional liability, anxiety, nervousness, amnesia, insomnia Uncommon (0.1% to 1%): Mental impairment Rare (less than 0.1%): Hallucinations Frequency not reported: Suicidal behavior

and ideation, hypomania

Renal

Rare (less than 0.1%): Acute renal failure

Respiratory

Common (1% to 10%): Pharyngitis, dyspnea, cough, bronchitis, respiratory infection, rhinitis Rare (less than 0.1%): Pulmonary thrombosis, pulmonary embolism Frequency not reported: Pseudo-croup, hoarseness

Pregnancy and Breastfeeding Warnings

- US FDA Pregnancy category C
 - Animal reproduction studies have shown an adverse effect on the fetus and there
 are no adequate and well-controlled studies in humans, but potential benefits may
 warrant use of the drug in pregnant women despite potential risks
 - Folic acid 5mg start 4 weeks prior and 12 weeks after conception
 - Animal studies: Delayed ossification and hydroureter and hydronephrosis
- Excreted into human milk
 - Breastfed infants should be monitored for drowsiness, adequate weight gain, and developmental milestones, especially in younger, exclusively breastfed infants

References

Drugs.com

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