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EAST AFRICAN COMMUNITY COMPETITION AUTHORITY

CONSUMER ALERT

GOVERNMENT OF INDIA BANS 156 FIXED DOSE COMBINATION(FDCs) MEDICINES

The East African Community Competition Authority has become aware through various media in India (India today, The Economic Times, One India) dated the 23rd August, 2024 that the Government of India through its Health Ministry has banned 156 fixed dose combination (FDCs) medicines, which included commonly used antibiotics, painkillers and multivitamins. In a gazette notice published by the Health Ministry on August 21, the production, marketing, and distribution of medications is now outlawed after it was found that they pose health risks.

According to the notification, the list includes antibiotics, anti-allergic drugs, analgesics, multivitamins, and combination dosages for fever and hypertension are among the prohibited FDCs. The decision comes following an expert group appointed by the central government as well as the Drug Technical Advisory Board (DTAB) made recommendations.

According to the media sources, the Central Government is satisfied that the use of the drug Fixed Dose Combination (hereinafter to be referred as FDC) of Amylase + Protease + Glucoamylase + Pectinase + Alpha Galactosidase + Lactase + Beta-Gluconase + Cellulase + Lipase + Bromelain + Xylanase + Hemicellulase + Malt diastase + Invertase + Papain is likely to involve risk to human beings whereas safer alternatives to the said drug are available," it stated.

The notification also stated that the matter was examined by an Expert Committee appointed by the Central Government and "the said Expert Committee considered this FDC as irrational." The Drugs Technical Advisory Board also examined the said FDC and recommended that "there is no therapeutic justification for the ingredients contained in this FDC. The FDC may involve risk to human beings. It therefore stated that in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under section 26 A of Drugs and Cosmetics Act 1940. In view of above, any kind of regulation or restriction to allow for any use in patients is not justifiable. Therefore, only prohibition under section 26A is recommended."

The list of major FDC medicines includes a combination dose of Omeprazole Magnesium and Dicyclomine HCl which is used for treating stomach pain, as well as a combination of Mefenamic Acid and Paracetamol Injection for reducing pain and swelling in various diseases.

Additional FDCs include a combination of povidone iodine, metronidazole, and aloe used to prevent and cure skin infections, as well as ursodeoxycholic acid and metformin HCl used to treat fatty liver in diabetics.

“The DTAB did not find the claims of these combination medicines correct and took the decision considering that the harm to the patient is more than the benefit,” the gazette notification stated. “Hence in the larger public interest, it is necessary to prohibit the manufacture, sale or distribution of this FDC under Section 26A of Drugs and Cosmetics Act 1940,” the ministry stated in the notification.

The 156 banned drugs include popularly used combinations of anti-allergic medicines with nasal decongestant, syrups that break down mucus and paracetamol. The list also includes combinations of antibiotics with acne cream and iodine solution. Combination of migraine medicine with one to prevent nausea, combination of supplements such as menthol with aloe vera, and combination of burn medicine silver sulfadiazine with an antiseptic agent, aloe extract, and vitamin are among some of the combinations banned.

On August 12, the Health Ministry issued a gazette notification prohibiting “the manufacture, sale and distribution of human use of drug fixed dose combination of Etodolac + Paracetamol” manufactured by Emcure Pharmaceuticals Ltd. “...the DTAB Sub-Committee considered the said fixed dose combination as irrational and recommended for its prohibition in public interest under section 26A of Drugs and Cosmetics Act, 1940,” the notification stated.

Following this recommendation, the central government has decided to prohibit the combination “with immediate effect as the said drug is found to have no therapeutic justification and may involve risk to the human beings.”

The Authority is of the preliminary view that the said banned FDCs medicines may be available and are being distributed and sold across the pharmacies within the East African Community.

Pursuant to section 301(b) of the EAC Competition Act, 2006, the Authority wishes to alert the general public that the attached list of FDCs medicines have been banned from being manufactured and distributed in India since they pose health risks to the human beings. The general public are therefore required to avoid the purchase or consumption of these specific medicines and report the matter to the EAC Competition Authority in case they come across the medicines at the pharmacies or selves by contacting: **Stellah Onyancha, on +255 27 216 2100 or email; sonyancha@eachq.org.**



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Appendix- complete list of all the 156 banned combination medicines

FDC of Amylase + Protease + Glucoamylase + Pectinase + Alpha Galactosidase + Lactase + Beta-Gluconase + Cellulase + Lipase + Bromelain + Xylanase + Hemicellulase + Malt diastase + Invertase + Papain
FDC of Antimony Potassium Tartrate + Dried Ferrous Sulphate
FDC of Benfotiamine + Silymarin + L-Ornithine L-aspartate + Sodium Selenite + Folic acid + Pyridoxine hydrochloride
FDC of Bismuth Ammonium Citrate + Papain
FDC of Cyproheptadine HCl + Thiamine HCl + Riboflavine + Pyridoxine HCl + Niacinamide
FDC of Cyproheptadine Hydrochloride + Tricholine Citrate + Thiamine Hydrochloride + Riboflavine + Pyridoxine Hydrochloride
FDC of Rabeprazole Sodium (As enteric coated tablet) + Clidinium Bromide + Dicyclomine HCl + Chlordiazepoxide
FDC of Fungal Diastase + Papain + Nux vomica Tincture + Cardamom Tincture + Casein Hydrolysed + Alcohol
FDC of Omeprazole Omeprazole Magnesium + Dicyclomine HCl
FDC of S-adenosyl methionine + Metadoxine + Ursodeoxycholicacid BP + L-Methylfolate Calcium eq. to L-Methylfolate + Choline bitartrate + Silymarin + L-ornithine L-aspartate + Inositol + Taurine
FDC of Silymarin + Thiamine Mononitrate + Riboflavin+ Pyridoxine HCl + Niacinamide + Calcium pantothenate + Vitamin B12
FDC of Silymarin + Pyridoxine HCl + Cyanocobalamin + Niacinamide + Folic Acid
FDC of Silymarin + Vitamin B6 + Vitamin B12 + Niacinamide + Folic acid + Tricholine Citrate
FDC of Sodium Citrate + Citric Acid Monohydrate Flavored with Cardamom Oil, Caraway Oil, Cinnamon Oil, Clove Oil, Ginger Oil + Alcohol
FDC of Sucralfate + Acelofenac
FDC of Sucralfate + Domperidone + Dimethicone
FDC of Sucralfate + Domperidone
FDC of Tincture Ipecacuanha + Tincture Urgenia + Camphorated Opium Tincture + Aromatic Spirit of Ammonia + Chloroform + Alcohol
FDC of Ursodeoxycholic Acid + Metformin HCl
FDC of Weak Ginger tincture + Aromatic Spirit of Ammonia + Peppermint Spirit +Chloroform +Sodium Bicarbonate +Compound Cardamom + Alcohol

FDC of Sucralfate + Pantoprazole Sodium + Zinc Gluconate + Light Magnesium Carbonate
 FDC of Aloe + Vitamin E Soap
 FDC of Povidone Iodine + Metronidazole + Aloe
 FDC of Azelaic acid + Tea Tree Oil + Salicylic acid + Allantoin + Zinc oxide + Aloe vera + Jojoba oil + Vitamin E + Soap noodles
 FDC of Azithromycin + Adapalene
 FDC of Calamine + Aloes + Allantoin
 FDC of Calamine + Diphenhydramine Hydrochloride + Aloe + Glycerine + Camphor
 FDC of Chlorphenesin + Zinc oxide + Starch
 FDC of Clindamycin Phosphate + Zinc acetate
 FDC of Gamma Benzene Hexachloride + Benzocaine
 FDC of Glucosamine hydrochloride + Diacerein + Menthol + Camphor + Capsaicin
 FDC of Hydroxyquinone 2.0%w/w + Octyl Methoxycinnamate 5.0% w/w + Oxybenzone 30 % w/w
 FDC of Ketoconazole +Zinc Pyrithione +D-Panthenol +Tea Tree Oil +Aloes
 FDC of Ketoconazole +Aloe vera+ Vitamin A Acetate
 FDC of Ketoconazole +Aloes + ZPTO
 FDC of Kojic Acid +Arbutin +Octinoxate +Vitamin E + Mulberry
 FDC of Lornoxicam + capsaicin + menthol + camphor
 FDC of Lornoxicam + Thiocolchicoside +Oleum Lini +Menthol + Methyl salicylate
 FDC of Menthol + Aloe vera Topical Spray
 FDC of Menthol + Lignocaine HCl+Aloe vera gel + Clotrimazole + Diphenhydramine
 FDC of Miconazole nitrate + Gentamicin + Fluocinolone Acetonide +Zinc Sulphate
 FDC of Miconazole +Tinidazole
 FDC of Minoxidil +Aminexil + Alcohol
 FDC of Minoxidil +Azelaic acid + saw palmetto
 FDC of Minoxidil +Aminexil
 FDC of Pine Bark extract + Kojic acid + Sodium Ascorbyl Phosphate
 FDC of Povidone Iodine + Tinidazole + Zinc sulphate
 FDC of Povidone Iodine + Ornidazole + Dexpanthenol
 FDC of Salicylic acid + Aloe vera + Allantoin + D-Panthenol
 FDC of Silver sulphadiazine +Chlorhexidine Gluconate solution +Allantoin + Aloe vera gel +Vitamin E acetate
 FDC of Sodium salicylate + Zinc gluconate + Pyridoxine HCl
 FDC of Tetracycline + Colistin Sulphate
 FDC of Clomiphene + Ubidecarenone
 FDC of Combikit Clomiphene Citrate + Estradiol Valerate
 FDC of Flavoxate HCl + Ofloxacin
 FDC of Clomiphene Citrate + N-Acetylcysteine
 FDC of Evening Primerose Oil +Cod liver oil
 FDC of Sildenafil Citrate +Papaverine +L-Arginine
 FDC of Tranexamic acid + Mefenamic acid + Vitamin K1
 FDC of Divalproex Sodium +Oxcarbazepine
 FDC of Divalproex Sodium +Levetiracetam
 FDC of Ergotamine tartrate + Caffeine + Paracetamol + Prochlorperazine maleate
 FDC of Piracetam + Ginkgo biloba extracts + Vinpocetin
 FDC of Ginkgo biloba + methylcobalamin + Alpha lipoic acid + Pyridoxine HCl
 FDC of Ginseng Extract + Dried extract of Ginkgo Biloba
 FDC of Meclizine HCl+ Paracetamol + Caffeine
 FDC of Nicergoline + Vinpocetine
 FDC of Gamma Linolenic Acid + Methylcobalamin
 FDC of Beclomethasone Dipropionate + Neomycin Sulphate + Clotrimazole + Lignocaine HCl

FDC of Boric acid+ Phenylephrine HCl + Naphazoline Nitrate + Menthol + Camphor
 FDC of Naphazoline HCl + Chlorpheniramine Maleate + Zinc Sulphate + Hydroxy Propyl Methyl Cellulose
 FDC of Chlorpheniramine Maleate + Naphazoline HCl + Zinc Sulphate + Sodium Chloride + Hydroxy Propyl Methyl Cellulose
 FDC of Chlorpheniramine Maleate + Naphazoline HCl + Hydroxy Propyl Methyl Cellulose
 FDC of Chlorpheniramine Maleate + Sodium Chloride + Boric Acid + Tetrahydrozoline HCl
 FDC of Chlorpheniramine Maleate + Phenylephrine HCl + Antipyrine
 FDC of Ketorolac Tromethamine + Chlorpheniramine Maleate + Phenylephrine HCl + Hydroxy Propyl Methyl Cellulose
 FDC of Ketorolac Tromethamine + Fluometholone
 FDC of Naphazoline HCl + Zinc Sulphate + Boric Acid + Sodium Chloride+ Chlorpheniramine Maleate
 FDC of Naphazoline HCl + Hydroxy Propyl Methyl Cellulose + Boric Acid + Borax + Menthol + Camphor
 FDC of Naphazoline HCl + Hydroxy Propyl Methyl Cellulose + Chlorpheniramine Maleate +Boric Acid + Sodium Chloride + Zinc Sulphate
 FDC of Naphazoline HCl + Hydroxy Propyl Methyl Cellulose + Chlorpheniramine Maleate +Boric Acid
 FDC of Naphazoline HCl + Chlorpheniramine Maleate + Methyl Cellulose
 FDC of Naphazoline HCl + Hydroxy Methyl Cellulose + Boric Acid + Menthol + Camphor
 FDC of Naphazoline HCl + Boric Acid+Menthol+Camphor +Methyl Cellulose + Chlorpheniramine Maleate + Zinc Sulphate + Sodium Chloride
 FDC of Naphazoline HCl + Phenylephrine HCl+ HPMC + Chlorpheniramine Maleate + Menthol+ Camphor
 FDC of Naphazoline HCl + Hydroxy Propyl Methyl Cellulose + Chlorpheniramine Maleate + Boric Acid + Sodium Chloride + Zinc Sulphate + Menthol + Camphor
 FDC of Naphazoline HCl + Hydroxy Propyl Methyl Cellulose + Chlorpheniramine Maleate + Boric Acid +Zinc Sulphate
 FDC of Naphazoline HCl + Azelastine HCl+ Sodium Carboxy Methyl Cellulose + Menthol + Camphor + Stabilized Oxychlorocomplex
 FDC of Naphazoline HCl + Sodium Carboxy Methyl Cellulose + Menthol + Camphor + Stabilized Oxychlorocomplex
 FDC of Naphazoline Nitrate + Chlorpheniramine Maleate + Phenylephrine HCl + Hydroxy Methyl Cellulose + Boric Acid+ Menthol+ Camphor
 FDC of Naphazoline Nitrate + Chlorpheniramine Maleate + Zinc Sulphate + Boric Acid + Sodium Chloride
 FDC of Norfloxacin + Tinidazole (with Betacyclodextrin) Eye ointment
 FDC of Ofloxacin + Beclomethasone Dipropionate + Lignocaine HCl
 FDC of Naphazoline HCl + Chlorpheniramine Maleate + Phenylephrine HCl+ Menthol+ Camphor
 FDC of Phenylephrine HCl + Naphazoline HCl +Menthol+ Camphor + Hydroxy Propyl Methyl Cellulose
 FDC of Phenylephrine HCl + Naphazoline HCl + Menthol + Camphor
 FDC of Sulphacetamide Sodium + Zinc Sulphate + Chlorpheniramine Maleate + Boric acid + Sodium Chloride
 FDC of Zinc Sulphate + Boric acid + Naphazoline HCl + Sodium Chloride + Phenyl Ethyl Alcohol
 FDC of Cetirizine HCl + Paracetamol + Phenylephrine HCl
 FDC of Cetirizine HCl + Phenylephrine HCl
 FDC of Levocetirizine + Phenylephrine HCl
 FDC of Levocetirizine + Phenylephrine HCl + Paracetamol
 FDC of Phenylephrine HCl + Paracetamol + Levocetirizine HCl + Menthol

FDC of Levocetirizine HCl + Ambroxol HCl + Paracetamol
 FDC of Levocetirizine HCl + Ambroxol HCl + Phenylephrine HCl
 FDC of Diethylcarbamazine Citrate + Chlorpheniramine maleate
 FDC of Diethylcarbamazine Citrate + Levocetirizine HCl
 FDC of Ambroxol HCl + Phenylephrine HCl + Guaiphenesin
 FDC of Bromhexine HCl + Phenylephrine HCl
 Etofylline + Theophylline anhydrous eq. to Theophylline hydrate + Ambroxol HCl
 FDC of Etofylline + Theophylline anhydrous eq. to Theophylline hydrate + Montelukast
 FDC of Ambroxol HCl + Terbutaline Sulphate + Ammonium Chloride + Guaiphenesin + Menthol
 FDC of Ambroxol HCl + Salbutamol Sulphate + Ammonium Chloride + Guaiphenesin + Menthol
 FDC of Cetirizine HCl + Terbutaline Sulphate + Ambroxol HCl + Guaiphenesin
 FDC of Dextromethorphan Hydrobromide + Chlorpheniramine Maleate + Ammonium Chloride + Sodium Citrate + Menthol
 FDC of Salbutamol Sulphate + Bromhexine HCl + Guaiphenesin + Ammonium Chloride + Menthol
 FDC of Terbutaline Sulphate + Bromhexine HCl + Chlorpheniramine Maleate
 FDC of Chlorpheniramine Maleate + P.G Sulphonate + Ammonium Chloride + Sodium Citrate + Menthol
 FDC of Aminophylline + Ammonium Chloride + Sodium Citrate
 FDC of Paracetamol + Chlorpheniramine Maleate + Phenyl Propanolamine
 FDC of Trithioparamethoxyphenyl Propene + Chlorpheniramine Maleate
 FDC of Aceclofenac 50mg + Paracetamol 125mg oral liquid
 FDC of Aceclofenac 50mg + Paracetamol 125mg tablet
 FDC of Adenosine triphosphate diphosphate + Magnesium Orotate
 FDC of Amoxicillin Trihydrate + Dicloxacillin Sodium + Lactobacillus
 FDC of Camylofin Dihydrochloride 25 mg + Paracetamol 300mg
 FDC of Cefixime + Acetyl Cysteine
 FDC of Cephalixin Monohydrate + Serratiopeptidase
 FDC of Cetyl Myristoleate + glucosamine Sulphate Potassium+ Methyl Sulfonyl methane
 FDC of Diacerin IP + Glucosamine Sulphate Potassium Chloride USP + MSM (Methylsulphonyl Methane) + Cetyl Myristoleate
 FDC of Paracetamol + Diclofenac Potassium + Caffeine Anhydrous
 FDC of Diclofenac sodium + Thiocolchicoside Injection
 FDC of Doxycycline + Ornidazole + Bromelain + Lactobacillus Rhamnosus + Lactobacillus Reuteri RC
 FDC of Doxycycline HCl + Betacyclodextrin + Serratiopeptidase
 FDC of Erythromycin stearate eq.to Erythromycin +Lactic acid Bacillus
 FDC of Etodolac + Paracetamol +Serratiopeptidase
 FDC of Flupirtine Maleate 400 mg + Paracetamol 325 mg tablet
 FDC of Glucosamine sulphate potassium chloride 410 mg + Chondroitin Sulphate 100 mg
 FDC of Glucosamine sulphate potassium chloride+ Methyl Sulphonyl Methane(MSM) + Sodium Borate+ Copper Sulphate pentahydrate+ Manganese Sulphate + Vitamin D3
 FDC of Glucosamine Sulphate Sodium Chloride +Manganese +Boron + Zinc + Copper
 FDC of Glucosamine sulphate + Chondroitin sulphate + Methylsulfonylmethane +Vitamin D3 + Vitamin E + Vitamin C + Selenium +Elemental Zinc +Elemental Manganese + Elemental Chromium + Elemental Copper +Elemental Boron
 FDC of Glucosamine sulphate + Methyl sufonyl methane + manganese sulphate +Vit E acetate +calcium Carbonate
 FDC of Glucosamine Sulphate + +Vitamin E acetate + Calcium Pantothenate + Vitamin D3
 FDC of Glucosamine Sulphate Potassium chloride +Calcium Carbonate from an organic source (oyster shell) eq. to elemental Calcium+ Vitamin D3
 FDC of Cetyl Myristoleate + Glucosamine Sulphate Potassium chloride + Methyl sulfonyl methane

FDC of Glucosamine Sulphate Potassium chloride + Methyl sulfonyl methane +Calcium carbonate +Vitamin E+ Manganese

FDC of Glucosamine Sulphate Potassium chloride + Calcium carbonate + Methyl sulfonyl methane +Vit D3

FDC of Glucosamine Sulphate Potassium + Methyl sulphate Sodium+ Sulphonyl Methane +Chondroitin Sulphate Sodium+ Calcium Carbonate +Vitamin D3+Sodium Borate+ Cupric Oxide+ Colloidal Silicon Dioxide+ Manganese Chloride

FDC of Methocarbamol + Diclofenac Sodium Injection

FDC of Paracetamol + Pentazocin

FDC of Sucralfate +Domperidone+ Simethicone

FDC of Sulfaquinoxaline +Diaveridine HCl+ Vitamin K

FDC of Tramadol HCl +Dicyclomine HCl + Domperidone

FDC of Tramadol HCl +Paracetamol +Caffeine +Taurine