Chief Medical Officer Directorate Pharmacy and Medicines Division



10 May 2024

Medicine Supply Alert Notice

Daktacort® (hydrocortisone 1% / miconazole 2%) cream

Priority: Level 2*

Valid until: Discontinued, supplies to be exhausted by end of May 2024

Issue

- 1. Daktacort® (hydrocortisone 1% / miconazole 2%) cream (30g, POM) has been discontinued with remaining supplies due to be exhausted by the end of May 2024 (*see Table 1).
- 2. Daktacort Hydrocortisone[®] (hydrocortisone 1% / miconazole 2%) cream 15g (OTC) remains available but cannot support increased demand until October 2024 (**see Table1).
- 3. Alternative cream formulations containing a different antifungal in combination with hydrocortisone (0.5% or 1%) remain available and can support increased demand.

Advice and Actions

- 4. Clinicians should:
 - not initiate any new patients on Daktacort[®] cream (30g); and
 - consider prescribing an alternative antifungal hydrocortisone combination cream, ensuring that the patient is not intolerant to any of the excipients (see Additional information); and
 - consider prescribing Daktacort Hydrocortisone[®] cream (15g) if it is deemed the most appropriate product when it is able to support increased demand in October 2024, noting use may be off label in light of its more limited range of licensed indications (see Additional information).

Additional Information

Table 1: Antifungal- hydrocortisone combination creams

Product	al- hydrocortisone combination Constituents	indication
Troduct	Constituents	maidation
Daktacort® (POM)*	Miconazole nitrate 2%w/w Hydrocortisone 1%w/w.	Inflamed dermatoses where infection by susceptible organisms and inflammation co-exist, e.g. intertrigo and infected eczema.
(POM)"	Excipients with known effect: 2 mg/g benzoic acid (E210) & 0.052 mg/g butylated hydroxyanisole (E320)	 Moist or dry eczema or dermatitis including atopic eczema, primary irritant or contact allergic eczema or seborrhoeic eczema including that associated with acne. Intertriginous eczema including inflammatory intertrigo, perianal and genital dermatitis.
		Organisms susceptible to miconazole are dermatophytes and pathogenic yeasts (e.g. Candida spp.). Also, many Gram-positive bacteria including most strains of Streptococcus and Staphylococcus.
Daktacort Hydrocortisone®	Miconazole nitrate 2% w/w; hydrocortisone 1% w/w	Athlete's foot and candidal intertrigo where there are co-existing symptoms of inflammation.
(P)**	Excipients with known effect: Benzoic acid (E210) 2 mg/g & butylhydroxyanisole (E320) 0.052 mg/g	
Canesten HC®	Each gram of cream contains:10mg clotrimazole & 10 mg hydrocortisone (1%)	 Skin infections where co-existing symptoms of inflammation, e.g. itching, require rapid relief: Dermatomycoses due to dermatophytes (e.g. Trichophyton species), moulds and other fungi & due to yeasts (Candida species) and skin diseases showing secondary infection with these fungi. Nappy rash where infection due to Candida albicans is present. Candidal vulvitis, candidal balanitis and candidal intertrigo.
	Excipients with known effect: Cetostearyl alcohol 100mg & Benzyl alcohol 20mg (in each gram of cream)	
Timodine [®]	Nystatin 3 %w/w Dimeticone 350 10%w/w Hydrocortisone 0.5 %w/w Benzalkonium chloride solution 0.2%w/w	 Dermatoses, including intertrigo, eczema, seborrhoeic dermatitis, hand dermatitis, and pruritis ani et vulvae, in which infection with Candida albicans is a factor. Severe nappy rash in which infection with Candida albicans is a factor.
	Excipients with known effect: Cetostearyl alcohol 1.51%w/w Butylated hydroxyanisole compound 0.4%w/w [containing butylated hydroxyanisole (E320) 20%, propyl gallate 10%, citric acid 10% and 60% propylene glycol (E1520)] Methyl hydroxybenzoate (E218) 0.1 w/w Propyl hydroxybenzoate (E216) 0.1% w/w Sorbic acid 0.1% w/w	
Nystaform HC®	Nystatin100,000 units/g Chlorhexidine 1%w/w Hydrocortisone 0.5 %w/w	Infected dermatoses where fungal (particularly monilial) and/or bacterial infections are present.
	Excipients with known effect: Cetostearyl alcohol 100 mg & Benzyl alcohol 10 mg (per gram of cream)	

Links to further information

- SmPC for Daktacort® cream
- SmPC for Daktacort Hydrocortisone® cream
- SmPC for Canesten HC® cream
- BNF: Hydrocortisone with miconazole
- BNF: Hydrocortisone with clotrimazole
- BNF: Hydrocortisone with chlorhexidine hydrochloride and nystatin
- BNF: Hydrocortisone with benzalkonium chloride, dimeticone and nystatin
- SmPC for Timodine® cream
- SmPC for Nystaform HC®

Specialist Pharmacy Service (SPS) website

- 5. The UK Department of Health and Social Care (DHSC) in conjunction with SPS have launched an online Medicines Supply Tool, which provides up to date information about medicine supply issues. To access the online Medicines Supply Tool you need to register with the <u>SPS website</u>. Registration for access to the website is available to UK healthcare professionals and organisations providing NHS healthcare. The tool is located under the Tools tab and then click on the Medicines Supply option.
- 6. We encourage prescribers, pharmacy professionals, and pharmacy procurement leads in Scotland to register with the SPS website and use its Medicine Supply Tool to stay up to date concerning medicines supply disruptions. Please be aware that while medicines supply issues will appear on the SPS website, some of the recommended actions may not always be appropriate / relevant within the Scottish context.

Enquiries

7. Enquiries from Health Boards or healthcare professionals should be directed in the first instance to PharmacyTeam@gov.scot (primary care) or NSS.NHSSMedicineShortages@nhs.scot (secondary care).