

# No rash decisions- a probable case of hypersensitivity to inert ingredients

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## Objective

To describe a probable case of hypersensitivity to levothyroxine tablet in a paediatric outpatient.

## Literature review

Hypersensitivity to levothyroxine has not been documented, however, inactive ingredients in tablet formulations may cause hypersensitivity reactions, including urticaria, pruritus, rash, flushing, angioedema, gastrointestinal symptoms, fever, arthralgia, serum sickness, and wheezing. [1] Case reports in adults have been published [2,3] however to the best of our knowledge, no cases in children have been reported.

## Clinical features

A 16-year-old Caucasian female was referred to a paediatrician for investigation of a two-month history of pain and fatigue, with no significant past medical history. Baseline bloods were within normal limits except for a mildly low vitamin D and deranged thyroid function tests (TFT) (TSH elevated at 26.7 mIU/L, with a free T4 of 10.6 pmol/L and a T3 of 5.6 pmol/L), with antithyroglobulin antibody in normal range and antithyroid peroxidase markedly elevated (greater than 1300 U/mL). The patient was diagnosed with Hashimoto's thyroiditis and commenced on levothyroxine tablets 50 microgram daily. On day 5 of treatment, the patient developed a rash including "itchy red spots" across the chin and forehead.

## Pharmacist interventions, case progress and outcomes

Levothyroxine administration was ceased by the paediatrician upon notification of the rash. Consultation with a paediatric endocrinologist occurred who confirmed that allergy to levothyroxine itself would be unlikely. The question of how to manage ongoing thyroid hormone supplementation was posed to the paediatric pharmacist. A literature search concluded the reaction was likely due to tablet excipients, or was incidental. Review of available levothyroxine tablet formulations including excipient lists occurred, with trial of an alternate tablet brand being recommended. The patient tolerated the new brand of levothyroxine with no rash reported after 7-days of treatment. Ongoing paediatrician review and TFT monitoring to assess response will occur.





## Discussion

Hypersensitivity reactions to levothyroxine including urticaria, pruritus and rash are most likely due to inactive tablet ingredients. Common allergens including food components and colouring agents should be considered. Trial of an alternate brand with differing excipients should occur prior to consideration of the need for alternate agents or allergy testing.

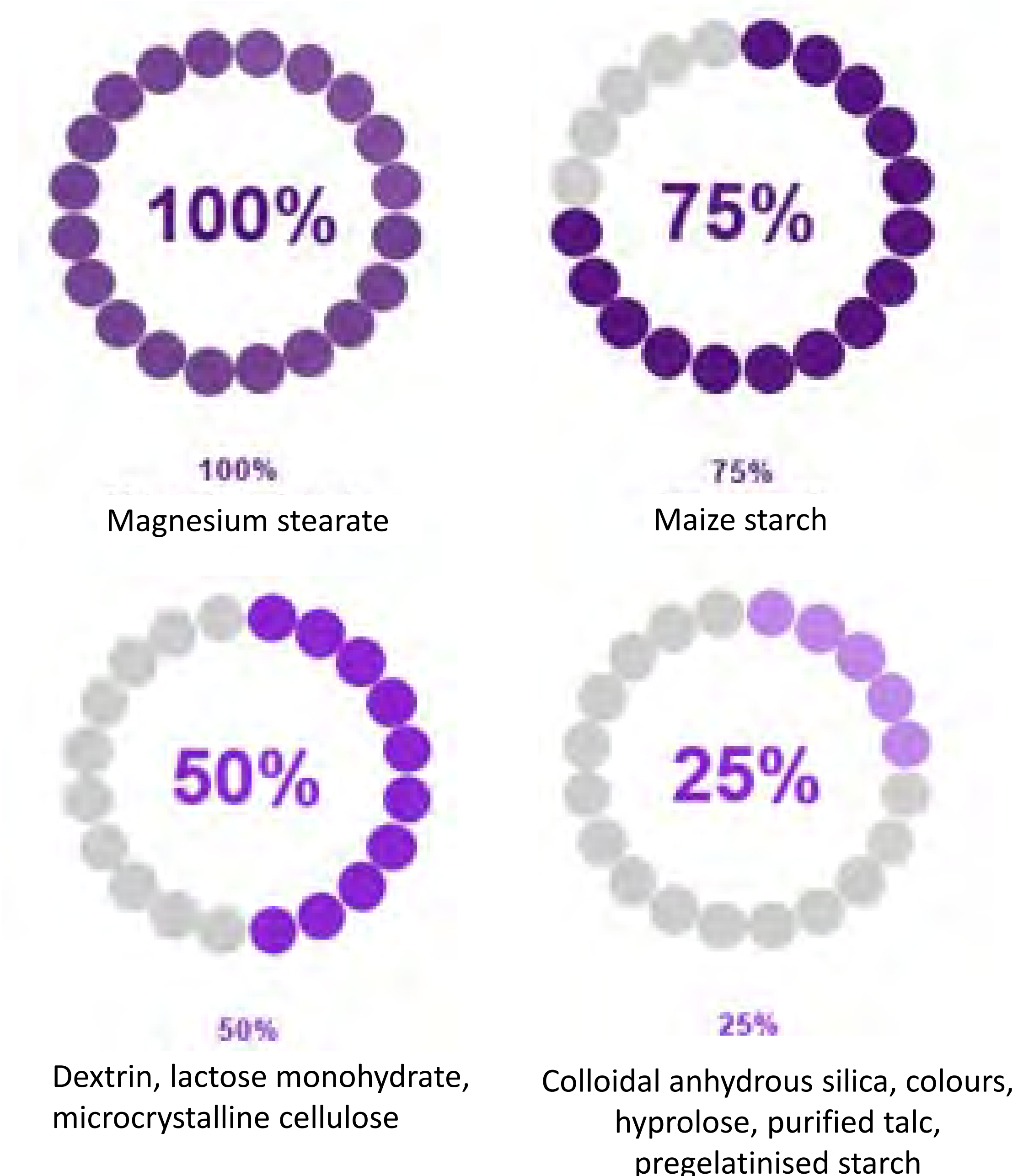
## References

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2. Sohail Siddiqui, M., & Shotliff, K. (2019). Levothyroxine-not all tablets are the same. *Prescriber*, 30(7), 31-34.
3. Ksouda, K., Affes, H., Masmoudi, A., Sahnoun, Z., Hakim, A., Ghozzi, H., ... & Zeghal, K. M. (2010). Levothyroxine induced eczematiform skin eruption and generalized pruritus: a case report. *Therapie*, 65(6), 587-589.

## List of excipients in PBS eligible brands of levothyroxine

|  |          |  |
|--|----------|--|
|   | Brand #1 | Microcrystalline cellulose, maize starch, purified talc, colloidal anhydrous silica and magnesium stearate.  |
|   | Brand #2 | Maize starch, lactose monohydrate, dextrin and magnesium stearate  |
|   | Brand #3 | Microcrystalline cellulose, pregelatinised starch, hypolose, magnesium stearate, Titanium Lake Blend TLB-964 WHITE (PI 138484) for the 50 microgram tablets, Lake Blend LB-505008 PURPLE (PI 110747) for the 75 microgram tablets, Lake Blend LB-520006 YELLOW (PI 110744) for the 100 microgram tablets and Allura Red AC Aluminium Lake for the 200 microgram tablets. |
|  | Brand #4 | Maize starch, lactose monohydrate, dextrin and magnesium stearate  |

## Frequency of excipient inclusion in PBS eligible brands of levothyroxine



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