

Updates on Preparations Allowed as General Sale List (GSL)

Dear Members,

On 1st Jun 2016, topical minoxidil lotion/foam, ketoconazole shampoo, and pheniramine/naphazoline eye drops were reclassified from P to GSL.

Back in Oct 2016, Health Sciences Authority (HSA) also released a list of items which *may potentially* be reclassified to GSL, provided if the **product license holders** choose to submit the reclassification applications, by fulfilling the specified conditions on indications, dosage form and strength, appropriate consumer pack size furnished with appropriate patient information on the correct use. The list included ophthalmic mast cell stabiliser, low potency topical steroids, topical NSAIDs, anti-diarrhoeals, mucolytics, and antispasmodics to name a few. More recent additions to the list are topical antifungals and antivirals (items no. 26-30 in the table below), released on 1st Mar 2017.

The forensic classification of these products remains status quo, unless the relevant reclassification applications are submitted and approved by HSA.

Kindly refer to the table below for the current classification status (updated as of 24 Mar 2017)

	Active ingredient/s	Dosage form	Proposed conditions suitable for GSL status	Current status (as of 24 Mar 2017)
Topical anti-hair loss preparations				
1	Minoxidil	Lotion/Foam (2%/3%/5%)	For treatment of hair loss	GSL
Topical anti-dandruff preparations				
2	Ketoconazole	Shampoo (2%)	For treatment of dandruff, seborrhoeic dermatitis	GSL
3	Ciclopirox	Shampoo (1.5%)	For relief of dandruff, seborrhoeic dermatitis	P – This product is no longer available in Singapore.
Ophthalmic antihistamine/decongestant				
4	Pheniramine (0.3%)/Naphazoline (0.025%) Antazoline (0.5%)/Tetrahydrozoline (0.4%)	Eye drops	For relief of eye itching and redness	GSL
Ophthalmic mast cell stabiliser				
5	Sodium cromoglycate	Eye drop (2%)	For prevention and treatment of allergic conjunctivitis	P
Low potency topical steroids				
6	Hydrocortisone +/- antifungal (e.g. clotrimazole, miconazole)	Cream/ Ointment/ Lotion (0.5%, 1%)	<u>Hydrocortisone only</u> Symptomatic relief of inflammation associated with steroid-responsive conditions such as dermatitis and eczema	P

			<u>Hydrocortisone + antifungal</u> Treatment of fungal infections with co-existing symptoms of inflammation e.g. itching, redness	
Topical NSAIDs				
7	Piroxicam	Gel (0.5%)	Relief of pain and swelling of muscles and joints	P
8	Ketoprofen	Gel (2.5%) Patch (30mg)	Relief of pain and swelling of muscles and joints	P
Anti-diarrhoeals				
9	Loperamide	Tablet/Capsule (2mg)	Symptomatic relief of acute diarrhoea	P
Preparations for sore throat/ulcers				
10	Benzylamine	Lozenge (3mg) Mouthwash (22.5mg/15mL) Spray (1.5mg/mL) Gel (10mg/g)	Temporary relief of inflammatory conditions of the oral cavity such as sore throat and mouth ulcers	P
11	Tyrothricin	Lozenge (0.5mg)	Temporary relief of sore throat	P
Mucolytics				
12	Ambroxol	Tablet (30mg) Capsule(75mg) Lozenge (15mg) Syrup (30mg/5ml)	Thinning of mucus in respiratory tract disorders with difficulty in expectorating	P
13	Bromhexine	Tablet (8mg) Syrup (4mg/5mL; 8mg/5mL)	Thinning of mucus in respiratory tract disorders with difficulty in expectorating	POM* for tablet, P for syrup
14	Acetylcysteine	Tablet/Capsule Granules (100, 200mg, 600mg)	Thinning of mucus in respiratory tract disorders with difficulty in expectorating	P
15	Carbocisteine	Tablet/Capsule (375mg) Syrup (2%, 4%, 5%)	Thinning of mucus in respiratory tract disorders with difficulty in	P

			expectorating	
Oral NSAIDs				
16	Naproxen	Tablet (220mg)	Relief of headache, backache, muscular aches and pains, minor pain of arthritis, toothache, menstrual pain. Reduces fever associated with common cold	P
17	Ibuprofen	Tablet/Capsule containing not more than 200mg Syrup 100mg/5mL	For relief of headache, migraine pain, dental pain, period pain, rheumatic pain, muscular pain, backache and fever Reduction of fever, relief of teething pain, toothache, earache, sore throat, minor aches and sprains	GSL/P/POM*, depending on product-specific reclassification Only Nurofen Tablet 200mg (OTC) (SIN09488P), Nurofen Express Liquid Capsule 200mg (SIN14562P), Nurofen For Children 100 mg/5 ml (OTC Pack) (SIN11880P) are GSL
Antispasmodics				
18	Hyoscine	Tablet/Capsule (10mg)	Symptomatic relief of abdominal pain, cramps and intestinal discomfort	P
19	Alverine	Capsule (60mg)	Symptomatic relief of abdominal pain, cramps and intestinal discomfort	P
20	Mebeverine	Tablet (135mg) Capsule (200mg)	Symptomatic relief of abdominal pain and cramps, bowel disturbances and intestinal discomfort	P
21	Dicyclomine + <i>antacid/simethicone</i>	Tablet (2.5mg) Syrup (5mg/5mL)	Symptomatic relief of gastric and abdominal pain or discomfort and/or bloatedness	P
Anthelmintics				
22	Albendazole	Tablet (200mg, 400mg) Syrup (400mg/10mL)	Treatment of common worm infections of the gut	P
23	Mebendazole	Tablet (100mg)	Treatment of common worm infections of the gut	P
Antihistamine/decongestant				
24	Loratadine/pseudoephedrine	Tablet (5/120mg, 10/240mg) Syrup (5/60 mg per	Relief of symptoms associated with allergic rhinitis and the common cold including nasal	P

		5mL)	congestion, sneezing, runny and itchy nose	
High-dose Vitamin Bs				
25	Vitamin B1, B6 and B12	Tablet (100mg/200mg/200mcg)	For relief of nerve pain	P, except Neurobion Tablet (OTC) (SIN15098P) which is GSL
Topical antifungals				
26	Ketoconazole	Cream (2%)	Treatment of fungal infections of the skin	P
27	Tioconazole	Cream (1%)	Treatment of fungal infections of the skin	P
28	Isoconazole	Cream (1%)	Treatment of fungal infections of the skin	P
29	Amorolfine	Nail lacquer (5%)	Treatment of fungal nail infections	P
Topical antivirals				
30	Acyclovir	Cream (5%)	Treatment of cold sores Max pack size not exceeding 2g	POM*

As the concepts of self-medication and self-care become increasingly popular among consumers nowadays, the availability of GSL medicines makes it possible for consumers to treat common minor ailments without the supervision of a health care professional.

Although manufacturers are required to provide appropriate labeling and packaging for products reclassified as GSL medicines, patients who are inexperienced may have difficulty reading and understanding label instructions. This can result in misuse of the product, potentially leading to adverse events or drug interactions with other medicines.

The PSS Community Chapter has written to HSA regarding pharmacists' concerns over potential misuse of medicines, such as loperamide, loratadine/pseudoephedrine and topical hydrocortisone should they be reclassified as GSL products. HSA has given its reassurance that they have deemed these drugs suitable for self-medication by the general public for short-term relief of symptoms after careful assessment. Factors such as the history of use, safety of the medicine and dosage were taken into consideration during evaluation.

Nevertheless, pharmacists play a significant role in patient education and counseling to promote safe and effective use of GSL products. If a patient is unsure about his/her medicines or health conditions, JUST ASK a pharmacist for advice.

The PSS Community Chapter will continue to work closely with HSA and provide timely feedback on the safe and appropriate use of reclassified medicines.

References:

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