

Ministry Of Health

Minister Office



وزارة الصحة

مكتب الوزير

Date: _____ Ref: _____ ٢٠١٦ ١٠٢ ٢٠١٦ ١٠٢

قرار وزاري رقم (١٠٢) لسنة ٢٠١٦

وزير الصحة:

- بعد الاطلاع أحكام القانون رقم ٢٨ لسنة ١٩٩٦ في شأن تنظيم مهنة الصيدلة وتداول الادوية .
- وعلى المادة (٤٢) من لائحته التنفيذية الصادر بالقرار الوزاري رقم ٣٩٥ لسنة ١٩٩٧ .
- وبناء على اقتراح السيد وكيل الوزارة المساعد لشئون الادوية والتجهيزات الطبية بتحديث قائمة الادوية والمستحضرات الصيدلانية المصرح ببيعها في الجمعيات التعاونية والاسواق المركزية المحلية والواردة في القرار الوزاري رقم ٦٢١ لسنة ١٩٩٨ .
- وبناء على مقترحات المصلحة العامة ، وما عرضه علينا السيد وكيل الوزارة .

قرر .

مادة أولى : يصرح بعرض وبيع وتداول الادوية والمستحضرات الصيدلانية الواردة في القائمة المرفقة لهذا القرار في الاسواق الرئيسية للجمعيات التعاونية والاسواق المركزية فقط . وعلى هذه الجهات اتباع الشروط الواردة في ملحق رقم (٢) المرافق للقرار رقم ٦٢١ لسنة ١٩٩٨ . وعلى من يرغب في ذلك من الجهات المذكورة مراجعة ادارة تسجيل ومراقبة الادوية الطبية والنباتية للحصول على الاشتراطات والمواصفات الخاصة بأماكن البيع والعرض .

مادة ثانية : تلغى المادة الاولى من القرار الوزاري رقم ٦٢١ لسنة ١٩٩٨ .

مادة ثالثة : يبلغ هذا القرار من يلزم لتنفيذه ويعمل به من تاريخ نشره في الجريدة الرسمية.

الدكتور / علي سعد العبيدي

وزير الصحة

د. علي سعد العبيدي
وزير الصحة

بالسيد اميد اداره تسجل راسم لوزير الادوية
بالسيد اميد اداره تسجل لوزير الادوية
حلت لقرار الادوية
المستأجر تعين على هادي التوفيق

List Of Substances which are Present In
Authorised Medicines For General Sale

- This list contains active ingredients which are present in medicinal products which can be classified as General Sale .
- The General Sale product must not be recommended or marketed as:
 1. Anthelmintic
 2. parenteral administration
 3. eye ointment or eye drop
 4. enema
 5. For use wholly or mainly for irrigation of wounds or of the bladder, vagina or rectum.

ANALGESICS:

Active ingredient	Conditions for GSL supply	Additional labelling requirements
Aspirin (Acetyl Salicylic Acid)	Max strength : • Effervescent tablets - 500mg • powders or granules - 650mg • non-effervescent tablets or capsules 325mg	<u>Warnings relating to reye's syndrome:</u> • There is a possible association between aspirin and reye's syndrome when given to children. Reye's syndrome is a very rare disease, which affects the brain and liver, and can be fatal. For this reason aspirin should not be given to children aged under 16 years unless specifically indicated (e.g. For kawasaki's disease).
Paracetamol e.g: Panadol Advance Tablets 500mg- Adol Tablets -Panadrex Tab. - Panadol baby infants,Panadol Syrupetc	<u>Tablets,capsules and Liquids</u> Max strength: • adults 500mg • children aged less than 6 years 120mg • children aged 6 years and over 250mg	• Paracetamol in combination with methionine is never gsl. <u>Labelling requirements:</u> • The statement "contains paracetamol" (<i>not necessary if product is for external use only, or if the product name includes the word 'paracetamol'</i>)

STOMACH UPSET/ Antacids :

- Each of these active ingredient can be found alone or in combination with another active ingredient in the medicinal product.

Active ingredient	Conditions for GSL supply	Additional labelling requirements
<u>Aluminum-containing active ingredients :</u> (1) Basic aluminum carbonate gel. (2) Aluminum hydroxide as : • aluminum hydroxide-hexitol stabilized polymer • aluminum hydroxide-magnesium carbonate codried gel • aluminum hydroxide-magnesium trisilicate codried gel • aluminum-hydroxide sucrose powder hydrated (3) Dihydroxyaluminum aminoacetate and dihydroxyaluminum aminoacetic acid .		• Prolonged use of aluminum-containing antacids in patients with renal failure may result in or worsen dialysis osteomalacia. • Prolonged use of aluminum-containing antacids by normophosphatemic patients may result in hypophosphatemia if phosphate intake is not adequate. In its more severe forms, hypophosphatemia can lead to anorexia, malaise, muscle weakness, and osteomalacia.

(4) Aluminum phosphate gel when used as part of an antacid combination product (5) Dihydroxyaluminum sodium carbonate. e.g.: Malox Sacchets, Suspension and chewable tablets (Combination aluminum Hydroxide + magnesium Hydroxide)	4- Aluminum phosphate gel when used as part of an antacid combination product and contributing at least 25 percent of the total acid neutralizing capacity the maximum daily dosage limit is 8 grams .	
Bicarbonate-containing active ingredients e.g: Eno Fruit Salt	maximum daily dosage limit: • 200 mEq for persons up to 60 years old • 100 mEq for persons 60 years or older	
Calcium-containing active ingredients: • Calcium, as carbonate or phosphate maximum e.g : Rennie, Chooz .etc	• daily dosage limit 160 mEq. calcium	
Citrate-containing active ingredients: • Citrate ion, as citric acid or salt	• maximum daily dosage limit 8 grams .	
Magnesium-containing active ingredients : (1) Hydrate magnesium aluminate activated sulfate . (2) Magaldrate (3) Magnesium aluminosilicates (4) Magnesium carbonate (5) Magnesium glycinate (6) Magnesium hydroxide (7) Magnesium oxide (8) Magnesium trisilicate e.g : Malox Sacchets. Suspension and chewable tablets (Combination aluminum Hydroxide + magnesium Hydroxide, Moxal & Moxal plus...etc		
Phosphate-containing active ingredients : (1) Aluminum phosphate (2) Mono or dibasic calcium salt (3) Tricalcium phosphate	1-maximum daily dosage limit 8 grams 2-maximum daily dosage limit 2 grams. 3-maximum daily dosage limit 24 grams.	
Potassium-containing active ingredients : 1) Potassium bicarbonate (or carbonate when used as a component of an effervescent preparation) 2) Sodium potassium tartrate . e.g : Gaviscon (Potassium Bicarbonate+Sodium alginate)	1-maximum daily dosage limit • 200 mEq. of bicarbonate ion for persons up to 60 years old • 100 mEq. of bicarbonate ion for persons 60 years or older	
Sodium-containing active ingredients : (1) Sodium bicarbonate (or carbonate when used as a component of an effervescent preparation) (2) Sodium potassium tartrate e.g: Eno Fruit Salt	1-maximum daily dosage limit • 200 mEq. of sodium for persons up to 60 years old • 100 mEq. of sodium for persons 60 years or older • 200 mEq. of bicarbonate ion for persons up to 60 years old	That part of the warning which states, "Keep this and all drugs out of the reach of children" is not required on a product which contains only sodium bicarbonate powder and which is intended primarily for other than drug uses.

	100 mEq. of bicarbonate ion for persons 60 years or older	
Tartrate-containing active ingredients: Tartaric acid or its salts e.g: Epinos Pineapple Effervescent Salt	maximum daily dosage limit 200 mEq	

SWEETNERS:

Approved Artificial sweetners:

- (1) Sucralose (e.g : tropicana slim –splenda....etc)
- (2) Aspartam (e.g. Canderol...etc)
- (3) Saccharin

THROAT LOZENGES AND MOUTH WASH:

- Throat lozenges contains antiseptic or soothing agents only.
- If local anesthetic is added like (Lidocaine, benzocaine) then the product can not be sold as GSL product.

1. THROAT LOZENGES:

Active ingredient	Conditions for GSL supply	Additional labelling requirements
Levomental e.g: Strepsils Cool		
2,4-Dichlorobenzyl alcohol e.g: Strepsils Honey&Lemon, Strepsils Orange...etc	Maximum strength 2mg	
Amylmetacresol e.g: Strepsils Honey&Lemon, Strepsils Orange...etc	Maximum Dose: 0.6mg	
Hexylcresorcinol e.g: Strepsils extra		
Dequalinium chloride	max daily dose 2mg	Do not use more than 8 times a day.
Vitamin C		
Natural soothing agents (Menthol, Natural pipperment,lemon,honey....etc) e.g: Isla Moos, Nice...etc.		
propolis lozenges		

مرفق القرار الوزاري رقم ١٠٢ لسنة ٢٠١٦ المؤرخ ٢٠١٦/٤/٢١

2. MOUTH WASH:

Active ingredient	Conditions for GSL supply	Additional labelling requirements
Fluoride Mouth Wash: contain fluoride compounds such as Sodium Fluoride. Eg: Listerine fluoride defense, Oral-B anti-bacterial with fluoride, Colgate phos-flu, Sensodyne Total care gentle mouth wash.		Not recommended for children below six years old.
Anti-Plaque/Anti-SEPTIC Mouth Wash: (1) Chlorhexidine Gluconate Eg: Corsodyl, G.U.M paroex. (2) Triclosan Eg: Colgate Plax, Eludril antibacterial mouth wash (3) Thymol: Eg: Tymol antiseptic mouth wash. (4) Cetylpyridinium Chloride (CPC): Eg: Crest pro-health mouth wash, Breath Rx (5) Povidone Iodine Eg: Betadine mouth wash, HiGeen mouth wash.		
WHITENING MOUTH WASH: 1. Hydrogen peroxide Eg: Colgate Peroxyl oral rinse 2. Sodium phosphate Eg: Listerin Whitening MW 3. Chlorhexidine digluconate Eg: Corsodyl MW 4. Essential oils and phenols Eg: Sensodyne ProNamel MW 5. Sodium Fluoride Eg: ACT total care	5- Daily use mouth rinses for the prevention of dental caries Maximum Dose: 0.2 per cent	

Active ingredient	Conditions for GSL supply	Additional labelling requirements
6. Xylitol Eg: Biotene MW		
7. Sodium lauryl sulfate Eg: Oral-B whitening		
8. Triclosan EG: Plax MW		

VITAMINS:

Vitamin C Effervescent : Max dose 2000mg
e.g.Redaxon – Sona Vite.

TOPICAL ANALGESICS,ANTI-RHEUMATIC AND COUNTER-IRRITANTS:

- It can come in different forms (Creams, Lotions, gels, Sprays, Liniments, oil, Patches)

(1) Rubifacients:

Active ingredient	Conditions for GSL supply
Salicylic Acid derivatives Eg: Salonpas gel/spray/patches, Moov cream/spray, Radian Massage cream	- To be used only as Rubifacients not for treatment of corns or callouses Cream, ointment or gel: - Maximum strength: 2% Medicated patches: - Maximum strength: 0.5% in the impregnating solution
Volatile oils : Camphor, Eucalyptus, Menthol, Peppermint oil, Clove oil, balm...etc. Eg: Vicks vaporub, Mentholatum, Tiger Balm, Mineral Ice, Axe Oil ...etc	
Methyl Nicotinate Eg: Algipan cream, Mentholatum Deep Heat Spray ..etc	
Capsicum Eg: Capsagel, Arthricare, Icy Hot, Zostrix, Moov cream/spray	
1. Glucosamine Sulphate 2. Glucosamine Sulphate & Chondroitin Sulphate Eg: Muscle & Joint cream, Relieff cream, Ethrich Balsam...etc	

(2) NSAIDs:

Active ingredient	Conditions for GSL supply	Additional labelling requirements
Diclofenac diethylammonium Eg: Voltarin emulgel, Clofen gel..etc	• use in adults and children aged 12 years and over • maximum period of 7 days. • Maximum strength: 2.32% w/w	• Not to be used for more than 7 days unless recommended by a doctor.

ANTISEPTICS/DISINFECTANTS:

- It can come in different forms Solutions, Creams, Lotions, Powders, Wipes, Soap Bars & External Vaginal Wash

Active ingredient	Conditions for GSL supply	Additional labelling requirements
Alcohol swabs		
Quaternary Ammonium Compounds (1) Benzalkonium Chloride Eg: CureChrome		
(2) Cetrimide: Eg: Cetrimid, Savlon		
Chlorhexidine & Other Diguanides: (1) Chlorhexidine Gluconate (2) Chlorhexidine Acetate Eg: Peridex, Periogard		
Peroxides & Permanganates: (1) Hydrogen Peroxide Solution (2) Benzoyl Peroxide eg: clear all medicated acne lotion..clear all medicated acne facial scrub..etc (3) Potassium Permanganate Solution	2- Max strength: 2.5 %	
Halogenated Phenol Derivatives : 1) Chlorocresol 2) Chloroxylonol Eg: Dettol 3) Chlorophene 4) Hexachlorophene 5) Triclosan (added to soaps, cosmetics to prevent bacterial contamination) E.g: Dermaplus Intimate cleanser antibacterial, Aqua Hygenizing gel for hands...etc	1- Max strength: 0.2% 2- Max strength: 5.0 %	
Aqueous Solution of Aluminium Acetate		
Povidone Iodine Eg: Betadine solution, Betadin Spray, Betadine paint...etc		

ANTI-DANDRUFF SHAMPOO :

Active ingredient	Conditions for GSL supply	Additional labelling requirements
Ketoconazole e.g. Clinalfa Medicated Anti-dandruff Shampoo 2% . Kenazole Shampoo 2% , Nizoral, Vavo...etc)	Shampoo: - For the prevention and treatment of dandruff. - Max strength: 2% w/v - Max pack: 100ml of product	Shampoo: - There should be a minimum of 3 days between applications. - If the scalp has not cleared within 4 weeks of treatment, consult a doctor or pharmacist.
Active ingredient	Conditions for GSL supply	Additional labelling requirements
Selenium Sulfide+Menthol+Salicylic Acid+Pyrrithione Zinc e.g :Selsun blue		
Salicylic acid e.g : Salicylic acid shampoo		
Pyrrithion zinc+Undecylenamid MEA-sulfosuccinat, Dinatriumsalz e.g:Squa Med Shampoo		
Aloe Vera & Zinc Pyrrithione e.g :Herbal Glo shampoo		

ANTI-LICE TOPICAL PREPARATIONS :

Active ingredient	Conditions for GSL supply	Additional labelling requirements
Dimeticone e.g: Delice solution	For external use: - For the eradication of headlice infestations in adults and children (aged six months and above) - Maximum strength: 4%	
Biococidine e.g: Parasidose treatment lotion		
Eucalyptus oil e.g: Moov head lice foaming gel		
Melaza extract (from neem tree) E.g: Picksan		
Apple vinegar (cyder viniger)		
ESSENTIAL OILS(Lavander,pine,rosemary,eucalyptus...etc) e.g;Liberella Shampoo		

PROTECTANTS/EMOLLIENTS:

- It can come in different forms Creams, Lotions, Gels that contain only soothing ingredients

Active ingredient	Conditions for GSL supply	Additional labelling requirements
Zinc Oxide Eg: Sudocrem, Care Zinc Oxide Castor Oil cream, J&J No More Rash cream		
Active ingredient	Conditions for GSL supply	Additional labelling requirements
White Petrolatum, Mineral Oil Eg: Vaseline, Soft Care Petrolatum Jelly, E45 cream/lotion		
Lanolin Eg: Health Care Lanolin Cream,		
Allantoin Eg: Seba Med products, Pregnacream		
Alpha Hydroxy Acid such as lactic/citric/glycolic acid Eg: Neutrogena Healthy Skin Anti-Wrinkle cream, Ponds Rejuveness Anti-Wrinkle cream		
Urea Eg: Eucerin cream		
Propylene Glycol		
Lecithin Eg: Nutraderm cream/lotion		
Glycerin Eg: Glycerin liquid, Glycare cream, Nivea products, Neutrogena products, K-Y jelly		
Dimethicone Eg: Natural Skin Protectant cream, Moisturel cream/lotion, Cetaphil, Olay products		

References:

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