

Publication of OTC List for General Sale: The Belize Experience

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BELIZE



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MINISTRY OF HEALTH
DIRECTOR OF HEALTH SERVICES

Licensing and
Accreditation
Unit

Drug Inspectorate
Unit

Pharmacy
Department

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The Drug Inspectorate Unit: Finding in Supermarkets



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The Drug Inspectorate Unit: Findings in Supermarkets



Product	Dosage form	Formula	Package size	Batch Number	Expiration Date
Ibuprofen 800mg	Tablet	Ibuprofen 800mg	10 blisters x 10	T142B17	Jan-20
Diclofenac 50mg	Blicap	diclofenac 50 mg/blicap		3526517	Jul-20
Sudagrip	Capsule	Amantadine capsule		36K16	Sep-20
Amoxicillin 500mg	capsule	amoxicilline 500mg/capsule	100 capsules/ b	L161005	Sep-19
Tetracycline ophthalmic	tube	tetracycline 1%	1%; 5 g tube	F0115	Jan-17
Cloranfenicol eye drops	bottle	chloranfenicol	bottle	E17075	May-20
Enteroguanil para ninos	tablet	nifuroxazida 50mg/tablet	200 tablets/ box	32	Sep-19
Aspirin	powder	acetylsalicylic acid 325mg/ satch	none on label	*002	Mar-18
Lombrininos	sachet	Levamisole 50mg/ sachet	40 sachets/ box	240	Aug-19
Parasitin 3	Tablet	levamisole 150mg/ tablet	30 x 1 tablet/ box	J21515	Oct-19
Fungifar	liquid bottle	timerosal 1g, salicylic acid 50g, re	25 ml/ bottle	9C-1	Dec-21
Cofal	bottle	mentol cristalizado 3.5 gr + Aceite	1.8 oz/ bottle	-	Jun-19
Fungifar C	tubes	clotrimazole 1g/ 100g	15 g/ tube	6C-08	Jun-20
Betaderm GC	tubes	betametasona 0.05g, gentamicina	30g/ tube	JL217-153	Jul-20
Pomada de la campana	cans	alantoina 0.05g, oxido de zinc 4.5	15 g/ can	none on label	None on label
Curaderma	cans	benzoic acid 6g, salicylic acid 2g,	12 cans / box	140715	Jul-20
Clotriplex	cans	clotrimazole 10mg, betametasona	12.5g/ tin	66727	Jul-20
Aleve gel	bottle	None on label	none on label	none on label	Dec-22
Muelina	bottle	lidocaine 0.3g, solucion de etanol	15 ml / bottle	170655	Jun-20
Fenugreek capsules	bottle	100 fenugraecum 100%/ capsule	50 capsules/ box	none on label	10/12/2019
Balsamo de Eucalypto	bottle	eucalypto menta , mentol natural,	none on label	none on label	Dec-22
Vitamin E capsules	bottle	dl - alfaticopheryl acetate 400 Uj	30 capsule/ bot	4115S8	Nov-17
Zepol	bottle	menta piperita , mentol natural , g	none on label	none on label	None on label

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Criteria for Inclusion

- Drugs which are effective and safe in order to be used in the prevention, relief of symptoms, or treatment of mild diseases, and are easy to identify
- Drugs with broad safety range, in such a way that the administration of dosage higher than those recommended, does not represent a serious danger for the health of the patient
- Have a broad dosage margin, so it can be adapted at the age and weight of the patient
- Drugs that do not generate tolerance or dependency when are used and that are not susceptible of abuse
- When it is used in accordance with the instructions do not mask serious diseases, nor delay the diagnosis and treatment of a condition that requires of medical care
- Drugs of safe utilization in all the age groups of the population
- Dosage forms that are not of IV or IM administration
- Drugs whose active ingredient have been available for least 5-10 years

Working Group on Drug Classification
Definition and Criteria to Apply to OTC Drugs

<http://www1.paho.org/english/ad/ths/ev/CM-DefinitionandcriteriaforOTC.pdf?ua=1>

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OVER THE COUNTER MEDICATION FOR GENERAL SALE: FEBRUARY, 2018



Ministry of Health - Belize



OVER THE COUNTER MEDICATIONS FOR GENERAL SALE

Drug	Strength/Presentation	Category
Acetylsalicylic Acid	325 mgs and lower doses	General OTC
Paracetamol	500 mgs and lower doses	General OTC
Paracetamol syrup	120 mg - 160mg/5ml	General OTC
Paracetamol Chewable	80 mg	General OTC
Ibuprofen	200 mg and lower doses	General OTC
Aluminum & Magnesium Hydroxide/Simethicone	Oral solution	General OTC
Aluminum or magnesium Hydroxide/Simethicone	320 mg	General OTC
Bismuth subsalicylate	Tablets	General OTC
Dextromethorphan	10 mg	General OTC
Eucalyptus & Menthol	drops	General OTC
Eucalyptus & Menthol	Rubbing vapor	General OTC
Neomycin & Bacitracin	Ointment	General OTC
Normal Saline 0.9% Drops	Drops	General OTC
Oral Rehydration Salts	Salt/ Liquid	General OTC
Senna laxative	Caplets	General OTC
Mineral Oil		General OTC
Petroleum Jelly		General OTC
Lubricating Jelly		General OTC
Magnesium Sulphate	Salt/ Liquid	General OTC
Isopropyl Alcohol	70% & under	General OTC
Zinc Oxide Cream		General OTC
Theobroma Oil (Cocoa Butter)		General OTC
Aloe Vera Gel		General OTC
Methyl salicylate		General OTC
Vitamins (oral)	Presentation for adults	General OTC
Antihistamine/anti-inflammatory /decongestant/cough suppressant	Mixed combination for adults	General OTC



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Areas Where Improvement is Needed

Common Information Requirements for Drugs Over the Counter



WORKING GROUP ON DRUG CLASSIFICATION (WG/DC)

COMMON INFORMATION REQUIREMENTS FOR DRUGS OVER THE COUNTER

Requirements for Drug Registration	New Entity	New Formulations	New Strength	New Association	Pharmaceutical equivalent: Generic	Pharmaceutical Equivalent: Similar	Drug Registration Renewal
Labeling/required documents							
1. Draft of the product final label	√	√	√	√	√	√	-

- Labelling and Required Documents
- Information to Include in the Primary Packaging
- Information to Include in the Secondary Packaging
- Information to Include in Insert

http://www1.paho.org/english/ad/ths/ev/CM-ComonInfo_requirements_OTC.pdf?ua=1

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Evaluation of Patient Leaflet



MINISTRY OF HEALTH
Drug Registration



Patient Leaflet Information or Package Insert:				
Criteria	Yes	No	Not Applicable	Comments
Brand Name				
International Non-Proprietary Name (INN) (generic name)				
Concentration				
Composition				
Dosage Form				
Route of administration				
Posology/dosage				
Maximum dose in 24 hours, for over-the-counter products.				
Condition of dispensing/sale				
Precautions				
Warnings				
Adverse reactions				
Contraindications				
Interactions				
Recommendations in case of overdose				
Using during pregnancy and breast-feeding				
Abuse and addiction				



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Defining the Condition of Sale



Ministry of Health Belize



Drug Registration Certificate

In accordance with the Food and Drugs (Registration, Licensing and Inspection) Regulations, 2017, the Ministry of Health grants the present drug registration certificate and marketing authorization in Belize:

PRODUCT REGISTRATION NO.:

NAME OF PRODUCT:

GENERIC NAME:

PRESENTATION:

PRODUCT LICENCE HOLDER:

PRODUCT MANUFACTURER:

CONDITION OF SALE:

HAS THERE BEEN ANY CHANGES?

- Antibiotic Sale by supermarkets
- Unauthorized distributors of medications
- Increased cooperation for authorized pharmaceutical importers and wholesalers
- Increased public awareness on the OTC List for General Sale in an effort to change the culture of purchasing medication in these establishments.



Areas Where Improvement is Needed

Next Steps

- Revision of the OTC list schedules for February, 2019
- Terminology to be reviewed and redefined to minimize ambiguity
- Expansion of the List: classification as General Sale or Pharmacy Sale

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THANK YOU



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