

Conditions for which over the counter items should not routinely be prescribed in primary care: exception criteria

1. General Exceptions:

NHS England recommends the following **general exceptions** for scenarios where patients should continue to have their treatments prescribed:

- Patients prescribed an OTC treatment for a **long term condition** (e.g. regular pain relief for chronic arthritis or treatments for inflammatory bowel disease).
- For the treatment of **more complex forms of minor illnesses** (e.g. severe migraines that are unresponsive to over the counter medicines).
- For those patients that have symptoms that suggest the **condition is not minor** (i.e. those with red flag symptoms for example indigestion with very bad pain.)
- Treatment for **complex patients** (e.g. immunosuppressed patients).
- Patients on **prescription only treatments**.
- Patients prescribed OTC products to **treat an adverse effect or symptom of a more complex illness** and/or prescription only medications should continue to have these products prescribed on the NHS.
- Circumstances **where the product licence doesn't allow the product to be sold over the counter** to certain groups of patients. This may vary by medicine, but could include babies, children and/or women who are pregnant or breast-feeding. Community Pharmacists will be aware of what these are and can advise accordingly.
- Patients with a minor condition suitable for self-care that **has not responded sufficiently** to treatment with an OTC product.
- Patients where the clinician considers that the presenting **symptom is due to a condition that would not be considered a minor condition**.
- Circumstances where the prescriber believes that in their **clinical judgement, exceptional circumstances** exist that warrant deviation from the recommendation to self-care.
- Individual patients where the clinician considers that their **ability to self-manage is compromised as a consequence of medical, mental health or significant social vulnerability to the extent that their health and/or wellbeing could be adversely affected**, if reliant on self-care. To note that being exempt from paying a prescription charge does not automatically warrant an exception to the guidance. Consideration should also be given to safeguarding issues.

These general exceptions **DO NOT** apply to over-the counter (OTC) products for the following conditions:

- Vitamins
- Minerals
- Probiotics
- Self-limiting conditions with limited evidence

2. Condition specific exceptions:

Further condition-specific exemptions are also given, as detailed in the table overleaf. These are also summarised in the NHS England quick reference guide, available at:

<https://www.england.nhs.uk/wp-content/uploads/2018/05/over-the-counter-quick-reference-guide.pdf>

Condition	Exception
Acute Sore Throat	'Red Flag' symptoms
Conjunctivitis	'Red Flag' symptoms
Coughs and colds and nasal congestion	'Red Flag' symptoms
Cradle Cap (Seborrhoeic dermatitis – infants)	If causing distress to the infant and not improving
Dandruff	No routine exceptions
Diarrhoea (Adults)	No routine exceptions
Dry Eyes/Sore (tired) Eyes	No routine exceptions
Earwax	No routine exceptions
Excessive sweating (Hyperhidrosis)	No routine exceptions
Haemorrhoids	'Red Flag' symptoms
Head Lice	No routine exceptions
Indigestion and Heartburn	No routine exceptions
Infant Colic	'Red Flag' Symptoms
Infrequent Cold Sores of the lip.	'Red Flag' symptoms
Infrequent Constipation	No routine exceptions
Infrequent Migraine	No routine exceptions
Insect bites and stings	No routine exceptions
Mild Acne	No routine exceptions
Mild Cystitis	'Red Flag' Symptoms
Mild Dry Skin	No routine exceptions
Mild Irritant Dermatitis	No routine exceptions
Mild to Moderate Hay fever/Seasonal Rhinitis	No routine exceptions
Mouth ulcers	No routine exceptions
Nappy Rash	No routine exceptions
Oral Thrush	No routine exceptions
Minor burns and scalds	No routine exceptions have been identified. However more serious burns always require professional medical attention.

Condition	Exception
	Burns requiring hospital A&E treatment include but are not limited to: <ul style="list-style-type: none"> • all chemical and electrical burns; • large or deep burns; • burns that cause white or charred skin; • burns on the face, hands, arms, feet, legs or genitals that cause blisters.
Minor conditions associated with pain, discomfort and/fever. (e.g. aches and sprains, headache, period pain, back pain)	No routine exceptions
Prevention of dental caries	No routine exceptions
Probiotics	ACBS approved indication or as per local policy
Ringworm/Athletes foot	No routine exceptions
Sun Protection	ACBS approved indication of photodermatoses (i.e. where skin protection should be prescribed)
Sunburn	No routine exceptions
Teething/Mild toothache	No routine exceptions
Threadworms	No routine exceptions
Travel Sickness	No routine exceptions
Vitamins and minerals	<ul style="list-style-type: none"> • Medically diagnosed deficiency, including for those patients who may have a lifelong or chronic condition or have undergone surgery that results in malabsorption. Continuing need should however be reviewed on a regular basis. • NB maintenance or preventative treatment is not an exception. • Calcium and vitamin D for osteoporosis. • Malnutrition including alcoholism (see NICE guidance) • Patients suitable to receive Healthy start vitamins for pregnancy or children between the ages 6 months to their fourth birthday. (NB this is not on prescription but commissioned separately)
Warts and Verrucae	No routine exceptions

3. Considerations for specific patient groups

Some queries had arisen locally regarding specific patient groups and whether the general exception criteria would apply to them. Most of these relate to the exception for patients where the clinician considers that their ability to self-manage is compromised as a consequence of medical, mental health or significant social vulnerability to the extent that their health and/or wellbeing could be adversely affected. The NHSE guidance is clear that the judgement on vulnerability should be made by the clinician. The clinical working group also further refined the exception around vulnerability from the draft version, to clarify that it applies to *individual* patients.

For the following patient groups please consider:

1. Care home patients

- *Consider the patient's ability to self-care and access to over-the counter medicines (some residential care home residents may self administer)*
- *If self-care not possible consider whether homely remedies policy in place and whether it covers the condition in question*
- *If no homely remedy policy in place and unable to self-care, prescribing of over-the-counter products may be appropriate under one or more of the general exception criteria*

2. Patients receiving domiciliary care or in assisted living accommodation

- *Consider the patient's ability to self-care and whether social care arrangements are in place for patients to access over-the-counter medicines*
- *If self-care is not possible, prescribing of over-the-counter products may be appropriate under one or more of the general exception criteria*

3. Patients with a mental capacity issue

- *If self-care is not possible, prescribing of over-the-counter products may be appropriate under one or more of the general exception criteria (e.g. Individual patients where the clinician considers that their ability to self-manage is compromised as a consequence of medical, mental health or significant social vulnerability to the extent that their health and/or wellbeing could be adversely affected)*

4. Children covered by Healthy Start criteria

- *Eligibility for Healthy Start is not covered by the general exceptions for being prescribed OTC products on prescription. If a patients qualifies to receive Healthy Start vitamins this is not on prescription but commissioned separately.*

5. Restrictions to product licence for over-the counter products

- *The product licence for some OTC products prevents it's sale to certain groups of patients. This may vary by medicine, but could include babies, children and/or women who are pregnant or breast-feeding. Community Pharmacists will be aware of what these are and can advise accordingly. Further guidance on the more commonly available medicines available over the counter for minor illnesses and self-limiting conditions and the restrictions on sale is detailed in appendix 1.*

APPENDIX 1
Common medicines available to purchase over the counter (OTC) for minor illnesses and self-limiting conditions

The table below contains a summary of some of the more commonly available medicines available over the counter for minor illnesses and self-limiting conditions. This is not an exhaustive list of all available products. Prescribers and pharmacists are advised to consult individual product summary of product characteristics (SPCs) for comprehensive product information, including all cautions and contraindications. The PAGB OTC Directory also contains summaries of products available OTC.

Minor illness/ self-limiting condition	Medication available over the counter (OTC) See PAGB OTC Directory or product SPC for information about specific products	Sales classification		Age restrictions	Contraindications
		GSL (general sale)	P (pharmacy only)		
Acute pain, headache, temperature	Paracetamol 500mg tablets	16 tablet packs	32 tablet packs*		Long term conditions requiring regular pain relief *larger quantities of up to 100 tablets may be sold at the pharmacist's professional discretion
	Paracetamol 120mg/5ml suspension	Up to 100ml	200ml	≥3 months ≥2 months for immunisation	Babies born before 37 weeks, babies weighing less than 4kg
	Paracetamol 250mg/5ml suspension	Up to 100ml	200ml	≥6 years	
	Ibuprofen 200mg, 400mg tablets Ibuprofen 100mg/5ml liquid	200mg 16 tablet packs	200mg ≥32 tablet packs All 400mg packs	≥3 months	Long term conditions requiring regular pain relief, asthma, unstable high blood pressure, taking anticoagulants, taking methotrexate, stomach ulcers/problem, not for use in Chicken Pox
	Co-codamol 8/500mg		All pack sizes	≥12 years	Severe Liver disease, breastfeeding, pregnancy
	Ibuprofen 5% gel Ibuprofen 10% gel	5% gel	10% gel	≥14 years	Pregnancy, breastfeeding, broken/ infected skin, asthma
	Diclofenac 2.32 and 3% gel		All pack sizes	≥14 years	Pregnancy, breastfeeding, broken/ infected skin, asthma
Hayfever/ allergies	Cetirizine 10mg tablets Cetirizine 1mg/ml solution	14 tablet packs 70ml solution	All other pack sizes	≥12 years	Patients with kidney problems, pregnancy, breastfeeding
	Loratadine 10mg tablets	10 tablet packs	All other pack sizes	≥12 years	Pregnancy, breastfeeding
	Chlorphenamine		All pack sizes	≥12 years	Pregnancy, breastfeeding
	Chlorphenamine 2mg/5ml solution		All pack sizes	≥1 year	Children with Asthma, children taking Monoamine oxidase inhibitors
	Acrivastine 8mg capsules	12 tablets	All other pack sizes	≥12 years <65 years	Pregnancy, breastfeeding
	Beclometasone 0.05% nasal spray	100 sprays	180 sprays	≥18 years	
	Sodium cromoglicate 2% eye drops	✓			
Athletes foot	Miconazole 2% cream/ powder Miconazole 0.16% powder	0.16% powder	2% cream/ powder		
	Terbinafine hydrochloride 1% cream/ gel/ powder/ spray	1% cream 1% spray	1% gel	Spray ≥16 years Others ≥12 years	Diabetic patients, pregnancy, breastfeeding
Cold sores	Aciclovir cream 5%		✓		Immunocompromised and terminally ill, only for face and lips
Conjunctivitis (uncomplicated/ bacterial)	Chloramphenicol 0.5% eye drops Chloramphenicol 1% eye ointment		✓	≥2 years	Pregnancy, breastfeeding, contact lenses should not be used when treating

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Cystitis	Sodium citrate 4g sachet	✓		≥16 years	Men, diabetic patients, heart disease, hypertension, renal disease, pregnancy, breastfeeding
	Potassium citrate 1.5g liquid/ 3g sachet/ 1.5g effervescent tablet			≥16 years	History of kidney disease, pregnancy, breastfeeding
Diarrhoea	Oral rehydration solutions/ sachets	✓			Patients with liver or kidney disease, patients on low sodium/ potassium diets, patients with diabetes
	Loperamide 2mg capsules	Up to 6 capsules	All other pack sizes	≥12 years	Inflammatory bowel disease Post bowel surgery Post pelvic radiation Colorectal cancer
Ear wax	Olive oil drops Sodium bicarbonate drops Arachis oil/chlorobutanol hemihydrate drops (Cerumol®) Docusate sodium 0.5% drops (Waxsol®) Acetic Acid 2% (EarCalm®) (for minor ear infection only)	Olive oil Sodium bicarbonate drops	All other drops/ sprays	Ear Calm not for <12 years	Perforated ear drums, Cerumol (arachis oil) nut allergy
Head lice	Dimeticone 4% gel/ lotion/ spray	100ml pack	All other pack sizes	≥6 months	
	Malathion 0.5% aqueous lotion	✓		≥6 months	
Haemorrhoids	Zinc oxide (e.g. Anusol®, Germaloids®)	✓		≥16 years	Pregnancy, breastfeeding, rectal bleeding or blood in stools
Indigestion, dyspepsia, heartburn, upset stomach	Sodium alginate Calcium carbonate Sodium bicarbonate	✓		≥12 years	Avoid in heart or renal failure
	Gaviscon infant		✓	≥12 months ≤ 2 years	Babies born before 37 weeks Avoid if excessive water loss likely (diarrhoea, vomiting etc)
	Bismuth subsalicylate (Pepto-Bismol®)		✓	≥16 years	Sensitivity to aspirin, do not take alongside aspirin
	Esomeprazole 20mg tablets (Nexium Control®)	✓		≥18 years ≤55 years	Pregnancy, breastfeeding, jaundice or liver disease
	Pantoprazole 20mg tablets (Pantoloc Control®)		✓	≥18 years ≤55 years	Pregnancy, breastfeeding, jaundice or liver disease
	Ranitidine 75mg tablets	Up to 12 tablets		≥16 years	Peptic ulceration, elderly taking NSAIDs
	Infant colic	Simeticone 40mg/ml	✓		
Dimeticone 42mg/5ml		✓			Fructose, glucose-galactose or sucrose intolerant patients (contains sucrose)
Lactase enzyme (Colief®)		✓			
Nappy rash	Titanium dioxide, titanium peroxide, titanium salicylate (Metanium®)	✓			
	Zinc oxide, Benzyl alcohol, benzyl benzoate, lanolin (Sudocrem®)	✓			
Nasal congestion	Sodium chloride 0.9% nasal drops, spray	✓			

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Scabies	Permethrin 5% dermal cream		✓	≥2 months	
	Crotamiton 10% cream	✓		≤3 years	Breastfeeding, pregnancy
Teething, sore mouth conditions (e.g. ulcers)	Lidocaine Hydrochloride (Bonjela®), Chlorocresol, Cetylpyridinium (Anbesol®)			≥16 years	Active peptic ulceration, pregnancy, breastfeeding, hypersensitivity to the active substances, anaesthetics of the amide-type, lidocaine is considered to be unsafe in patients with porphyria
	Choline salicylate, cetalkonium chloride (Bonjela®) Bonjela teething gel	✓		≥2 months	Heart disease, liver disease
Threadworms	Mebendazole 100mg tablets (Ovex®)		✓	≥2 years	Pregnancy, breastfeeding
Thrush/ oral thrush	Clotrimazole 1% cream		✓	≥16 years ≤65 years	
	Clotrimazole 2% cream Clotrimazole 10% intravaginal cream (Canesten Cream Combi®)	✓		≥16 years ≤60 years	Pregnancy
	Clotrimazole 500mg pessary and clotrimazole 2% cream (Canesten Combi®)	✓		≥16 years ≤65 years	
	Fluconazole 150mg capsule and clotrimazole 2% cream (Canesten Duo®)		✓	≥16 years ≤60 years	Lactose intolerance, pregnancy
	Fluconazole 150mg capsule		✓	≥16 years ≤60 years	Lactose intolerance, pregnancy
	Miconazole 2% oral gel (15g) (Daktarin® oral gel)		✓	≥4 months	Pregnancy, breastfeeding, patients taking warfarin
Sore throat	Benzydamine spray/ oral rinse (Difflam®)		✓	≥12 years	Pregnancy, breastfeeding
Minor skin conditions (dermatitis, mild to moderate dry skin)	Clobetasone 0.05% cream (Eumovate® eczema and dermatitis cream)		✓	≥12 years	Broken or inflamed skin, pregnancy, breastfeeding
	Hydrocortisone 1% cream		✓	≥10 years	Not be used on the eyes or face, the ano-genital area or on broken or infected skin including impetigo, cold sores, acne athlete's foot, or infected bites and stings
	Crotamiton 10% cream (Eurax®) Crotamiton 10% and hydrocortisone 0.25% cream (Eurax HC®)	Eurax	Eurax HC	≥3 years Eurax HC ≥10 years	Broken or inflamed skin, pregnancy, breastfeeding
	Emollient creams, lotions, gels	✓			
	Urea 5%, lauromacrogols 3% (E45 Itch Relief®)	✓			Broken or inflamed skin
	Calamine lotion Colloidal oatmeal ointment (Aveeno®)				
Warts and verrucae	Salicylic acid and lactic acid gel	Bazuka treatment gel	Other preparations		Diabetic Patients, face, neck, ano-genital area Moles, birthmarks, hairy warts or skin lesions, broken skin
	Salicylic acid and lactic acid paints		✓		Diabetic patients, face, neck, ano-genital area Moles, birthmarks, hairy warts or skin lesions, broken skin Impaired peripheral blood circulation
	Scholl freeze, Bazuka® sub zero	✓		≥4 years	Diabetic Patients, face, neck, ano-genital area Moles, birthmarks, hairy warts or skin lesions, broken skin