Generic Name:
Oxitriptan
Trade Name:
No trade name
Company:
Multiple manufacturers
Notes:

In a May 2, 2019, statement, FDA indicated that several compounding pharmacies and physicians had contacted the agency to determine if compounders can use the bulk drug substance oxitriptan to compound oral drugs under section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act) for an identified patient with tetrahydrobiopterin (BH4) deficiency, a group of rare inborn errors of metabolism.

The agency has informed these stakeholders that it does not intend to object to the compounding of oral oxitriptan for patients with BH4 deficiency who have a prescription identifying the disorder, as long as the drug is compounded in compliance with all other conditions of section 503A of the FD&C Act.

This group of disorders is also identified by the names primary tetrahydrobiopterin (BH4) deficiency, atypical phenylketonuria (PKU), or BH4-deficient hyperphenylalaninemia. Patients with 6-pyruvoyl-tetrahydropterin synthase (6-PTPS) deficiency are among those included in this group of disorders.

On February 19, 2019, FDA issued a final rule that placed six bulk drug substances on the list of bulk drug substances that can be used in compounding under section 503A of the FD&C Act (referred to as the ?503A bulks list?) and identified four others, including oxitriptan, that FDA did not place on the 503A bulks list. FDA evaluated oxitriptan, also known as 5-hydroxytryptophan or 5-HTP, for inclusion on the 503A bulks list as a treatment for depression or insomnia and did not include it on the list.

Patients with BH4 deficiency who have questions should contact their health care provider or contact FDA via druginfo@fda.hhs.gov. Health professionals and compounders with questions about using the bulk drug substance oxitriptan to compound oral drugs for BH4 deficiency under section 503A of the FD&C Act should contact compounding@fda.hhs.gov.

Medication Monitor Categories:
Alerts and Recalls