

Hemady™ (dexamethasone) – New orphan drug approval

- On October 3, 2019, the FDA approved Dexcel Pharma's [Hemady \(dexamethasone\)](#) 20 mg tablets, in combination with other antimyeloma products for the treatment of adults with multiple myeloma.
- Dexamethasone is available in a variety of different formulations for oral, injection, topical, and ophthalmic administration. Dexamethasone is generically available as an oral [tablet](#) and elixir.
 - The generic tablet is available in 0.5 mg, 0.75 mg, 1 mg, 1.5 mg, 2 mg, 4 mg and 6 mg strengths.
 - The generic tablets and elixir are approved for allergic states, dermatologic diseases, endocrine disorders, gastrointestinal diseases, hematologic disorders, neoplastic diseases, nervous system diseases, ophthalmic disease, renal diseases, respiratory diseases, rheumatic disorders, and some miscellaneous diseases.
- Hemady is contraindicated in patients with systemic fungal infections and hypersensitivity to dexamethasone.
- Warnings and precautions of Hemady include alterations in endocrine function, immunosuppression and increased risk of infections, alterations in cardiovascular/renal function, venous and arterial thromboembolism, vaccination, ophthalmic effects, gastrointestinal perforation, osteoporosis, myopathy, behavioral and mood disturbances, Kaposi's sarcoma, Hemady in combination with anti-myeloma products, and embryo-fetal toxicity.
- The most common adverse reactions with Hemady use were cardiovascular, dermatologic, endocrine, fluid and electrolyte disturbances, gastrointestinal, metabolic, musculoskeletal, neurological/psychiatric, ophthalmic, abnormal fat deposits, decreased resistance to infection, hiccups, increased or decreased motility and number of spermatozoa, malaise, moon face, and weight gain.
- The recommended dose of Hemady is 20 mg or 40 mg orally once daily on specific days depending on the treatment regimen. Refer to the prescribing information of the other anti-myeloma products used in combination with Hemady for specific Hemady dosing.
- Dexcel Pharma's launch plans for Hemady are pending. Hemady will be available as a 20 mg tablet.