



Medicine Supply Notification

MSN/2020/042

Ketotifen 1mg/5ml elixir (Zaditen®)

Tier 2 – medium impact*

Date of issue: 17/07/2020

Summary

- Zaditen® 1mg/5ml elixir is currently out of stock with no confirmed resupply date.
- Zaditen® 1mg tablets are available and can support demand of the elixir if deemed appropriate.
- Unlicensed imports of ketotifen elixir have been sourced; lead times vary.

Actions Required

For patients with insufficient supplies of elixir during this period, clinicians should consider:

- prescribing Zaditen® 1mg tablets (see supporting information below); or
- prescribing unlicensed imports of ketotifen 1mg/5ml elixir and work with local pharmacy teams to ensure orders are placed within appropriate time frames as lead times may vary (see supporting information);

Supporting Information

- Zaditen® 1mg tablets and 1mg/5ml elixir were discontinued in 2019, however, in June 2020 both preparations were re-introduced back to the UK market.
- Standard Zaditen® tablets should be swallowed whole. However, if patients cannot swallow whole tablets, and use of unlicensed imports of the elixir is not considered appropriate, UKMi advise the tablets can be dispersed in a known volume of water (10 to 15ml), for administration (considered unlicensed). If this is deemed appropriate, prescribers and pharmacists should ensure that patients and carers are counselled on how to prepare and administer the dose required accurately.
- The following specialist importers have confirmed they can source unlicensed ketotifen 1mg/5ml elixir (please note, there may be other companies that can also source supplies):
 - Alium Medical
 - Target Healthcare
 - Waymade PLC
- Any decision to prescribe an unlicensed medicine must consider the relevant guidance and NHS Trust or local governance procedures. Please see the links below for further information.
 - [Prescribing unlicensed medicines](#), General Medical Council (GMC),
 - [The supply of unlicensed medicinal products](#), Medicines and Healthcare products Regulatory Agency (MHRA)
 - [Professional Guidance for the Procurement and Supply of Specials](#), Royal Pharmaceutical Society
- When prescribing a product that is not licensed in the UK, due to a supply issue with the licensed alternative, prescribers must indicate on the FP10 prescription that an unlicensed product is required. This can be done by annotating the prescription with the following wording: **“special order”**.

Enquiries

If you have any queries, please contact DHSCmedicinesupplyteam@dhsc.gov.uk

*Classification of Tiers can be found at the following link: <https://www.england.nhs.uk/publication/a-guide-to-managing-medicines-supply-and-shortages/>