UMKC
School of Pharmacy
Drug Information Center

UMKC Drug Information Center
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Dr. ,

Thank you for your question regarding available resources to identify medications that are safe to use when patients report allergies to dyes. The Institute for Safe Medication Practices (ISMP) notes that there are reports of patient intolerances or allergies to color additives that are approved for use by the Food and Drug Administration (FDA). Patients may experience reactions ranging from mild to severe including rashes, hives, or anaphylaxis. The most common additives involved with allergic reactions are the following blue, red, and yellow dyes[1]:

- FD&C blue #1 (Brilliant Blue)
- FD&C red #4 (carmine, approved for use in externally applied drugs)
- FD&C red #40 (Allura Red)
- FD&C yellow #5 (tartrazine)
- FD&C yellow #6 (Sunset Yellow)

Searching for a particular dye can be a challenge due to labeling guidelines set in the Code of Federal Regulations (CFR). Title 21-Food and Drugs requires that prescription drugs for use other than oral include all inactive ingredients in the labeling; however, color additives may be designated as coloring without providing specific components.[2] All OTC products require listing each inactive ingredient in the "Drug Facts" section of their labels.[1]

FD&C yellow #5 (tartrazine) must be declared in the labeling for over the counter (OTC) and prescription drug products administered orally, nasally, rectally, vaginally, or for use in the area of the eye.[3-4] Prescription drug regulations require a warning statement regarding allergic-type reactions caused by FD&C yellow #5 (tartrazine) in the "Precautions" section of the package insert.

Although not required, companies may voluntarily list inactive ingredients within the "Description" section of the package insert.[1] Package inserts are available through the FDA website under Drugs@FDA, National Library of Medicine's DailyMed website, specific medication websites within prescribing information (e.g., Ozempic.com), or via an internet search, however, this method should be consulted last due to the possibility of finding outdated information.

Overall, it is best practice to search the "Description" and "Precaution" sections of the package insert, or "Drug Facts" section of an OTC product first to determine what additives may be present in the formulation. If this information is not available, the pharmaceutical company's medical information department should be able to provide further specifics on inactive ingredients within their formulation. Please let us know if we can help you with anything else.

Sincerely,

Vance Howerton, PharmD Candidate 2022
UMKC Drug Information Center

References:

1. Identifying Color Additives in Regulated Drug Products. Institute for Safe Medication Practices (ISMP). June 17, 2021. Accessed January 5, 2022. https://www.ismp.org/resources/identifying-color-additives-regulated-drug-products
2. Food and Drugs, 21 C.F.R § 201.100(b)(5)(ii). 2021. Accessed January 5, 2022. https://www.ecfr.gov/
3. Food and Drugs, 21 C.F.R § 201.20(a). 2021. Accessed January 5, 2022. https://www.ecfr.gov/
4. Food and Drugs, 21 C.F.R § 201.20(b). 2021. Accessed January 5, 2022. https://www.ecfr.gov/