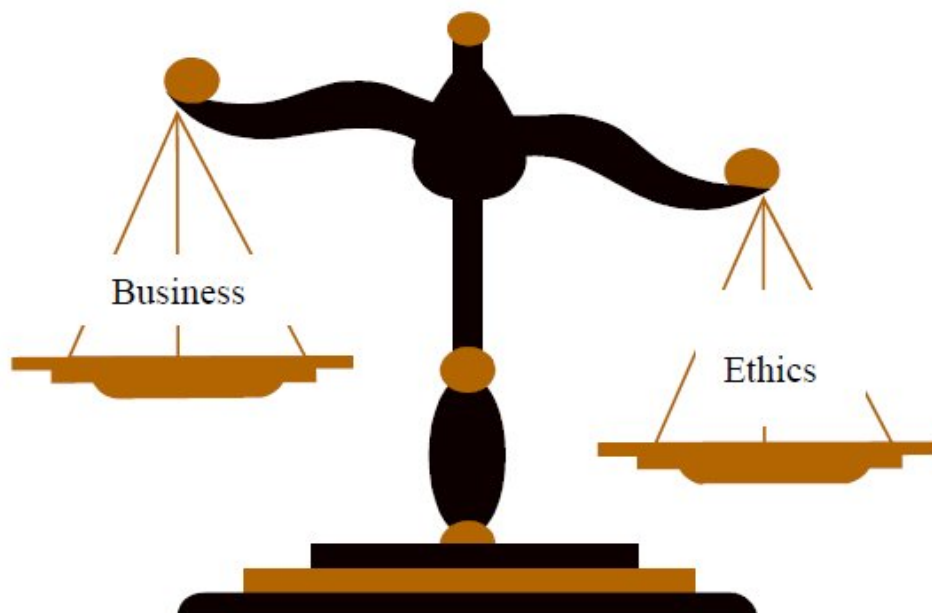




# OVER – THE - COUNTER MEDICINES LIST FOR ETHIOPIA

SECOND EDITION



Food, Medicine & Health Care  
Administration & Control Authority of Ethiopia

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Addis Ababa

## **ACKNOWLEDGEMENT**

The Food, Medicine and Healthcare Administration and Control Authority of Ethiopia (EFMHACA) would be pleased to express its gratitude to the World Health Organization (WHO) for its technical assistance, meeting all financial expenses associated with consultative workshops and printing of Over The Counter List of Medicines for Ethiopia. The Authority would also like to give special appreciation to the National Drug Advisory Committee and all participants of the consultative workshops for their invaluable contributions in scrutinizing and finalizing this list.

## **FOREWORD**

Pharmacotherapy has always been an essential part of healthcare system and will remain so in the future. This relies on the availability of safe, effective and affordable medicines with the required quality, in reasonable amount. Moreover, on the rational prescribing, dispensing and use of such medicines. Ethiopian drug policy ensures that medicines which are required for prevention, diagnosis, treatment, mitigation and rehabilitation of diseases affecting the majority of Ethiopian people have to be identified and classified to respective levels of health service delivery and some of medications are classified as Over The Counter medicine which could be available for the public without prescription.

It gives me a great pleasure to introduce the second edition of Over The Counter medicine for Ethiopia to all beneficiaries, which is the fruit of the joint effort of the staff of the Authority, the National Drug Advisory Committee, development partners as well as the participants of the review workshops.

Finally, I would like to express my gratitude to all those who have directly or indirectly extended their helping hands in the revising and printing of the list. I also call upon health professionals and interested parties to continue their usual support in updating the list by forwarding comments and suggestions to the Food, Medicines and Healthcare Administration and Control Authority of Ethiopia.

## 1. Introduction

Ethiopian drug policy ensures that medicines which are required for prevention, diagnosis, treatment, mitigation and rehabilitation of diseases affecting the majority of Ethiopian people have to be identified and classified to respective levels of health service delivery.

FMHACA prepared and revised National List of medicines in light of the latest development in the fields of medicine and pharmacy.

Taking into consideration the revised National List of medicines, the current over-the-counter medicines list was revised. Revising and updating over-the-counter medicines list is important for increasing access of these medicines as well as for public to take a more active role in their own healthcare.

Over-the-counter (OTC) medicines are medicines that may be sold directly to a consumer without a prescription from pharmacy personnel, as compared to prescription drugs, which are dispensed only to consumers possessing a valid prescription. The Food, Medicines and Healthcare Administration and Control Authority (FMHACA) of Ethiopia decide whether a medicine is safe enough when used without prescription.

Though these drugs are legally classified as over-the-counter (i.e., no prescription is required), they still have some risks. Some interact with other medicines, supplements, foods or drinks. Others cause problems for people with certain medical conditions. Therefore it has to be dispensed by pharmacy personnel with a sufficient counseling about the condition as well as the medicament besides the maximum quantity dispensed at one time should be determined.

As a general rule, over-the-counter medicines have to be used primarily to treat a condition that does not require the direct supervision of a doctor and they are proving to be reasonably safe and well-tolerated. Consequently, all users of this list are strongly invited to send their comments and suggestions to Food, Medicine and Healthcare Administration and Control Authority of Ethiopia, P. O. box 5681, Tel. +251-11-552-41-22, [www.fmhaca.gov.et](http://www.fmhaca.gov.et) Addis Ababa, Ethiopia.

<b>Antacids</b>				
<b>Ser. No.</b>	<b>Name</b>	<b>Strength</b>	<b>Dosage Form</b>	<b>Maximum Quantity Allowed to be Dispensed at One Time</b>
1.	Aluminum Hydroxide	320 mg/5 ml 360 mg/5 ml 500 mg	Mixture/Gel Suspension Tablet (Chewable)	2 bottles 2 bottles 30 tablets
2.	Aluminum Hydroxide + Magnesium Hydroxide♣	220 mg + 195 mg/5ml 400 mg + 400 mg	Suspension Tablet (Chewable)	2 bottles 30 tablets
3.	Aluminium Hydroxide+ Magnesium Hydroxide+ Simethicone♣	225mg+200mg+25mg/5ml	Suspension	2 bottles
4.	Aluminum Hydroxide + Magnesium Trisilicate♣	310 mg + 620 mg/5ml 120 mg + 250 mg ; 250 mg + 500 mg	Suspension Tablet (Chewable)	2 bottles 30 tablets
5.	Magnesium Hydroxide	375 mg/5 ml, 7.75 % 300 mg; 311 mg	Mixture Tablet (Chewable)	2 bottles 30 tablets
6.	Magnesium Trisilicate	500 mg	Tablet (Chewable)	30 tablets
<b>Antispasmodics/Spasmolytic Analgesics</b>				
<b>Ser. No.</b>	<b>Name</b>	<b>Strength</b>	<b>Dosage Form</b>	<b>Maximum Quantity Allowed to be Dispensed at One Time</b>
1.	Hyoscine (Scopolamine) Butylbromide	5mg/5ml 10mg 7.5mg, 10mg	Drops Tablet Suppository	1 bottle 10 tablet 10 suppositories

♣ And any other combination ratio proven to be therapeutically effective can be used



**Antiemetic**

<b>Ser. No.</b>	<b>Name</b>	<b>Strength</b>	<b>Dosage Form</b>	<b>Maximum Quantity Allowed to be Dispensed at One Time</b>
1.	Dimenhydrinate	50mg	Tablet	15 tablets

**Cathartics and Laxatives**

<b>Ser. No.</b>	<b>Name</b>	<b>Strength</b>	<b>Dosage Form</b>	<b>Maximum Quantity Allowed to be Dispensed at One Time</b>
1.	Bisacodyl	5mg, 10mg 5mg	Suppository Tablet	10 suppositories 10 tablets
2.	Cascara Sagrada	125mg	Tablet	10 tablets
3.	Glycerin	1g, 1.36g, 2g, 2.76g	Suppository	10 suppositories
4.	Magnesium Sulphate		Oral powder	1 sachet
5.	Psyllium		Powder	1 bottle
6.	Senna	total sennosides, 7.5mg	Tablet	10 tablets

**Medicines Used for Diarrhea**

<b>Ser. No.</b>	<b>Name</b>	<b>Strength</b>	<b>Dosage Form</b>	<b>Maximum Quantity Allowed to be Dispensed at One Time</b>
1.	Oral Rehydration Salt		Powder	4 sachets

## Antiflatulents

Ser. No.	Name	Strength	Dosage Form	Maximum Quantity Allowed to be Dispensed at One Time
1.	Activated Charcoal	125mg, 250mg	Tablet	20 tablets
2.	Simethicone	60mg, 80mg, 95mg 95 mg, 125 mg	Tablet (chewable) Capsule	20 tablets 20 capsules

## Antihaemorrhoidal Agents

Ser. No.	Name	Strength	Dosage Form	Maximum Quantity Allowed to be Dispensed at One Time
1.	Bismuth Subgallate Compound* (Bismuth Subgallate + Bismuth Oxide + Peru Balsam + Zinc Oxide)	2.25% + 0.875% + 1.875% + 10.75% 59mg + 24mg + 49mg + 296mg	Ointment Suppository	2 tube 10 suppositories

\*And any other antihaemorrhoidal preparation proven to be therapeutically effective can be used



## Antitussives/Expectorants/Mucolytics

Ser. No.	Name	Strength	Dosage Form	Maximum Quantity Allowed to be Dispensed at One Time
1.	Bromhexine Hydrochloride	4mg/5ml	Elixir	1 bottle
2.	Dexchlorpheniramine	2mg/5ml 2mg, 4mg, 6mg	Syrup Tablet	1 bottle 10 tablets
3.	Dexchlorpheniramine + Guaifenesin + Pseudoephedrine	2mg +100mg + 20mg/5ml	Syrup	1 bottle
4.	Dextromethorphan Hydrobromide	15mg/ml 5mg, 7.5mg, 15mg/5ml 15mg	Drops Syrup Tablet	1 bottle 1 bottle 10 tablets
6.	Dextromethorphan Hydrobromide + Guaicol Sulphonate	0.3gm+7.6gm/100ml	Syrup	1 bottle
7.	Diphenhydramine+ Sodium Citrate+ Ammonium Chloride	12.5mg +60mg + 130mg/5ml	Syrup	1 bottle
8.	Guaifenesin	100mg, 200mg 200mg 100mg/5ml	Tablet Capsule Syrup	15 tablets 15 Capsules 1 bottle

## Antiasthmatics

Ser. No.	Name	Strength	Dosage Form	Maximum Quantity Allowed to be Dispensed at One Time
1.	Ephedrine + Theophylline	6mg + 30mg/5ml 2.24% + 0.30% 11mg + 120mg	Elixir Syrup Tablet	1 bottle 1 bottle 30 tablets
2.	Salbutamol (Albuterol)	0.1mg/dose 2mg/5ml	Oral Inhalation (aerosol) Syrup	1 canister 1 bottle

		2mg, 4mg, 4mg(s/r)	Tablet	10 tablets
3.	Theophylline+ Guaifenesin	150mg + 90mg; 300mg + 180mg 150mg + 90mg/15ml 150mg + 90mg	Capsule Elixir Tablet	30 capsules 1 bottle 30 tablets

### **Analgesics / Antipyretics**

<b>Ser. No.</b>	<b>Name</b>	<b>Strength</b>	<b>Dosage Form</b>	<b>Maximum Quantity Allowed to be Dispensed at One Time</b>
1.	Acetylsalicylic Acid	75mg, 100mg, (soluble); 300mg,324mg(microfined) 75mg, 81mg, 100mg, 500mg (enteric coated)	Tablet	20 tablets
2	Diclofenac Sodium	25mg, 50 mg	Tablet	20 tablet
3	Ibuprofen	300mg 200mg, 400mg (enteric coated, optional) 100mg/5ml	Capsule Tablet Syrup	20 capsules 20 tablets 1 bottle
4	Paracetamol	100mg/ml 125mg, 250mg 120mg/5ml, 250mg/5ml 100mg, 500mg	Drops Suppository Syrup Tablet	1 bottle 15 suppositories 1 bottle 20 tablets

### **Antimigraine Headache Medicine**

<b>Ser. No.</b>	<b>Name</b>	<b>Strength</b>	<b>Dosage Form</b>	<b>Maximum Quantity Allowed to be</b>
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				<b>Dispensed at One Time</b>
1.	Acetylsalicylic Acid + Paracetamol+ Caffeine	250mg + 250mg + 65mg	Tablet	20 tablets

### **Antirheumatics**

<b>Ser. No.</b>	<b>Name</b>	<b>Strength</b>	<b>Dosage Form</b>	<b>Maximum Quantity Allowed to be Dispensed at One Time</b>
1.	Acetylsalicylic Acid	300mg,324mg (microfined) 500mg (enteric coated)	Tablet	20 tablets
2.	Acetylsalicylic Acid + Paracetamol + Caffeine	250mg + 250mg + 65mg	Tablet	20 tablets
3.	Ibuprofen	300mg 200mg, 400mg (enteric coated, optional) 100mg/5ml	Capsule Tablet Syrup	20 capsules 20 tablets 1 bottle

### **Anthelmintics**

<b>Ser. No.</b>	<b>Name</b>	<b>Strength</b>	<b>Dosage Form</b>	<b>Maximum Quantity Allowed to be Dispensed at One Time</b>
1.	Albendazole	100mg/5ml 200mg, 400mg	Oral Suspension Tablet	3 bottles 6 tablets
2.	Levamisole	40mg	Tablet	6 tablets
3.	Mebendazole	100mg/5ml 100mg, 500 mg	Oral Suspension Tablet	2 bottles 12 tablets/
4.	Niclosamide	500mg	Tablet (chewable)	4 tablets
5.	Piperazine	500mg, 622.5mg, 706mg, 750mg,937.5mg, 1g /5ml	Elixir	2 bottles

		(Citrate) 300mg (Adipate)	Tablet	8 tablets
6.	Pyrantel Pamoate	250mg base/5ml	Oral Suspension	1 bottle
		125mg base	Tablet	8 tablets

## Vitamins

Ser. No.	Name	Strength	Dosage Form	Maximum Quantity Allowed to be Dispensed at One Time
1.	Ascorbic Acid (Vitamin C )	200mg/ml 100mg, 500mg, 1g	Drops Tablet	1 bottle 30 tablets
2.	Multivitamin Preparations*		Drops Syrup Tablet	1 bottle 1 bottle 30 tablets
3.	Multivitamin with Minerals and/or Extracts*		Drops Syrup Tablet	1 bottle 1 bottle 30 tablets
4.	Vitamin B Complex Preparations*		Tablet	30 tablets

\*Any combinations proven to be therapeutically effective can be acceptable

## Ear, Nose and Throat Preparations

Ser. No.	Name	Strength	Dosage Form	Maximum Quantity Allowed to be Dispensed at One Time
1.	Amyl-Meta-Cresol + Dichlorobenzyl Alcohol	0.6mg + 1.2mg	Lozenges	30 Lozenges
2.	Chlorhexidine Gluconate	0.12%	Oral Solution	1 bottle
3.	Dequalinium Chloride	0.25mg	Lozenges	30 Lozenges
4.	Hexetidine *	0.1%	Solution	1 bottle(500 ml)
5.	Hexidine	0.1gm/100ml, 0.2%	Oral Solution	1 bottle
6.	Hydrogen Peroxide	1.5%, 3%	Solution	1 bottle

7.	Menthol + Eucalyptus Oil + Light Magnesium Carbonate	2% +10% 7%	Inhalation	1 bottle
8.	Saline Solution	0.09%	Solution	1 bottle

\*Any preparation proven to be therapeutically effective can be acceptable

### Antihistamines And Antiallergics

Ser. No.	Name	Strength	Dosage Form	Maximum Quantity Allowed to be Dispensed at One Time
1.	Chlorpheniramine Maleate	2mg/5ml 2mg, 4mg, 6mg	Syrup Tablet	1 bottle 15 tablets
2.	Dexchlorpheniramine Maleate	2mg, 4mg, 6mg 2mg/5ml	Tablet Syrup	15 tablets 1 bottle
3.	Pheniramine Aminosaliclylate	50mg, 75mg	Tablet	15 tablets

### Anti-infectives, Topical

Ser. No.	Name	Strength	Dosage Form	Maximum Quantity Allowed to be Dispensed at One Time
1.	Benzoic Acid+ Salicylic Acid	6% +3%, 12% +6%	Ointment	2 tubes
2.	Benzyl Benzoate	25%	Lotion	300 ml
3.	Gamabenzene Hexachloride	1%	Cream	1 tube
4.	Gentian Violet	0.5%, 1%	Solution	1 tube
5.	Salicylic Acid	2%, 5%, 10%	Ointment	1 tube
6.	Selenium Sulphide	2.5%	Suspension	1 bottle
7.	Sulphur	5%, 10%	Ointment	1 tube

8.	Zinc Undecenoate + Undecenoin Acid	20% +5%	Ointment	1 tube
		20% +2%	Powder	1 bottle
		20% +2%	Powder (aerosol)	1 bottle

### **Keratolytics /Caustics Agents**

<b>Ser. No.</b>	<b>Name</b>	<b>Strength</b>	<b>Dosage Form</b>	<b>Maximum Quantity Allowed to be Dispensed at One Time</b>
1.	Camphor		Cream, Lotion, Solution	1 tube/bottle
2.	Salicylic Acid	2%, 5%, 10%	Ointment	1 tube
3.	Salicylic Acid + Lactic Acid + Polidocanol	2gm+0.5gm+0.2gm /10gm	Tincture	10 gm

### **Topical Agent For Psoriasis and Eczema**

<b>Ser. No.</b>	<b>Name</b>	<b>Strength</b>	<b>Dosage Form</b>	<b>Maximum Quantity Allowed to be Dispensed at One Time</b>
1.	Ichthammol	10%, 20%	Ointment	1 tube

### **Antipruritics**

<b>Ser. No.</b>	<b>Name</b>	<b>Strength</b>	<b>Dosage Form</b>	<b>Maximum Quantity Allowed to be Dispensed at One Time</b>
1.	Calamine	5%	Lotion	1 bottle
2.	Calamine + Zinc Oxide	4%+3%	Cream	1 tube
		15%+5%	Lotion	1 bottle

<b>Skin Disinfecting Agents</b>				
<b>Ser. No.</b>	<b>Name</b>	<b>Strength</b>	<b>Dosage Form</b>	<b>Maximum Quantity Allowed to be Dispensed at One Time</b>
1.	Chlorhexidine Gluconate + Cetrimide	1.5%+15%, 0.3%+3%w/v	Solution	1 bottle
2.	Ethyl Alcohol	70%	Solution	1 bottle
3.	Hydrogen Peroxide	3%, 6%	Solution	1 bottle
4.	Iodine	2%	Solution	1 bottle
<b>Dermatologicals, Others</b>				
<b>Ser. No.</b>	<b>Name</b>	<b>Strength</b>	<b>Dosage Form</b>	<b>Maximum Quantity Allowed to be Dispensed at One Time</b>
1.	Methylsalicylate ♣		Ointment	1 tube
2.	Talc Dusting Powder		Powder	1 bottle
♣ Any other rubifacient proven to be therapeutically effective can be used				
<b>Contraceptives</b>				
<b>Ser. No.</b>	<b>Name</b>	<b>Strength</b>	<b>Dosage Form</b>	<b>Maximum Quantity Allowed to be Dispensed at One Time</b>
1.	Drospirenone +Ethinyl Estradiol	3mg +0.03mg	Tablet (Film Coated)	1 pack
2.	Levonorgestrel (D-Norgestrel)	0.75mg	Tablet	1 pack
3.	Levonorgestrel (D-Norgestrel)+ Ethinylestradiol with/without Iron*	0.15mg + 0.03mg; 0.25mg + 0.05mg, 0.5mg + 0.05mg,	Tablet	1 pack

		0.3mg + 0.03mg, 0.05mg +0.03mg (6tablets), 0.075mg + 0.04mg (5tablets), 0.125mg +0.03mg (10tablets)		
4.	Norethindrone (Norethisterone) + Ethinylestradiol	0.5mg +0.035mg	Tablet	1 pack
5.	Norethindrone (Norethisterone) + Mestranol and Iron*	1mg +0.05mg	Tablet	1 pack
6.	Condoms (Male, Female)			As needed
* Each iron tablet contains: Ferrous Fumarate-75mg				

### Miscellaneous

Ser. No.	Name	Strength	Dosage Form	Maximum Quantity Allowed to be Dispensed at One Time
1.	Aluminum Sulphate +Calcium Hypochlorite + Sodium Carbonate	in the ratio of 23:1:1 by weight	Powder (Water treatment Powder)	1 sachet
2.	Calcium Hypochlorite + Iron Sulphate + Bentonite +Potassium Permanganet Polyacrylamide + Sodium Carbonate		Powder (Water treatment Powder)	1 sachet
3.	Formaldehyde	3%, 8% (w/w or v/v)	Solution	1 bottle
4.	Halazone	4mg	Tablet	15 tablets
5.	Iodized Salt			
6.	Saccharin		Tablet	1 bottle
7.	Sodium Chloride Free Salt		Crystal	1 bottle
8.	Sodium Dichloroisocyanurate	67mg, 75mg	Tablet	1 bottle
9.	Sorbitol			



## Participants List

No.	Name	Address	Profession
1	Shibru Asfaw	Bethzatha Higher Clinic	Physician
2	Fetlewiwork Haile	Addis Ababa Regional Health Bureau	P.Nurse
3	Sara Tesfaye	Dr Nega ENT Clinic	P.Nurse
4	Dessie Kiber	Amhara Health Bureau	P.Nurse
5	Teshita Shute	Kenema Parmacy	Pharmacist
6	Kaleb Terefe	SNNPR Regional Health Bureau	Pharmacist
7	Mastewal Kerebih	FMHACA	Health Officer (MPH)
8	Ephrem Abebe	School of Pharmacy AAU	Pharmacists
9	Dr.Kedier Abo	Halleluiah Higher Clinic	Physician
10	Gebriel Lishan	Black Lion Hospital	Pharmacist
11	Netsanet Behabtu	FMHACA	Pharmacis
12	Tesfaye Bayou	TAZMA	Physician
13	Tesfaye Worku	Meskerem MCH clinic	Gynecologist
14	Misrak Feleke	St.Paul mellenium medical College	Pharmacist
15	Gebru w/maiden	Ethiopian Pharmaceutical association	Pharmacist
16	Abraham G/giorges	WHO	Pharmacist
17	Yusuf Edris	FMHACA	Pharmacist
18	Redae G/tsadik	Tigray Regional Health Bureau	Pharmacist
19	Worku Tesfa	Beza medium Clinic	Health officer
20	Melaku Hamibisa	Ethiopian Druggist Association	Druggist
21	Fekerte Sahlu	Life Addis H.c	Nurse
22	Dr. Petros Mitiku	PHSP-E	Physician
23	Afework Nida	FMHACA	Pharmacist
24	Prof. Eyasu Makonnen	FM-AAU	Pharmacologist
25	Kebebush Omer	Amen Dental.	Physician
26	Dr.Yilikal Adamu	Addis Ababa University	Ophthalmologist
27	Dr.TekleAb Zaid	PHSP-E	Physician
28	Ermias Mulugeta	Bethzatha Health center	Physician
29	Dr.Selamawit Ashagre	Police Hospital	Gynecologist
30	K/Mariam G/Michal	FMHACA	Pharmacist
31	Raey Yohannes	FMHACA	Pharmacologist
32	Yeshialem Bekele	FMHACA	BSC nurse

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