DEVIATIONS FROM ETHICAL DRUG PROMOTION IN INDIA

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Abstract

The promotion of drugs must be in compliance with the regulations and laws of the country in which they are promoted. Promotion of drugs following ethical standards is required to allow doctors to prescribe the drugs rationally and minimize the risks for patients. But in developing countries like India, doctors rely on drug promotional material for their source of information. Doctors access these promotional materials either through sales representatives or drug advertisements in medical journals. An extensive analysis was conducted of drug advertisements in medical journals in India. The claims made in the advertisements, and the extent of information given in the advertisements were compared against the WHO's criteria for ethical drug promotion. It was found that the majority of the advertisements published do not comply with WHO's ethical criteria as most of them lacked one or another required drug information. The findings of the study lead to suggestions of measures that can be taken by Indian government organizations to ensure ethical promotion of drugs.

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Introduction

Drug promotion involves all the information and persuasive activities of the manufacturers and distributors, mainly intended for the supply, and purchase of drugs either to patients or health care professionals. The main purpose of setting ethical standards is to make the promotional materials more reliable, accurate, and up-to-date and to minimize the misuse of drugs^{1, 2}.

According to the WHO Expert Committee, advertisements should contain the name of the active ingredient, brand name, content of active ingredient per dosage form or regimen, other ingredients that may cause a problem, therapeutic uses, dosage form, side effects, precautions, contraindications and drug interactions³.

WHO's ethical criteria also prohibit offering gifts and financial incentives to doctors and the use of scientific and educational activities for promotional purposes¹.

Ethical criteria for the promotion of medicinal products may differ from country to country. Acceptability depends on the political, economic, social, cultural, educational, scientific, and technical situations, therapeutic traditions, and development level of the health care system of a country. Also, the promotion of drugs must be in compliance with the regulations of the country following the ethical guidelines³.

Some countries require the drug promotional materials to contain complete information while other countries require only a brief summary of the drug¹. However, the basic, ethical principle underlying drug promotion is the same in all countries - the promotional material must be reliable and accurate. It should not disguise the original nature of the drug³.

Drug advertisements in India have been seen promoting therapeutic uses and exaggerating the positive effects of the drug to increase sales. They have been seen to downplay the risks and to omit critical information for the safe prescription of the drug. Physicians relying on such advertisements may prescribe inappropriate drugs to their patients².

Hence, the extent of deviations in promoting drugs to healthcare professionals, and patients, and the impact of these drug promotions on the prescribing behavior of physicians, is of significant concern.

Background

Drug advertisements published in medical journals and promotional materials from sales representatives should contain the drug information as recommended by WHO. In India, however, most of the drug promotional materials do not have all the suggested information⁴. Promotional materials for drugs have been seen with therapeutic uses but not information on drug interactions, contraindications, and side effects.²

Sales representatives often visit physicians with sample drugs, token gifts, drug brochures, and reminder advertisements that give the name of a drug, but not the drug's uses.⁵

Samples of older drugs are given for free, in large quantities, to doctors in India. As there is no regulation on the distribution of samples, this distribution of drugs and promotional materials by the sales representatives in the name of drug promotion may influence the prescribing behavior of physicians.^{2, 6}

Forms of Drug Promotion

Promotion of drugs may involve visits to doctors by medical representatives promoting their drugs. It may also be through magazines, medical journals, newspapers, radio ads, and Direct-to-Consumer Advertisements by pharmaceutical companies.⁶

DTCA. Direct-to-Consumer Advertisements target the public directly through broadcast and print advertisements.⁷

There are mixed opinions on Direct-to-Consumer Advertisements, as some argue the need for the public to know about the drug's properties. The knowledge would allow an earlier diagnosis of any diseases, and aid in getting better treatment. Saskatoon urologist Peter Barret

said that knowledge about drugs may intervene with the treatment, and patients may want the drugs of their own choice. It may be a burden for the doctors to explain why the drug prescribed to their patients is more appropriate. However, many agree on regulatory approval of the ads before they are aired or printed.^{7,8}

In recent times, there is an increased health concern among the public, aided in part by the wealth of information available on the Internet. Hence, people are seeking more drug information⁹.

The marketing of drugs to consumers is done mainly through television, newspapers, magazines, and the radio. Today, various pharmaceutical companies are promoting their drugs through digital media, including web-sites, online display advertising, search engine marketing, social media campaigns, and mobile advertising.⁷

Direct–To-Consumer Advertisements are banned in India on Schedule H and Schedule X drugs. Schedule H drugs are sold only with a prescription from a registered medical practitioner¹⁰. Schedule X drugs are narcotic and psychotropic drugs which cause delusion, hallucination, psychosis, sedation, and hypnosis.¹¹

But due to the accessibility of Internet, some Schedule H drugs are being marketed directly to consumers in India. The drugs seen commonly in DTC advertisements include antacids, antiflatulents, cold rubs, analgesic balms, creams, vitamins/tonics/health supplements, medicated skin treatments, analgesic/cold tablets, antiseptic creams/ liquids, and glucose powders.¹²

Printed forms of advertisements. For a general practitioner, the most visible of all the sources of information are printed advertisements. The commonly seen ways of printed

advertisements include direct mail advertisements which are booklets or leaflets that advertise a branded drug, handouts by medical representatives during visits to doctors, advertisements in medical journals, newspapers and magazines targeting doctors.¹³

Journal advertisements. Doctors often misinterpret the impact of journal advertisements, on their prescribing behaviors. However, the more a drug is seen in journals, the more it is recalled by doctors and they prescribe it more often¹⁴. The advertisements in journals are visually appealing, and the inclusion of references increases a drug's credibility with doctors. Hence, most of the pharmaceutical companies include references in their journal advertisements.¹⁵

In 1996, a study on the advertisements published in the Indian edition of BMJ was conducted by B. Gitanjali, et al¹⁶. The local edition of BMJ published in India had been available since 1986. The 116 advertisements published in five issues of BMJ India from August to December 1992 were compared to 87 advertisements published in four issues of the British edition in March 1993. The advertisements were studied for indications for treatment, dosage, precautions, contraindications, adverse effects, prices of the drugs, the postal address of the drug company, and whether or not the claims made in the advertisements were referenced.¹⁶

It was found that many drug advertisements published in the Indian edition made false claims and did not include all the drug information as proposed by WHO. The generic name was absent in 19 (16%) of the Indian advertisements and none of the British advertisements; scientific information was inadequate in 23 (20%) of Indian and in three (3%) of British advertisements. An address for further information was provided in 76 (66%) Indian and 80 (92%) British advertisements. The price was mentioned in 76 (66%) Indian and 84 (97%)

British advertisements. In addition, ten randomly selected advertisements published in the Indian edition were sent to a clinical pharmacologist from Britain, a member of the medical therapeutic committee in Victoria, Australia, and a pharmaceutical advisor to the International Organization of Consumers Unions (now Consumer International) in Malaysia. They found that all the advertisements were misleading or made unsubstantiated claims. As per B. Gitanjali, et al, for its local editions, BMJ should have stringent codes for advertising and follow WHO's ethical criteria.¹⁶

Regulatory Agencies for Drug Promotion in India

Drug promotion in India is regulated primarily through voluntary codes by industry and medical organizations. When making these codes the industry associations did not include certain aspects of drug promotion or made them vague, allowing wide latitude for drug promotion. They focused on increasing the sales and profits for the industry. As a result voluntary codes lack transparency and omit large areas of drug promotion.¹⁷

Given the huge number of products are available on the market, selection of the right drug and its proper use is an increasingly difficult task for health care professionals. The availability of scientific therapeutic information is essential for drugs to be prescribed rationally. But the misleading information available outweighs scientific therapeutic information. Hence the regulatory agencies need to ensure that all health professionals have access to appropriate information.⁶

Medical representatives through their weekly or monthly visits distribute samples and attractive eye-catching brochures to physicians. Pharmaceutical companies claim their new formulations to be superior to existing, effective and inexpensive products with which

prescribers and consumers are familiar. This motivates unwary doctors prescribe new products without verifying whether the claims made are justified⁶. The use of ineffective, poor quality, harmful medicines may result in therapeutic failure, exacerbation of the disease, resistance to medicines and sometimes even death. Misuse may result in loss of confidence in health systems, health professionals, and pharmaceutical manufacturers. Hence governments need to establish strong regulatory authorities to ensure that the drug promotion is regulated effectively.⁶

IFPMA (International Federation of Pharmaceutical **Manufacturers** & Associations). The IFPMA code of pharmaceutical marketing practices, written in 1981, is a self-regulatory code for ethical conduct and promotion. It was established before the WHO's ethical criteria on medicinal drug promotion which was written in 1988. This code includes standards for the ethical promotion of pharmaceutical products to health care professionals and other stakeholders, such as medical institutions and patient organizations. The code aims at the provision of scientific and educational information about products to health care professionals, and encourages appropriate use¹⁸. The IFPMA code of 2007 placed more restrictions on gifts offered by medical representatives, and the sponsorship by companies for health care professionals to attend events. This code applies to all drugs. IFPMA regularly monitors compliance of companies by the Code Compliance Network (CCN). The CCN is comprised of individuals from the member companies and associations experienced in the application of industry codes. The experts from CCN also exchange best practices in code compliance and implementation. They discuss advancements and drawbacks in drug promotion strategies. 18, 19

According to the IFPMA Code of Practice:

- Pharmaceutical companies must provide accurate, balanced, and scientifically valid data on products. Promotion must be ethical, accurate, balanced and must not be misleading.
- Information in promotional materials must support proper assessment of the risks and benefits of the product and its appropriate use.
- Pharmaceutical companies' interactions with stakeholders must at all times be ethical, appropriate and professional. Nothing should be offered or provided by a company in a manner or on conditions that would have an inappropriate influence.¹⁹

OPPI. Organization of Pharmaceutical Producers of India established in 1965, is an association of research and innovation driven pharmaceutical companies in India. The member companies are committed to the ethical standards set out in this code. It plays a major role in guiding drug promotional activities by pharmaceutical companies in India. The OPPI is a signatory to the IFPMA code. The OPPI has adapted the IFPMA code to provide local guidelines.¹⁹

The OPPI code includes standards for ethical promotion of pharmaceutical products to healthcare professionals and helps ensure that member companies' interactions with healthcare professionals and other stakeholders, such as medical institutions and patient organizations, are appropriate and perceived as such. OPPI member companies must comply directly with applicable national codes as, and when, they come into existence.¹⁹

According to OPPI, the promotion of drugs should be transparent, the interaction of companies with healthcare professionals should be beneficial to patients and it should encourage

the appropriate use of pharmaceutical products. The promotional materials should be accurate and not misleading; the information should be consistent across labeling, packaging, leaflets, datasheets, and all promotional material. Promotion should be capable of substantiation either by reference to the approved labeling or by scientific evidence. Such data should be made available upon request to healthcare professionals.¹⁹

WHO. The World Health Organization issued ethical criteria on medicinal drug promotion in 1988. In accordance to the ethical criteria the advertisements should contain:

- The name of the active ingredient(s) using either international nonproprietary names (INN) or the approved generic name of the drug;
- The brand name;
- Content of active ingredient(s) per dosage form or regimen;
- Name of other ingredients known to cause problems;
- Approved therapeutic uses;
- Dosage form or regimen;
- Side-effects and major adverse drug reactions;
- Precautions, contraindications and warnings;
- Major interactions;
- Name and address of manufacturer or distributor;
- Reference to scientific literature as appropriate.¹

Drugs and Magic Remedies Act. In India, the Drugs and Magic Remedies Act of 1954 (objectionable advertisements) plays a major role in curbing the advertisements that mislead the true properties of the drug. The Act prohibits the advertisement of certain drugs for:

- prevention of conception,
- maintenance or improvement of the capacity of human beings for sexual pleasure,

• correction of menstrual disorders in women.²⁰

Central Ethical Committee. To tackle the unethical promotion of drugs a Central Ethical Committee was formed. The Central Ethical Committee constitutes an Expert Committee at central level in New Delhi. It collects and reviews the complaints and other information related to misleading and confusing advertisements received from professionals and the public. The information is then sent to the various state drug control authorities. The drug control authorities through the Drugs and Magical Remedies Act take necessary legal action on unethical advertisements.⁶

The Central Ethical Committee compiles and publishes data on unethical practices and discrepancies in promotional material. It disseminates the information to health professionals. It reports on unethical promotion to the FDA and request remedial action.⁶

Process of Banning drugs in India. The Drugs Technical Advisory Board (DTAB) is the highest decision-making body under the Union health ministry on technical matters. It is the final authority on imposing a ban on drug. The Drug Technical Advisory Board, through its executive committee, reviews a drug and imposes a ban on a drug if the drug has harmful effects. The Deputy Drug Controller General of India (DCGI) notifies all state drug authorities, chemist associations and manufacturers about the ban on the drug.²²

DCGI also informs Indian Medical Association (IMA) about the ban order. It publishes the names of banned drugs in the IMA newsletter. The IMA news letter has wide reach and is fast in disseminating the information to state branches from where it is accessible to doctors. These banned drugs are also published in the British Medical Journal and the New England Journal of medicine.²²

Methods

A search for drug advertisements in Indian pharmaceutical journals was done in Gandhi Medical hospital in Hyderabad, India. The medical journals that were published in 2013 that were available in the library were chosen. Thirteen journals were available in the library. Among them four journals that do not have any drug advertisements were excluded from the study. From the remaining nine journals the latest issue of the journal that was available on the date of the library visit was reviewed.

Only peer reviewed journals and those listed in Pubmed were considered for the study.

Advertisements pertaining to medical equipment and surgical appliances were excluded.

The pharmaceutical journals studied included:

- 1) Indian Journal of pharmaceutical sciences, Year 2013 (Sep-Oct), Volume 75, Issue 5 Readership: Pharmacists, pharmacologists
- Indian Journal of Public health, Year 2013 (Oct-Dec), Volume 57, Issue 4
 Readership: Public health physicians, social workers, paramedical personnel, nurses, policy makers
- 3) Indian Journal of dermatology, venereology, and leprology , Year 2013 (May-June), Volume 79, Issue 3
 - Readership: Dermatologist, cosmetologists, venereologists, leprologists, trichologists, pediatricians and internists
- 4) Indian Pediatrics, Year 2013 (December), Volume 50, Issue 12

Readership: Pediatricians

- 5) Indian Journal of Ophthalmology, Year 2013 (March), Volume 61, Issue 3
 Readership: Ophthalmologist, optometrists
- 6) Indian Journal of Surgery, Year 2013 (Oct), Volume 75, Issue 5 Readership: Surgeons

7) Indian Journal of Tuberculosis, Year 2013 (July), Volume 60, Issue 3

Readership: members of the WHO, International Union against Tuberculosis and Lung Diseases (IUATLD), as well as all the State and District Tuberculosis Officers in India.

8) Indian journal of Allergy, Asthma, and Immunology, Year 2013 (July-Dec), Volume 27, Issue 2

Readership: Doctors of all specialties, Aerobiologists, Microbiologists, Biotechnologists,

Immunologists

9) Indian journal of Nephrology, Year 2013 (Sep-Oct), Volume 23, Issue 5

Readership: Nephrologists

The World Health Organization proposed criteria for ethical standards in drug advertising. It has been 21 years since the WHO Expert Committee first published its Ethical Criteria for Medicinal Drug Promotion. These were proposed to form the basis for model national legislation to enable governments to improve national regulatory standards for pharmaceutical promotion. They applied to prescription drugs, over-the-counter drugs, and any other product promoted as medicine. The criteria could be used by government, the pharmaceutical industry, the advertising industry and people of all walks of life¹. Hence the criteria for drug promotion by WHO is taken as the standard and each of the advertisements were

In accordance with the WHO Expert Committee, drug advertisements should usually contain:

- Legible text 1)
- Brand name 2)
- 3) Active ingredients
- Therapeutic uses 4)
- Dosage Form 5)
- Adverse Drug Reactions or Side Effects 6)

analyzed to check if it had all the drug information per the criteria.

- 7) Precautions, warnings and contra-indications
- 8) Drug interactions
- 9) Address of the manufacturer¹

Of the 104 advertisements, the drugs that belong to Schedule H were identified and analyzed separately. Schedule H drugs are sold only with a prescription from a registered medical practitioner.¹⁰ These drugs are restricted from self medication as they might have varied effects on public safety. Hence the advertisements pertaining to these drugs are analyzed separately.

Results

The 104 advertisements that were found in the nine pharmaceutical journals were compared to the WHO's criteria for drug advertisements.

The findings from the 104 advertisements are summarized in Table 1. The Appendix contains images of all these advertisements.

Table 1. Content of Selected Advertisements Compared to WHO Guidelines

S.n o	D R U G	Generic Name	Prescription Only Drugs	Legible Text	Brand Name	Active Ingredients	Therapeutic Uses	Dosage Form	Adverse Drug Reactions or Side Effects	Precautions, warnings, contra- indications	Drug interactions	Address of the manufacturer
1	Tusq-dx	Chlorpheniramine maleate		X	X	X	X					X
2	Nupod	Cefpodoxime	X	X	X	X	X					
3	Tonact-TG	Atorvastatin Atorvastatin+Fenofibrate	X	X	X	X	X					
4	Harty	Docosahexaenoic acid	X	X	X	X	X					
5	Clopitab	Clopidogrel	X	X	X	X	X					
6	Ramistar	Ramipril	X	X	X	X	X					
7	Pinom	Olmesartan	X	X	X	X	X					
8	Ascoril	Terbutaline	X	X	X		X					
9	Reswas	Levodropropizine		X	X	X	X	X				
10	Zyrcold	Ambroxol		X	X	X	X					X
11	Sylkam	Etizolam	X	X	X		X	X				
12	Healsat+	Diclofenac	X	X	X	X	X					X

S.n o	D R U G	Generic Name	Prescription Only Drugs	Legible Text	Brand Name	Active Ingredients	Therapeutic Uses	Dosage Form	Adverse Drug Reactions or Side Effects	Precautions, warnings, contra- indications	Drug interactions	Address of the manufacturer
13	Zerodol s/ Zerodol sp	Aceclofenac, Serratiopeptidase, Paracetamol	X	X	X	X	X					
14	Tusq-X	Terbutaline		X	X	X	X					X
15	Supamove	Diclofenac	X	X	X	X	X					
16	Havmax-forte		X	X	X		X					
17	Dailyshine			X	X		X	X				
18	Lornid-IP		X	X	X	X	X					X
19	Tatkaal			X	X	X	X					X
20	B-g-prot l			X	X		X	X				
21	Mecoblend	Folic Acid (Vit B9)		X	X	X	X					
22	B-colen	Biotin		X	X		X					X
23	Orovit active	R u t i n		X	X		X					X
24	Zerodol-p	Aceclofenac + Paracetamol	X	X	X	X						
25	Folera-MD	Methylcobalamin		X	X	X	X					X
26	Preglac-kit			X	X	X	X					X
27	Tonabolin-XT	Ferrous Ascorbate	X	X	X	X	X					X
28	B-protin	Folic acid (vit b9)		X	X		X					X
29	D-protin	Folic acid (vit b9)		X	X		X					X
30	Pro-PL	Protein + Carbohydrates + Fat + Minerals + Vitamins		X	X		X	X				X
31	Huntred			X	X	X	X					
32	Clenol –LB	Clindamycin	X	X	X	X	X					
33	Cymet plus	Metoprolol	X	X	X	X	X					

S.n o	D R U G	Generic Name	Prescription Only Drugs	Legible Text	Brand Name	Active Ingredients	Therapeutic Uses	Dosage Form	Adverse Drug Reactions or Side Effects	Precautions, warnings, contra- indications	Drug interactions	Address of the manufacturer
34	Sensodent-KF	Potassium nitrate/sodium monofluorophosphate	X	X	X	X	X					X
35	Hexidine	Chlorhexidine	X	X	X	X	X					X
36	Xyzal	Levocetirizine	X		X		X	X	X	X		X
37	Atarax	Hydroxizine	X		X	X	X	X	X	X		X
38	Candid-B	Clotrimazole and Beclomethasone	X	X	X	X	X					X
39	Dermogem			X	X	X	X					X
40	Panderm+	Clobetasol Propionate		X	X		X					X
41	Halosys-S	Halobetasol	X	X	X	X	X					
42	Stator	Atorvastatin	X		X		X	X	X	X	X	X
43	Melnora			X	X		X					
44	Deletus	Dextromethorphan	X	X	X	X	X	X	X	X	X	X
45	Solvin cold	Phenylephrine		X	X	X	X					
46	Solvin cough	Dextromethorphan		X	X	X	X					
47	Novex-DS	Ormeloxifen	X	X	X		X	X				X
48	Zomelis	Vildagliptin	X	X	X	X	X					X
49	Starfix-OF	Cefixime, Ofloxacin	X	X	X	X	X					X
50	Ud-life	Ursodeoxycholic acid	X	X	X		X					X
51	Cognistar	Cerebroprotein hydrolysate	X	X	X		X					X
52	Sorbitrate	Isosorbide dinitrate	X		X		X	X	X	X	X	X
53	Gluformin	Metformin	X		X	X	X	X	X	X		X
54	Tribet	Pioglitazone	X		X	X	X	X	X	X	X	X

S.n o	D R U G	Generic Name	Prescription Only Drugs	Legible Text	Brand Name	Active Ingredients	Therapeutic Uses	Dosage Form	Adverse Drug Reactions or Side Effects	Precautions, warnings, contra- indications	Drug interactions	Address of the manufacturer
55	Leedz,roxel,tisko,tiscold,kf-4, zel-100 dt		X	X	X	X	X					X
56	Emtax-AZ	Cefixime & azithromycin	X	X	X	X	X					X
57	Zathrin	Azithromycin	X	X	X		X					
58	Zitrobid-CF	Cefixime, azithromycin	X	X	X	X	X					X
59	Starfix-AZ	Cefixime + Azithromycin	X	X	X	X	X					
60	A - p h y l	Acebrophylline	X	X	X		X					
61	Liv.52 HB			X	X		X	X				X
62	Wakfree	Diacerein	X	X	X	X	X					X
63	Nacnano	Diclofenac	X	X	X	X						
64	Systaflam gel	Diclofenac	X	X	X		X					
65	Systaflam-MR capsules	Thiocolchicoside	X	X	X	X	X					
66	Dailycal ortho			X	X	X	X					
67	Cyra-d	Rabeprazole + Domperidone		X	X	X	X					
68	Cyra	Rabeprazole		X	X	X	X					
69	Dexorange	Ferric ammonium citrate	X	X	X	X	X					
70	Omilcal forte	Tribasic Calcium Phosphate		X	X	X	X					X
71	Newtel	Telmisartan	X	X	X		X					
72	Amcard	Amplodipine	X	X	X	X	X					
73	Strea			X	X		X	_				
74	Oscicare	Glucoseamine sulphate potassium chloride	X	X	X		X					
75	Venusia			X	X		X					X
76	Af-k	Ketoconazole & zinc pyrithione	X	X	X	X	X					

S.n o	D R U G	Generic Name	Prescription Only Drugs	Legible Text	Brand Name	Active Ingredients	Therapeutic Uses	Dosage Form	Adverse Drug Reactions or Side Effects	Precautions, warnings, contra- indications	Drug interactions	Address of the manufacturer
77	Physiogel		X	X	X		X					X
78	Zimivir	Valacyclovir	X		X		X	X	X	X	X	X
79	Momate- XL	Mometasone furoate	X	X	X		X					X
80	Triglow – M	Hydroquinone	X		X	X	X	X	X	X	X	X
81	Bontress	Capixyl		X	X	X	X					
82	Atopiclair		X		X		X					X
83	Follihair			X	X		X	X				
84	Sorvate/Sorvate c	Calcitriol/calcitriol & Clobetasol propionate	X		X	X	X	X	X	X		X
85	Pycnogenol		X	X	X		X					X
86	Grilinctus	Guaifenesin	X	X	X		X					X
87	Monlevo	Montelukast+levocetrizine	X	X	X	X	X					X
88	Divigel	Estradiol		X	X	X	X					X
89	Alprocontin	Alprazolam	X		X	X	X	X	X	X	X	X
90	Zolam	Alprazolam	X	X	X		X					X
91	Fenaplus	Diclofenac + paracetamol	X	X	X	X	X					
92	Metolaz	Metolazone	X	X	X	X	X					X
93	Genevac – B	Recombinant hepatitis b vaccine	X	X	X		X					X
94	Calcirol	Cholecalciferol		X	X		X					X
95	Relaxyl	Mephenesin		X	X		X					X
96	Rabipur	Rabies antiserum	X	X	X	X	X	X	X	X	X	X
97	S c c - 4		X	X	X		X					

S.n o	D R U G	Generic Name	Prescription Only Drugs	Legible Text	Brand Name	Active Ingredients	Therapeutic Uses	Dosage Form	Adverse Drug Reactions or Side Effects	Precautions, warnings, contra- indications	Drug interactions	Address of the manufacturer
98	Thyrobest	Thyroxine sodium	X	X	X		X					
99	Beta s	Beta glucans	X	X	X	X	X					
100	Cancure duo	Asparanin, asparagamine, beta glucan & swertian	X	X	X	X	X					
101	Liv R	Oleanolic acid, swerilactones & amarogenitine	X	X	X	X	X					
102	Redement	Oleanolic acid, bacoside & saponins	X	X	X	X	X					
103	Regen	Chondroidin sulphate, glucosamine bydrochloride, apocynin	X	X	X	X	X					
104	Stemact	Andrographide & satavarin	X	X	X	X	X					

Table 1. The 104 drug advertisements and generic names and the WHO's ethical criteria seen in each of the advertisement. An X in a box indicates that the advertisement contained the suggested criteria. The drugs that belong to Schedule K were also indicated by X in the column labeling "Prescription Only Drugs". Copies of the advertisements may be found in the Appendix by the S.no.

The advertisements in Table 1 were summarized by compliance with WHO's ethical criteria. The number of all drugs satisfying each of the ethical criteria as well as the number of prescription only drugs satisfying the criteria are provided in Table 2.

Table 2: Advertisements Satisfying Each of the WHO Ethical Criteria.

WHO Criteria Considered for the Study	No of Ads Satisfying the Criteria in all - 104 (% of All Ads)	Prescription Only Drugs- 71 (% of All Ads)	Others- 33(% of All Ads
Legible text	93 (90%)	60 (84%)	33 (100%)
Brand name	104 (100%)	71 (100%)	33 (100%)
Active ingredients	65 (62%)	47 (66%)	18 (54%)
Therapeutic uses	102 (98%)	69(97%)	33 (100%)
Dosage form	20 (19%)	14 (20%)	6 (18%)
Adverse drug reactions or side effects,	12 (11%)	12 (17%)	0 (0%)

Precautions, warnings, contra-indications	12(11%)	12 (17%)	0 (0%)
Drug interactions	8 (7%)	8 (11%)	0 (0%)
Address of the manufacturer	55 (52%)	36 (51%)	19 (57%)

Table 2. The number and percentages of drug advertisements satisfying each of the WHO criteria. The advertisements and their percentages were also presented for prescription only drugs and others.

Among the advertisements presented in Table 1 the drug advertisements on Relaxyl gel, Zerodol p, Nacnano, Grilinctus were found twice that is in two different journals. Hence only one advertisement per drug (Relaxyl gel, Zerodol p, Nacnano, Grilinctus) was considered for the study and listed in Table 1.

Among the drug advertisements studied, all of the 104 drug ads possessed brand name. Only 19% of them possess drug dosage information, 11% possess precautions/contraindications, and 11% of the ads possess adverse effects. In approximately 52% of the drug ads, the pharmaceutical company's address was seen (Table 2).

In the analysis of drug advertisements based on prescription only drugs and others, legible text was found in 84% of drugs in prescription only drugs and 100% in others. Side effects/Adverse drug reactions and contraindications were found in 17% of the advertisements in prescription only drugs and 0% in others. Drug interactions were found in 11% of prescription only drugs and 0% in others

In the advertisements studied, a few included claims such as "superior efficacy", "proven to be safe", "first time in India", "complete relief", "free from side effects", "pure", "sure bet", and "widely prescribed brand" without supporting evidence. The advertisements with such claims are listed in Table 3.

Table 3: Advertisements with Misleading Claims

Drug	Claims Made in the Advertisement	Indications
Tusq – dx	Total cough relief	For symptomatic relief from dry cough ²⁶
Zerodol	Strikes out pain and traumatic swelling	Pain and swelling ²⁸
Zerodol –p	Extra speed and power	Head ache, pain and fever ²⁹
Tusq – x	The ideal expectorant	Bronchodilation, asthma ²⁷
Supamove cream	First time in India a therapeutic breakthrough – osteoarthritis	Muscles and joint pains, Rheumatoid Arthritis,tendonitis/Trauma Osteoarthritis ²⁷
Tatkaal	World's only Side effect free contraceptive pill	Contraceptive pill ²⁶
Wakfree	Rebuilds cartilage Restores elasticity of cartilage Relieves pain No pain just walk	Osteoarthritis ²⁹
B-colen	Family is now complete	Rapid weight loss, malnutrition-vit b supplement ²⁶
Orovit active	Ideal choice for Pcos management	Pcos ²⁷
B-protin	Complete nutrition that tastes best	
D-protin	For diet compromised diabetic patients	
Pro-pl	Comprehensive nutrition for healthy mother and healthy baby	Pregnancy and lactation ²⁷
Clenol-LB	Put full stop to vulvo vaginal infections for the first time in India cleno-lb	
Sensodent kf	Widely prescribed brand by dentists, extra foaming	Dental caries prophylaxis, hypersensitive teeth ²⁵
Hexidine	Gingivitis, oral hygiene, tonsilitis, sore throat, Pharyngitis, icu patients	Gingivitis, cleansing skin and wound areas ²⁸
Xyzal	Most prescribed anti histamine in chronic urticaria	
Dermogem	A legend gateway to restore skin vitality	
Stator	Statin adds 2 years to life	High cholesterol ²⁷
Solvincold	Cold, cough and fever for young and old	Cold in adults ²⁹
Solvin cough	Dry cough in adults and children	
Sorbitrate	For anginaprophylaxis, trusted therapy for more than 5 decades	Angina ²⁸
Tribet	Sure bet for better control, efficacy similar to insulin+metformin	

Drug	Claims Made in the Advertisement	Indications
Emtax-az	Combination is more effective than	
Lintax-az	cefixime or azithromycin alone	
Zathrin –	Purity redefines cure, superior clinical	
Azithromycin	efficacy, simplified dose, best quality	Pharyngitis, tonsilitis, sinusitis ²⁹
Azidifolityetti	azithromycin with widest dosage range.	
	Gold standard iron therapy with added	
Hunt red	advantage, dysfunctional uterine	Anemic, vitamin deficiency ²⁹
	bleeding, post hysterectomy	
Pinom	Achieve rapid blood pressure goals	Low blood pressure ²⁶
Clopitab	Lifeline uninterrupted	
Harty	Aao fit rahe (Stay fit)	
	Efficacy comparable to interferons &	
	antivirals	
	Well tolerated and safe compared with	
	interferons & antivirals	
Liv.52 hb	-free from harmful side effects such as	
	Mone marrow depression, pancreatitis	
	& peripheral neuropathies,	
	neurovegetative syndrome.	
	Devoid of toxicity following acute and	
NT	repeated administration.	<u> </u>
Nac nano	India's 1st diclofenac gel with nano	
	technology	
Systaflam gel	Better patient compliance with bigger benefits	Topical anti-inflammatory and
Systaflam-MR	benefits	analgesic. ²⁵
capsules	Superior protection	Anti inflammatory ²⁶
	Stimulates cartilage regeneration, stops	Osteoarthritis, rheumatoid
Oscicare	cartilage degeneration	arthritis ²⁶
Omilcal forte	Optimum ratio of ca & P	
Relaxyl	Complete relief from low back pain	Low back pain ²⁹
	Essential hypertension, hypertension	
Newtel	with diabetes, diabetic nephropathy,	Hypertension ²⁵
	hypertension with LVH	
	First Indian brand of amlodipine,	Angina pectoris, Hypertension
Amcard	cardiac care on merit	mild/moderate, Prinzmetal
		angina ²⁵
Cymet plus	For effective 24hr BP control	
Strea	Under eye problems could be a	
Sucu	nightmarish experience for your patients	
Zimivir	High bioavailability & convenient	Herpes ²⁶
	dosing for Herpes	
Triglow cream	First time in India triple combination	
	with microsphere	
Melnora	Reverses gray hair	

Drug	Claims Made in the Advertisement	Indications
Bontress	Stimulates hair growth, prevents hair	
	loss	
Atopiclair	Clinically proven to be safe and	
	effective in adults, children and infants	
Follihair	Stop hair fall, promote hair growth,	
	increase hair density	
Divigel	The only thing you will see is the results	
Alprocontin	Consistent performance, simplified OD	
	treatment, low abuse potential, lower	
	inter dose anxiety. Smooth & consistent	
	anxiolytic effect.	
Zolam	Soothes the restive mind round the	
	clock.	
Fenaplus	Powerful, yet safer.	
Metolaz	Significantly reduces both systoloc and	
	diastolic BP	
	Works even when GFR is low.	
	For the first time in India a versatile	
	antihypertensive diuretic	
Genevac-b	Proved superior efficacy, the name you	
	can trust	
Calcirol	India's 1st vit d3, 100 million patients	
	are benefitted with calcirol, so rich in vit	
	D3 it's like the second sun	
Rabipur	Pure, powerful protection	
Scc4+ pouch	Simplest way to treat TB	
	99.6% sputum conversion rate in 60	
	days	
Stemact	Protection that is proven	
Redement	Experiencing 30's in 60 s	. 1 61 1 11 11

Table 3. Drug advertisements that were observed with exaggerated or false claims without supportive references.

Discussion

Any advertisements with incomplete or misleading information may influence the prescribing behavior of the doctor and pose a risk to patients.

In the above analysis, none of 104 drug advertisements complied with the WHO's ethical standard as they lack one or more required information. Only 11% of the advertisements included adverse events and side effects (Table 2). These findings indicate that pharmaceutical companies are not publishing possible adverse events of drugs.

Very few of the reviewed advertisements (12) had precautions, warnings, and contraindications. Only eight advertisements were seen publishing the drug interactions (see Table 2). Thus, physicians who rely on drug advertisements in medical journals may prescribe such drugs without indicating precautions and warnings to their patients. This may be of serious concern as patients may take the drug lacking required information.

About 19% of the advertisements did not contain dosage information in the ads which may lead to inappropriate drug usage. Active ingredients of the drugs were seen in only 62% of the advertisements (Table 2). The other advertisements did not have active ingredients mentioned; thus, the doctors were provided with insufficient information on the drug's contents.

The drug advertisements were analyzed based on the drugs that are available only on prescription (Schedule H) and others that are not part of Schedule H as they might have varied effects on public safety. Of the 104 drug advertisements 71 were found to be available only on prescription (Schedule H) and 33 were not Schedule H drugs.

Little difference was found in the percentage of advertisements with dosage form, active ingredients, and therapeutic uses were found in prescription only drugs and others. But the drug advertisements that are not part of Schedule H did not have contraindications/precautions/drug interactions/side effects. Hence the drugs that are not prescription only drugs did not have all the information as proposed by WHO.

In the advertisements listed in Table 3, claims such as superior protection, complete relief, free from side effects, pure, extra power, most trusted, etc., are made without supporting references. Claims on safety include free from side effects, safer, clinically proven to be safe were made without proper scientific evidence. This may influence the treatment choices by physicians. The claims pertaining to efficacy include proved superior efficacy, 99.6% of sputum conversion (SCC+ pouch), powerful, protection that was proven. Thus, a few of the advertisements were seen with exaggerated claims and a few others are with false claims.

The misleading advertisements are seen in the form of an expansion of indications or an exaggeration of efficacy and also seen downplaying the seriousness or the incidence of adverse reactions. Such misleading information creates a wrong perception of the efficacy and safety of products among prescribers and consumers.

The drug promotional material form one of the important sources of information for physicians. One of the reasons may be the lack of time to critically appraise the advertised drug. Physicians may prescribe the drug when influenced by the misleading or false claims made in the advertisement. Therefore, physicians should not completely rely on promotional literature as a source of drug information.

The International Federation of Pharmaceutical Manufacturers Association adopted a revised version of IFPMA Code of Practice in 1994 on ethical drug marketing. The pharmaceutical firms marketing drugs in developed countries generally seem to be following the guidelines. But the same drugs were marketed for other indications in India²³. Therefore pharmaceutical companies need to take initiatives to regulate the unethical drug promotional practices while marketing the drugs in India.

Health care providers need to be informed by regulatory authorities, and urged to report any misleading drug advertisements as in FDA's BAD AD program. In FDA's program, health care professionals are asked to recognize any misleading and illegal information in drug advertisements and report them to the FDA. The FDA then evaluates all the reports, and if any of the advertisements are seen violating the regulations, the FDA will take action to stop the misleading drug promotion²⁴.

The impact of drug promotional literature can be lessened by educating undergraduate students, interns and resident doctors, on how to analyze the promotional literature as they are the one who interacts with pharmaceutical representatives. It would make them learn to focus in a practical way on treatment goals when making prescribing decisions, and to develop their own personal formulary for commonly treated conditions.

Conclusion

It was found that in India pharmaceutical companies are publishing drug advertisements without complete information recommended by WHO (see Table 1 and Table 2). Only 12 advertisements out of the 104 advertisements reviewed contained adverse drug reactions/side effects and contraindications/precautions/warnings. Doctors should not completely rely on drug advertisements as a source of information on new drugs. They should be cautious while accepting the claims made in the advertisements. Healthcare professionals should get involved in the reporting of misleading drug promotions to the regulatory authorities, and the authorities reviewing and banning the ads may lessen unethical drug promotion.

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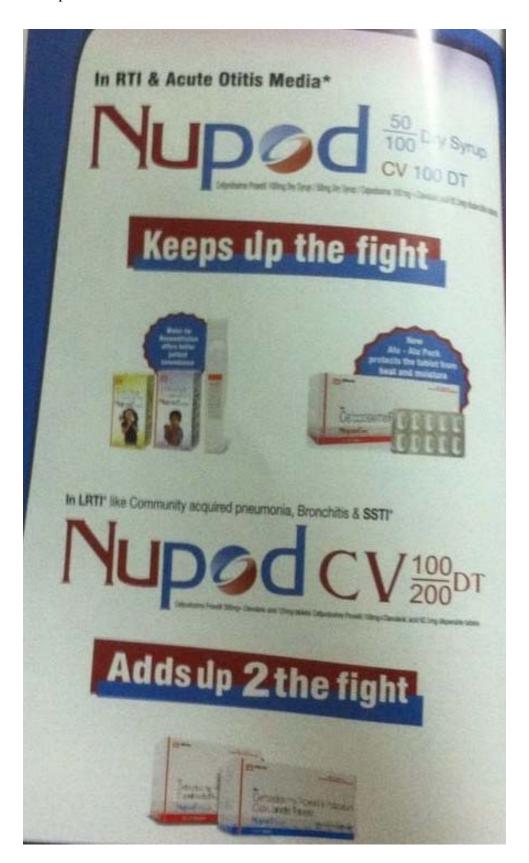
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Appendix: Advertisements

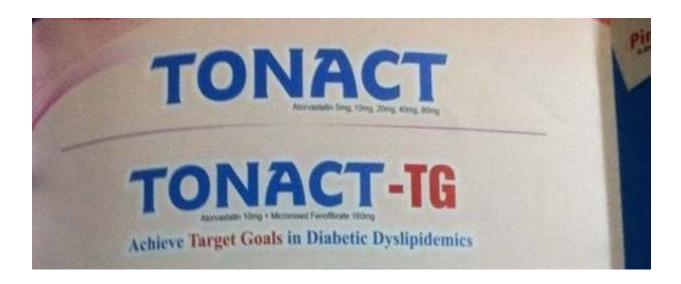
1. Tusq-Dx



2. Nupod



3. Tonact/Tonact - TG



4. Harty



5. Clopitab



6. Ramistar



7. Pinom



8. Ascoril



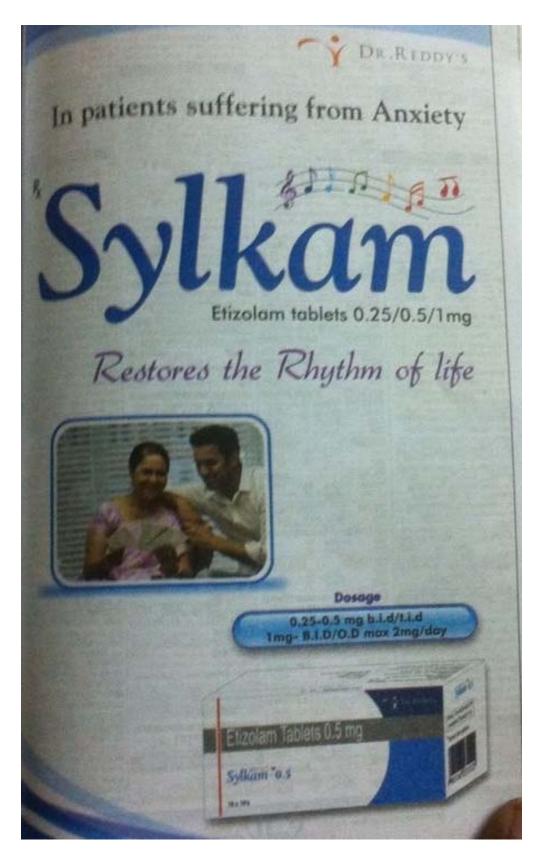
9. Reswas



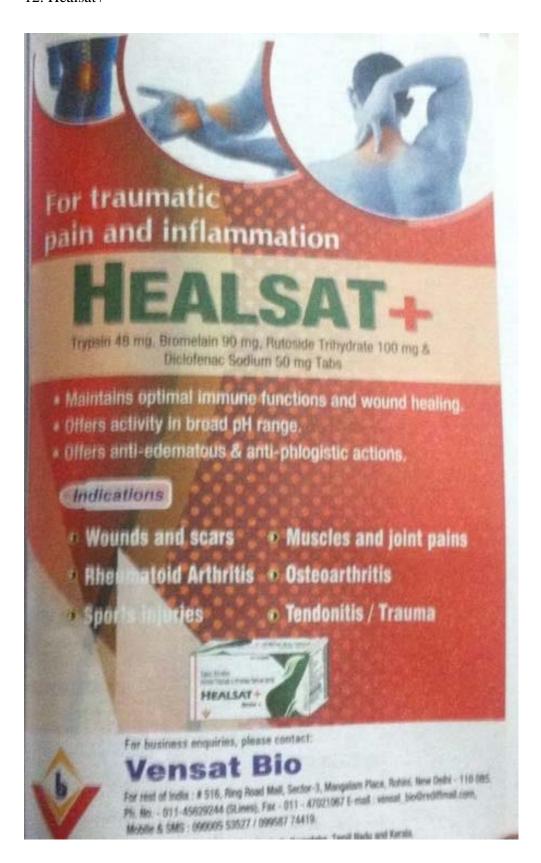
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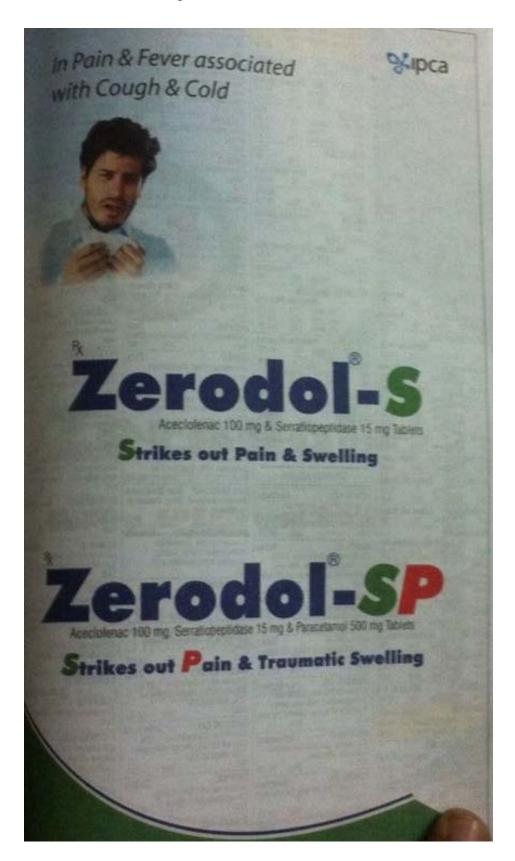
11. Sylkam



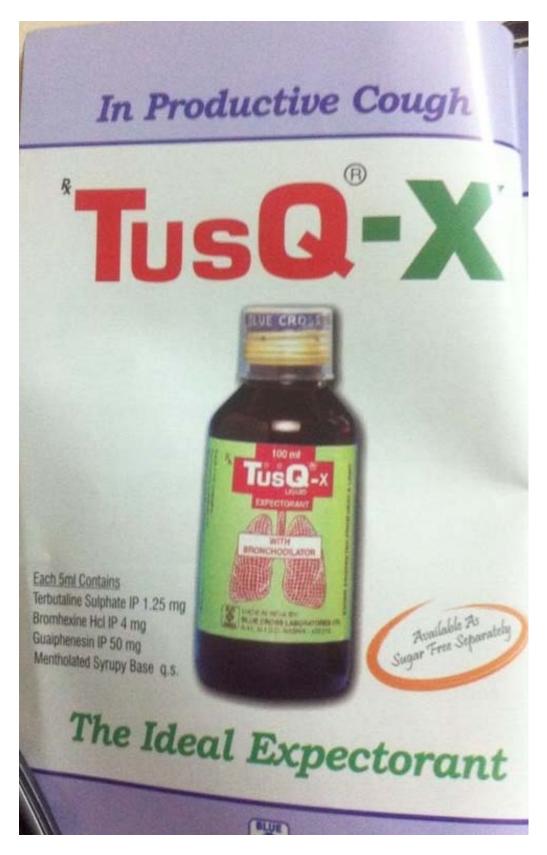
12. Healsat+



13. Zerodol s/ Zerodol sp



14. Tusq-X



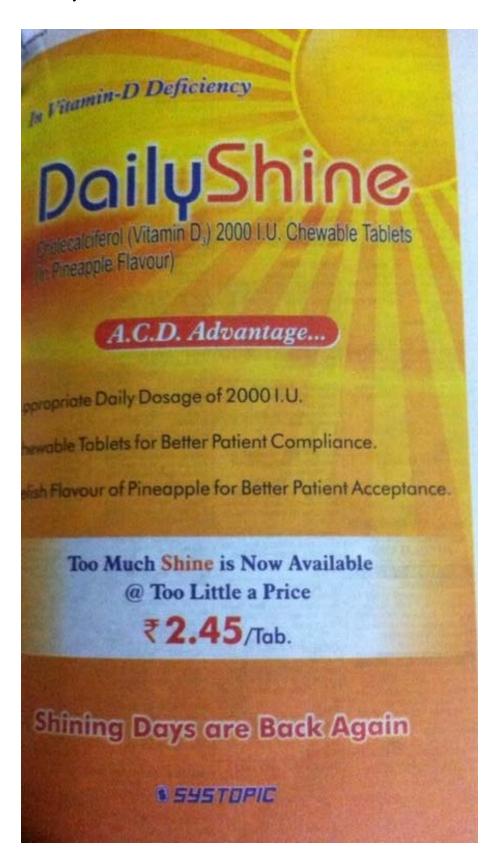
15. Supamove



16. Havmax-forte



17. DailyShine



18. Lornid-IP



19. Tatkaal



20. B-G-Prot L



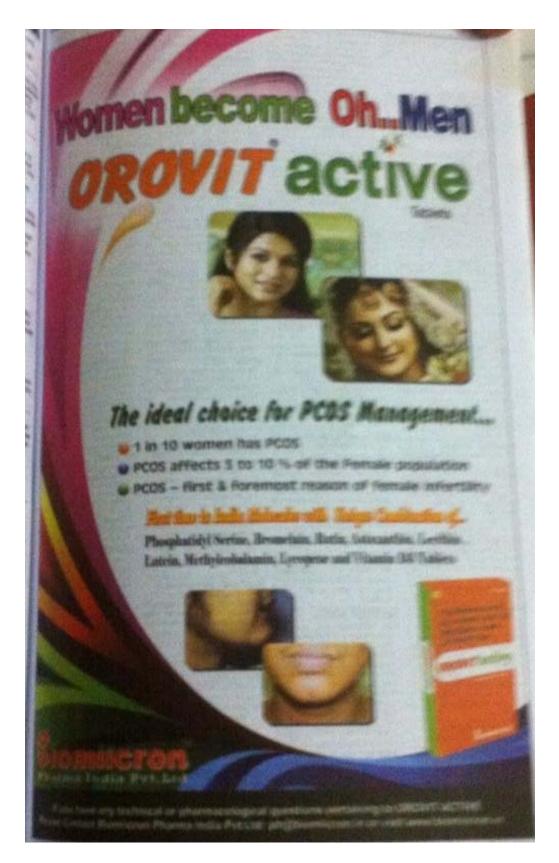
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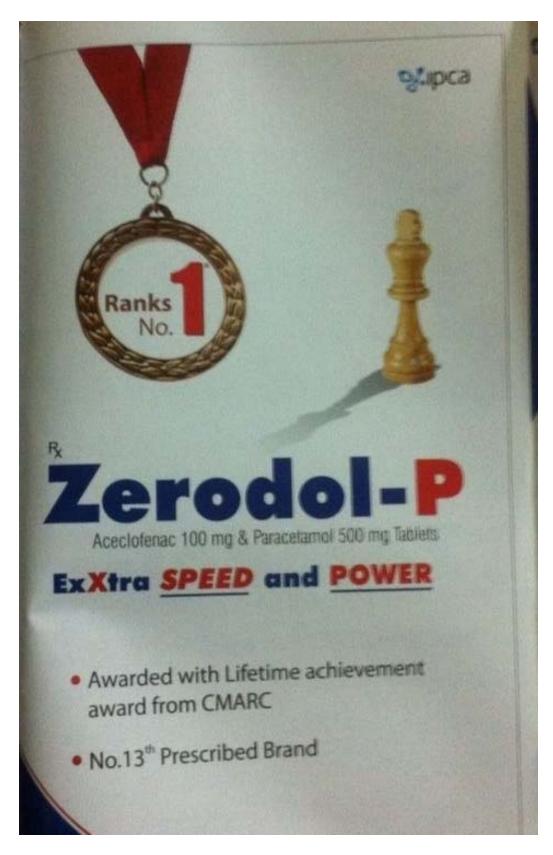
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23. Orovit active



24. Zerodol-p



25. Folera-MD



26. Preglac-Kit



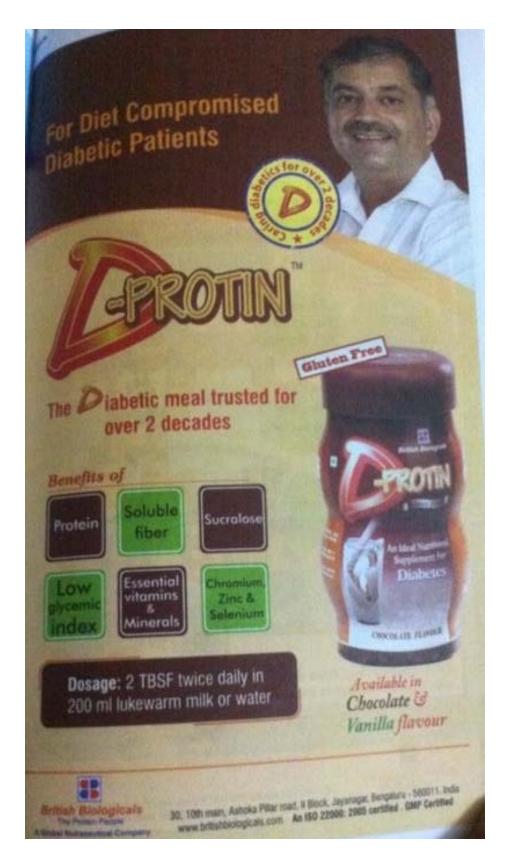
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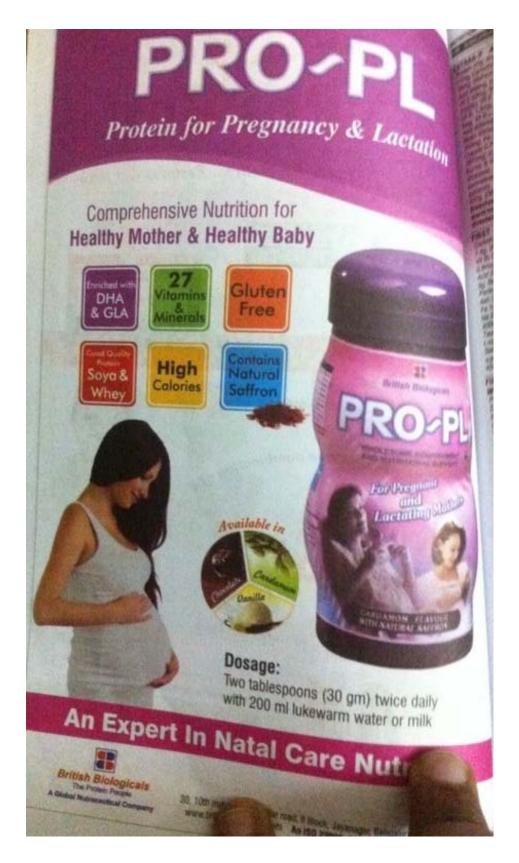
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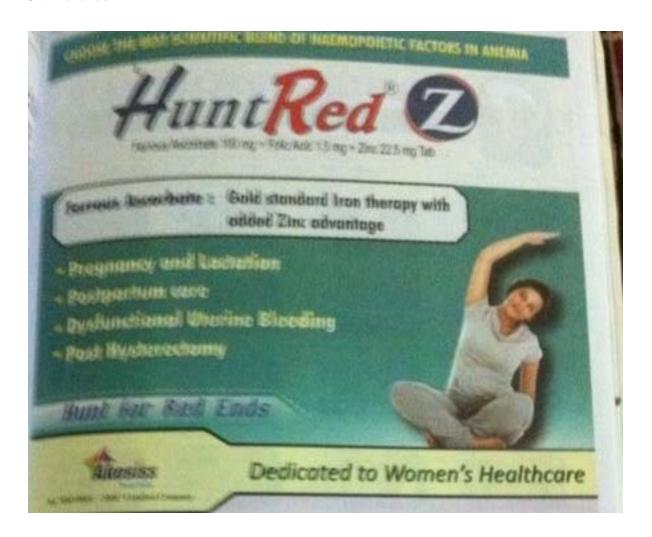
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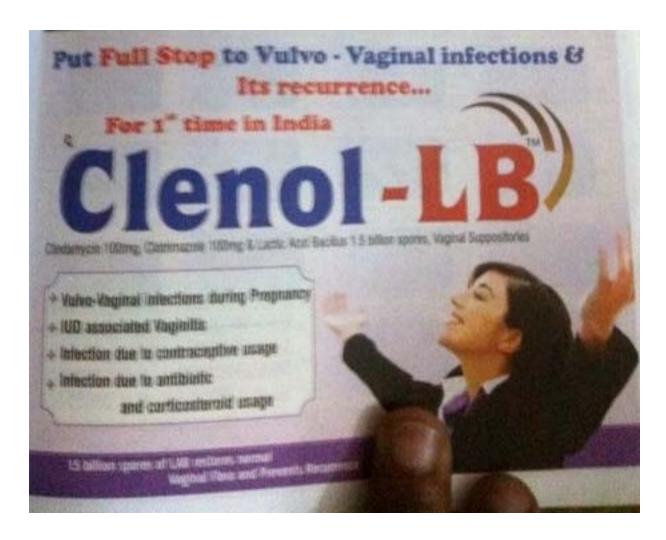
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31. HuntRed



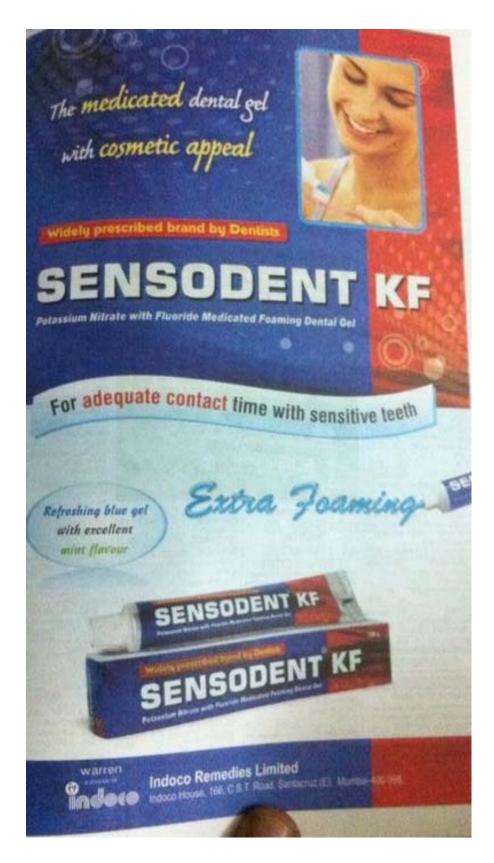
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33. Cymet plus



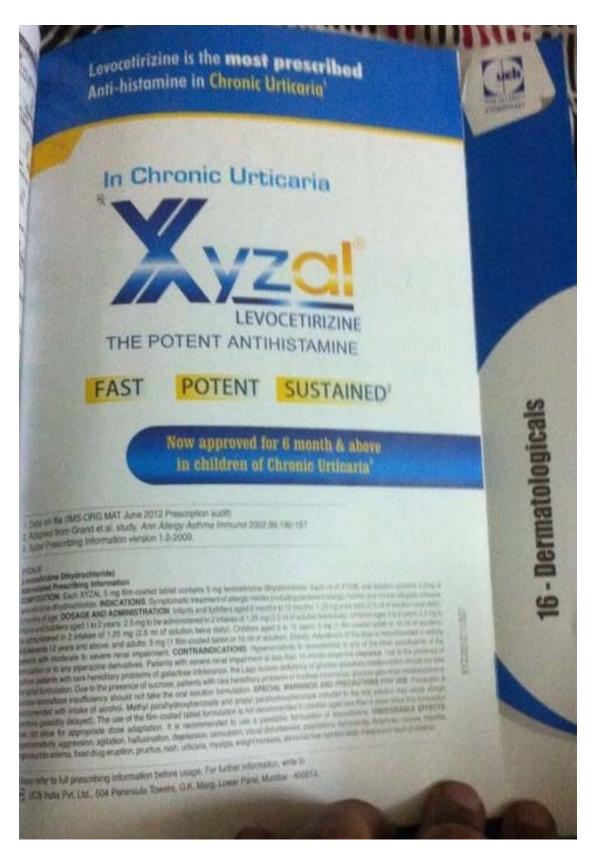
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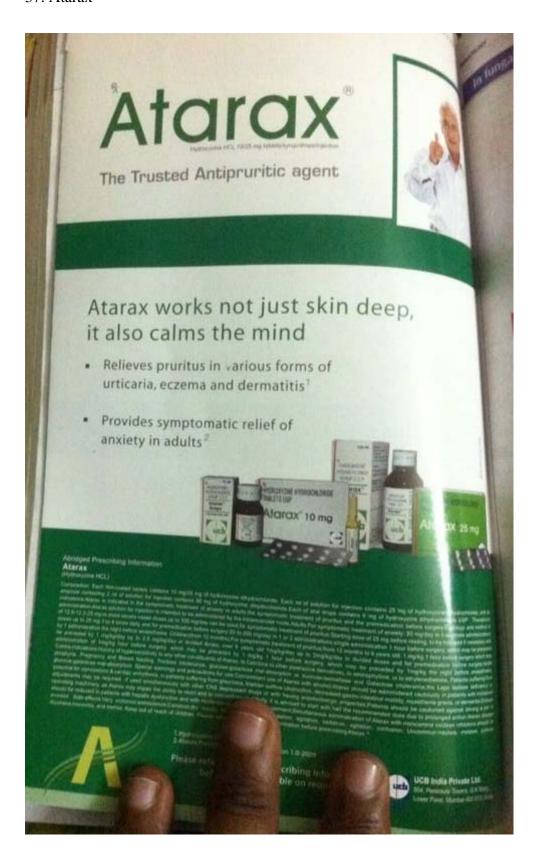
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36. Xyzal



37. Atarax



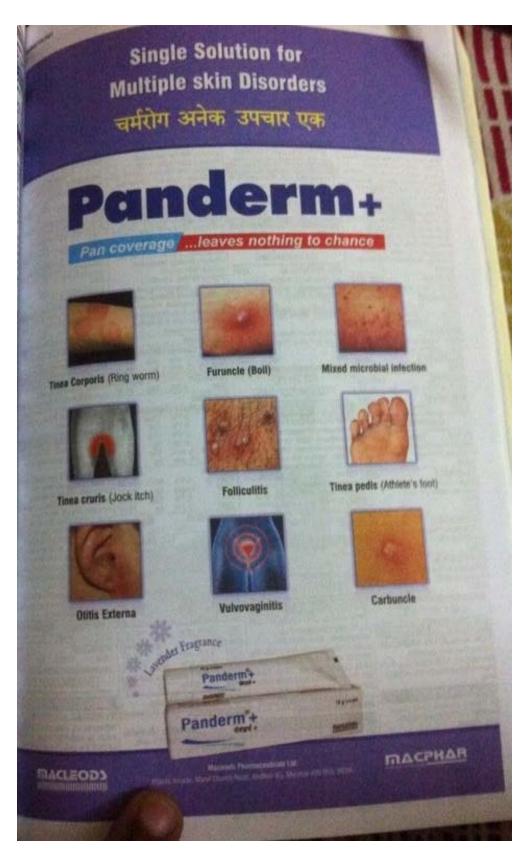
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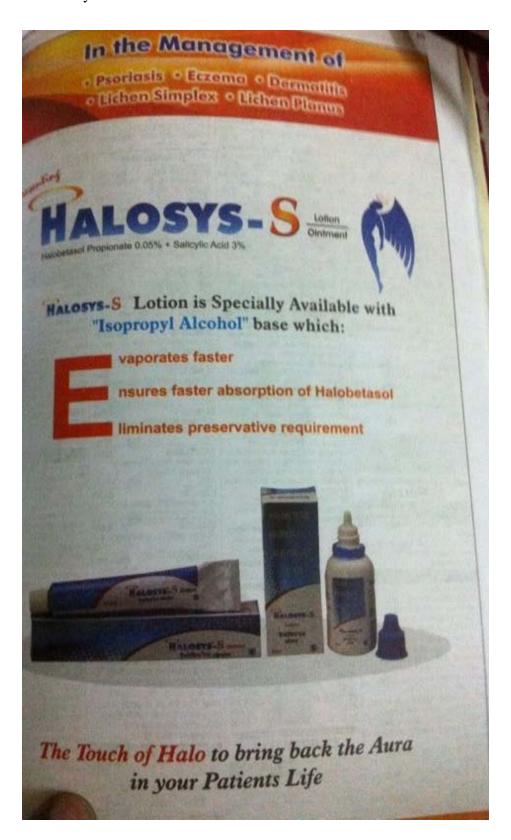
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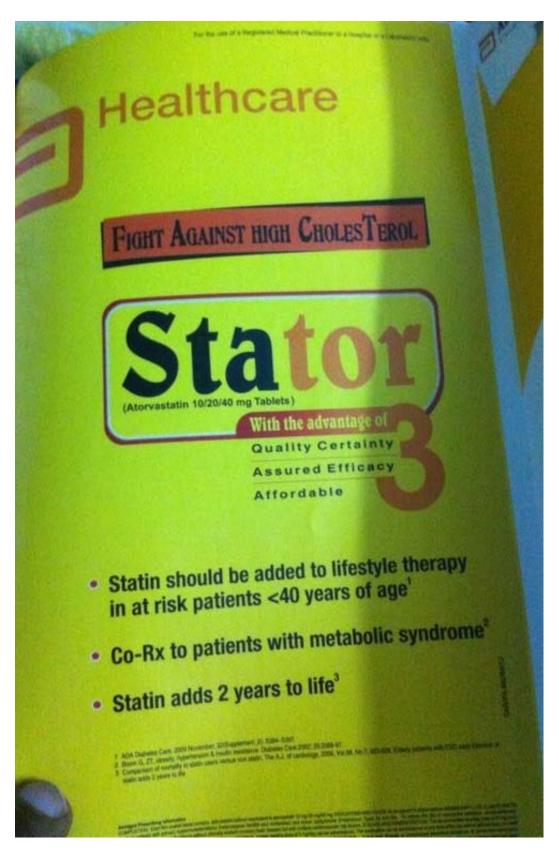
40. Panderm+



41. Halosys-S



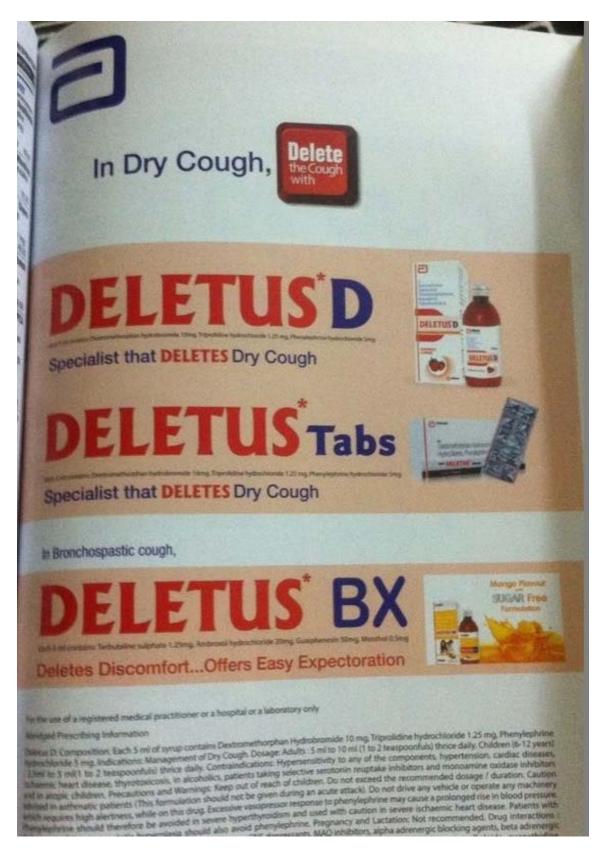
42. Stator



43. Melnora



44. Deletus



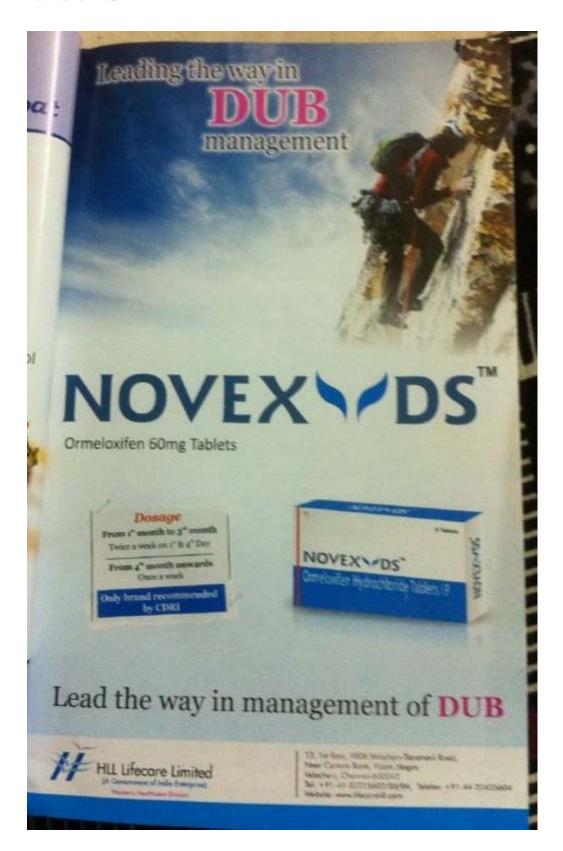
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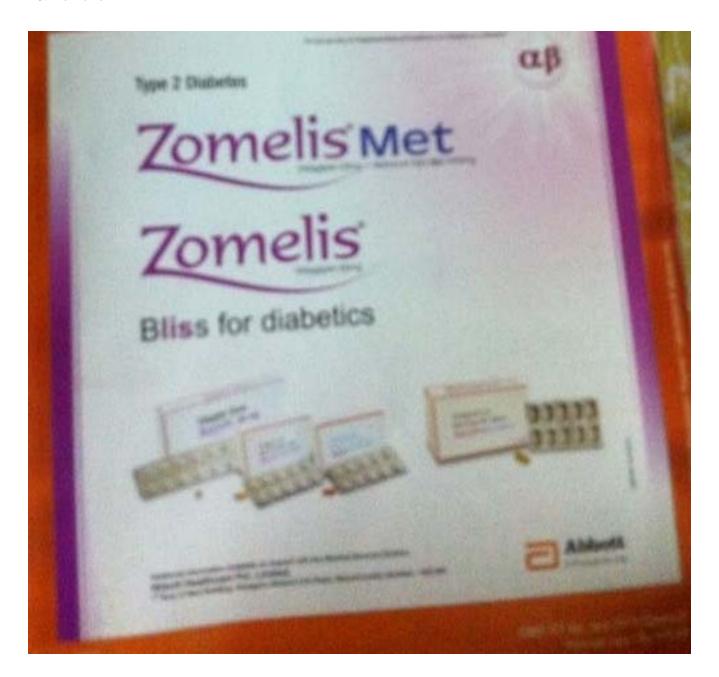
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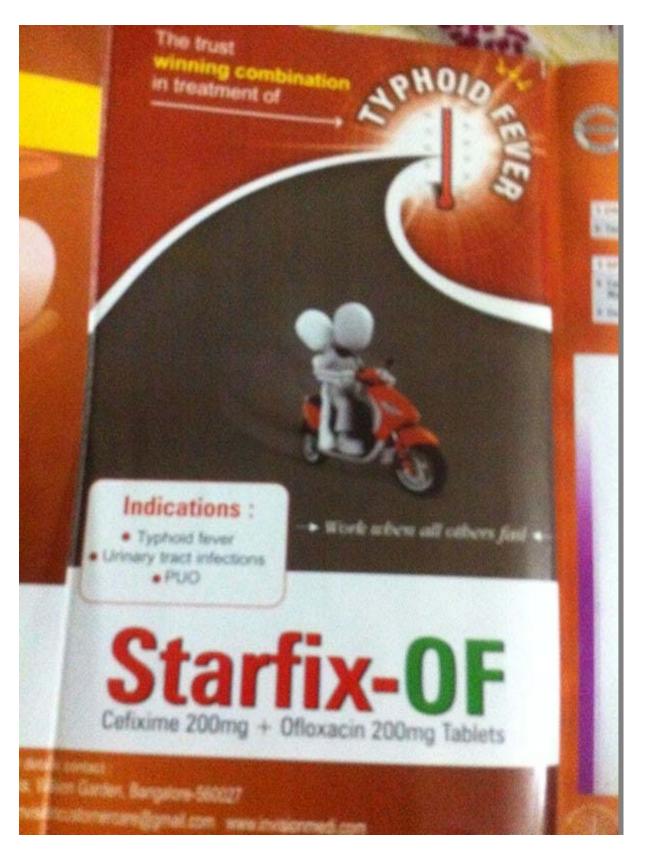
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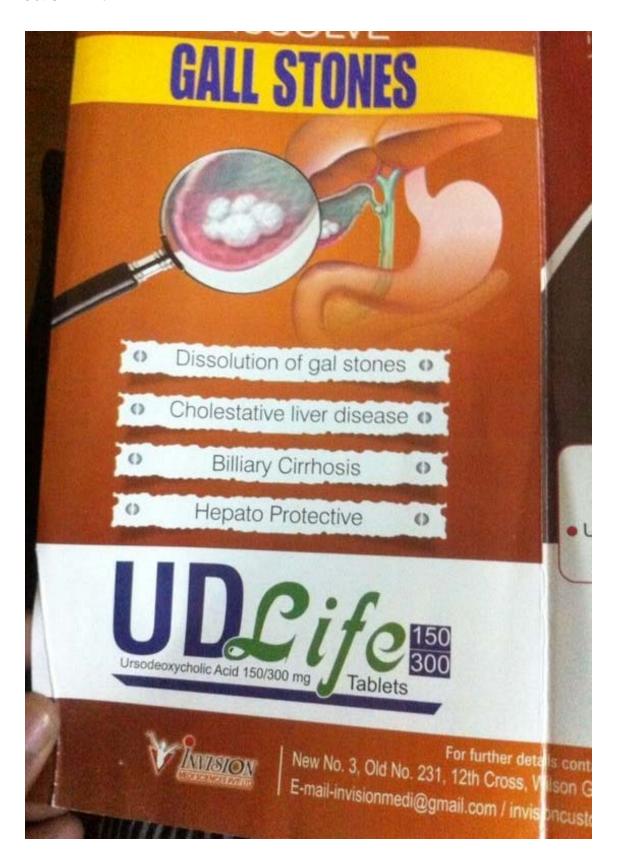
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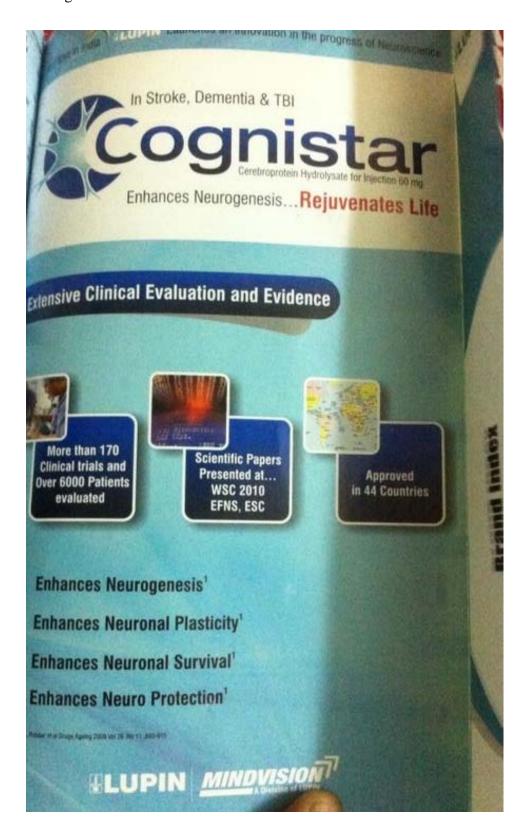
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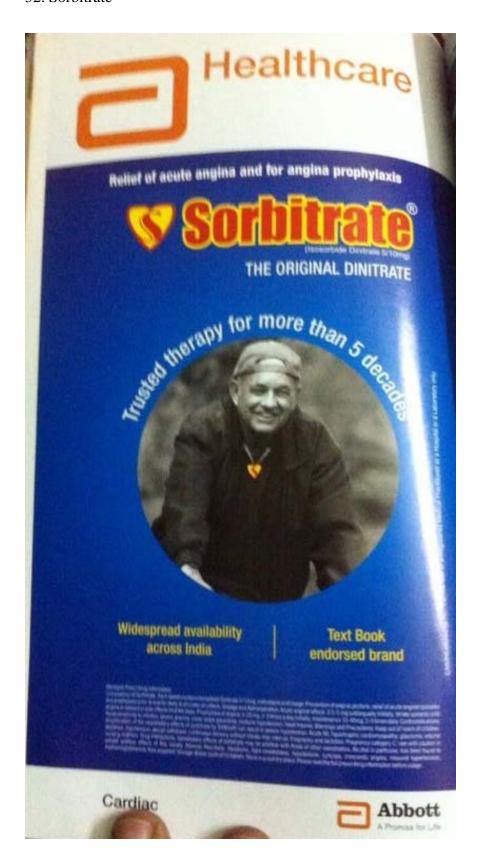
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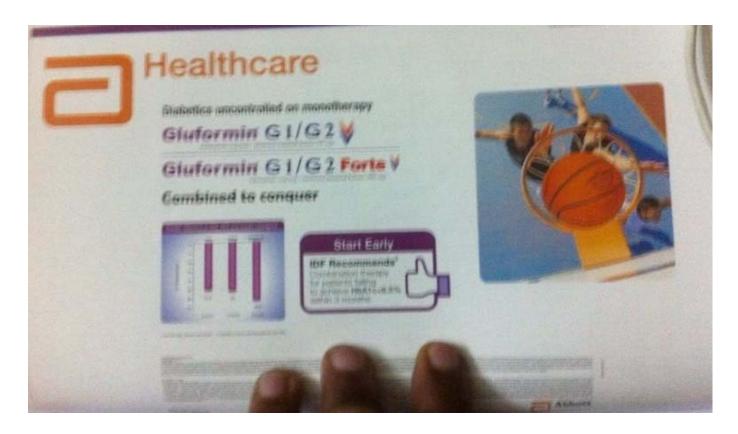
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52. Sorbitrate



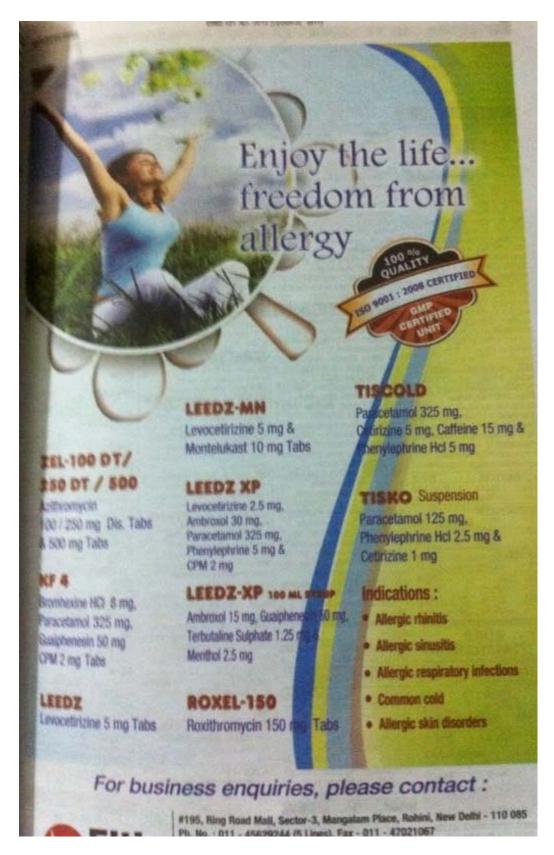
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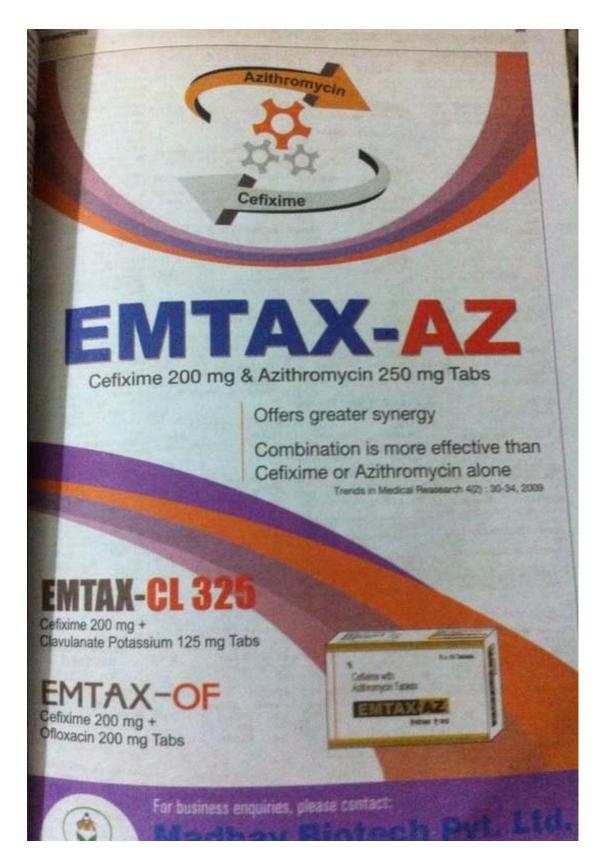
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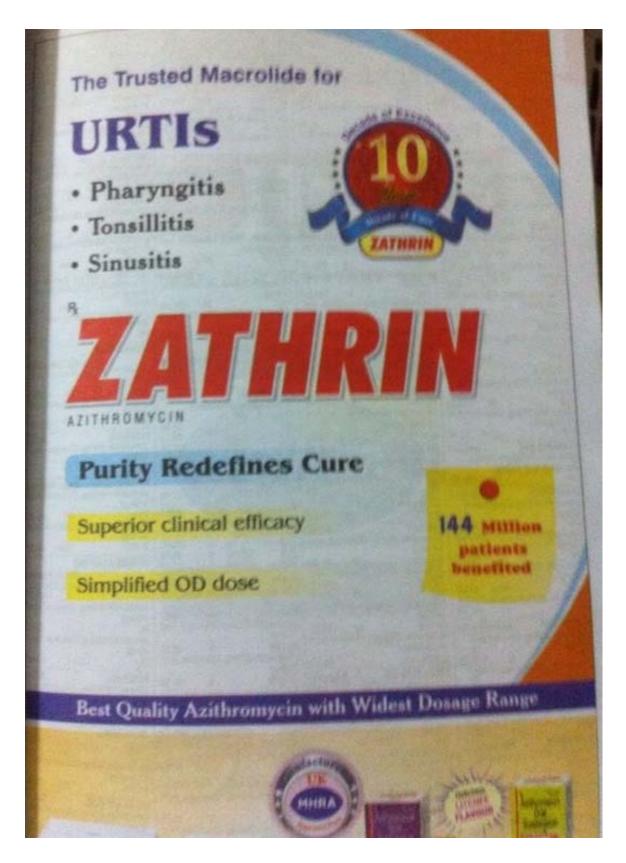
55. Leedz, Roxel, Tisko, Tiscold, KF-4, Zel-100 DT



56. Emtax-AZ



57. Zathrin



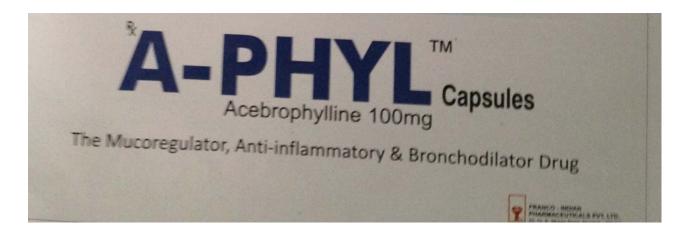
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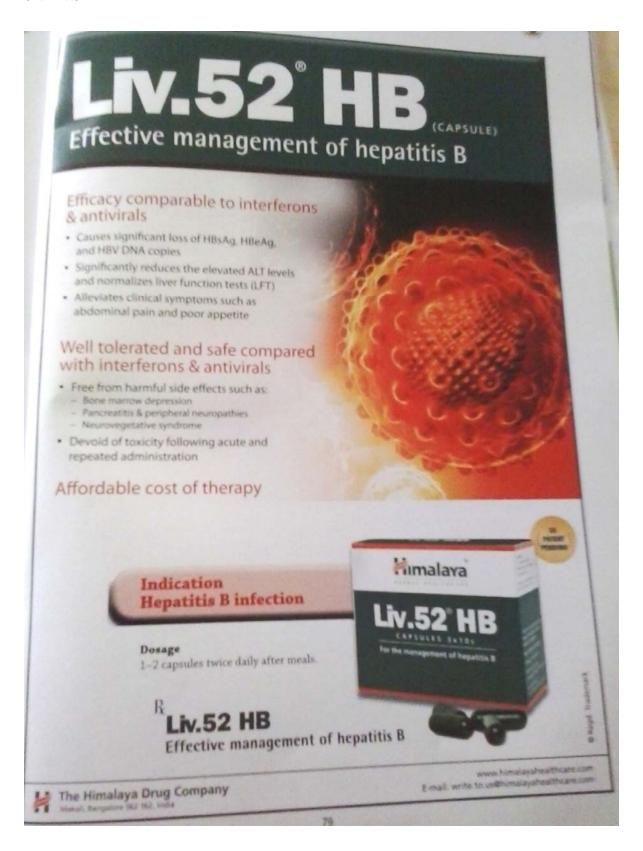
59. Starfix - AZ



60. A-Phyl



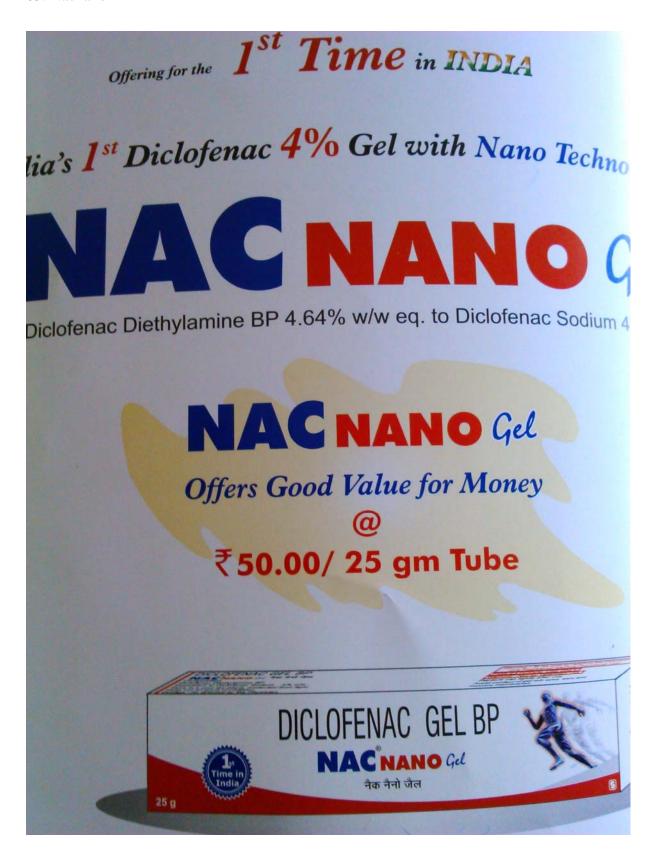
61. Liv.52 HB



62. Wakfree



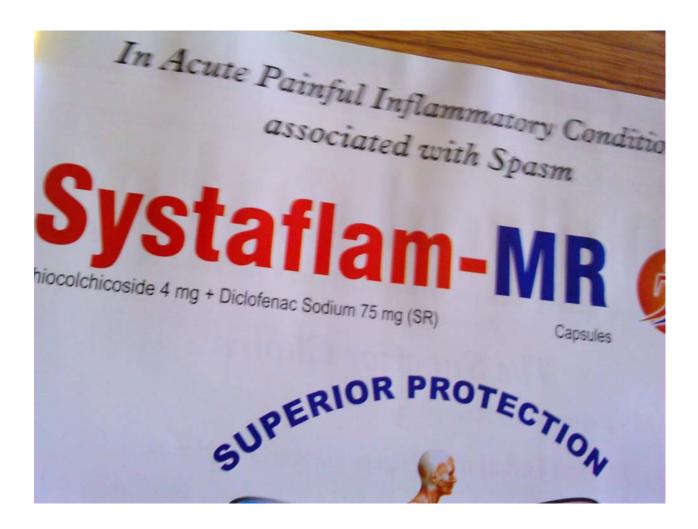
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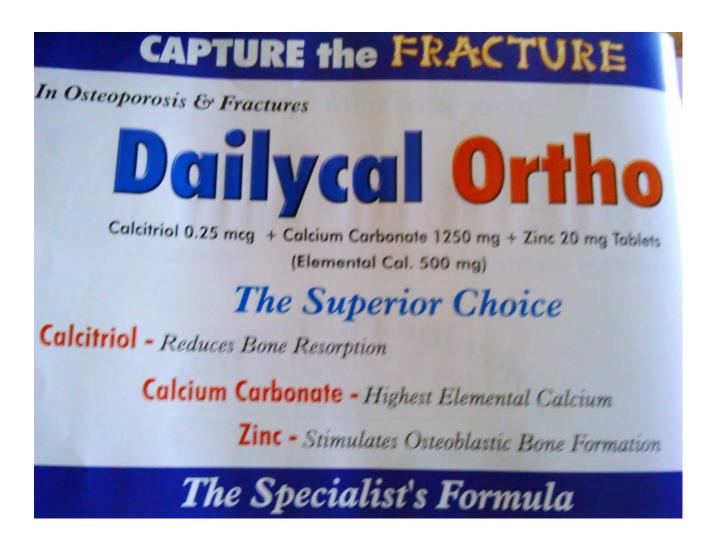


64. Systaflam gel

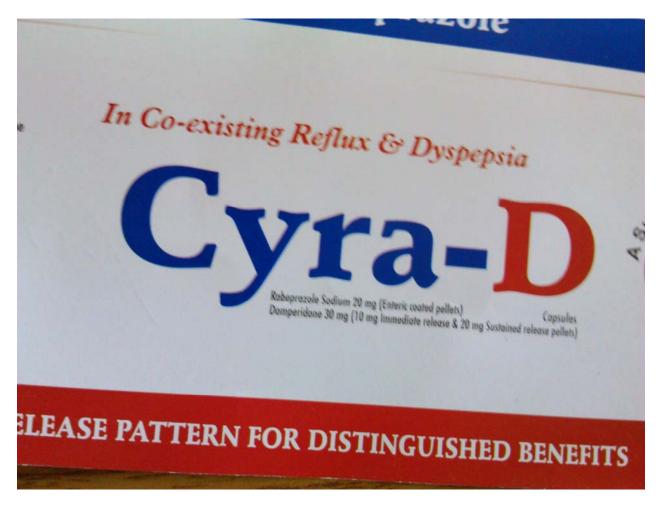


65. Systaflam - MR





67.CyraD



68. Cyra



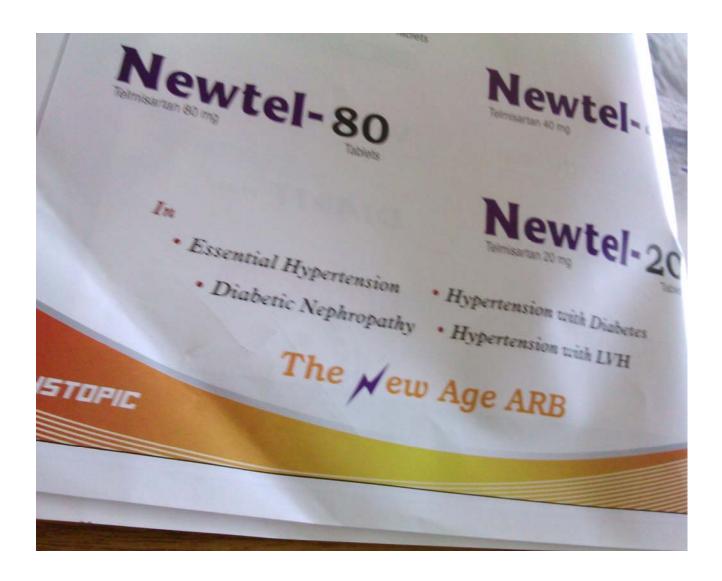
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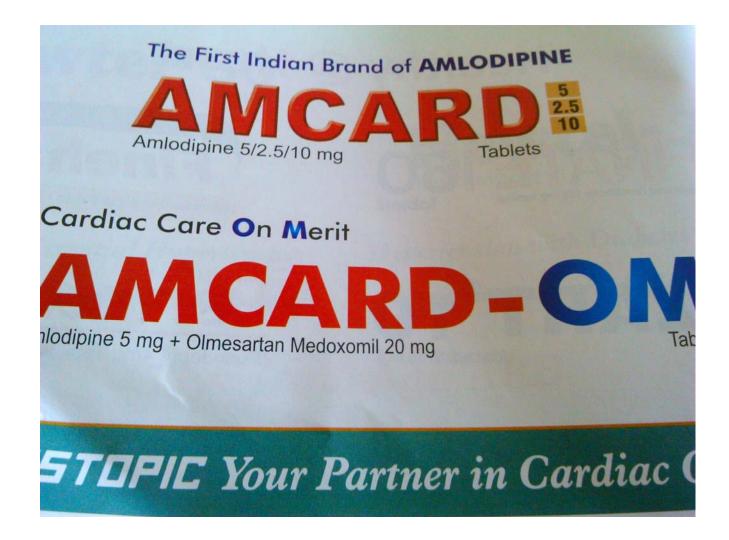
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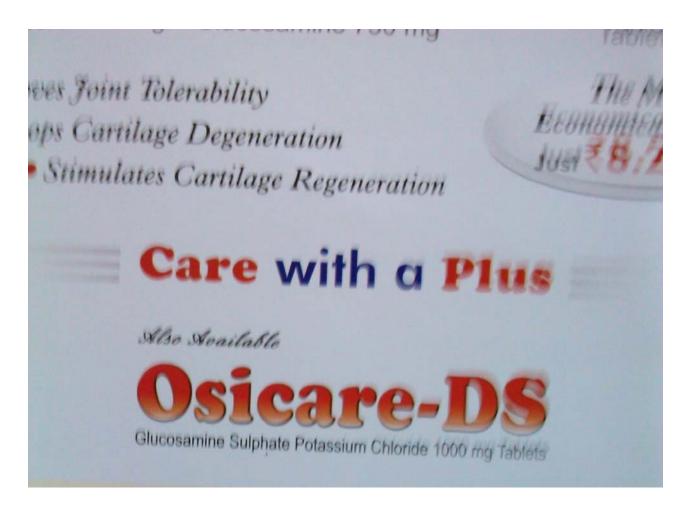
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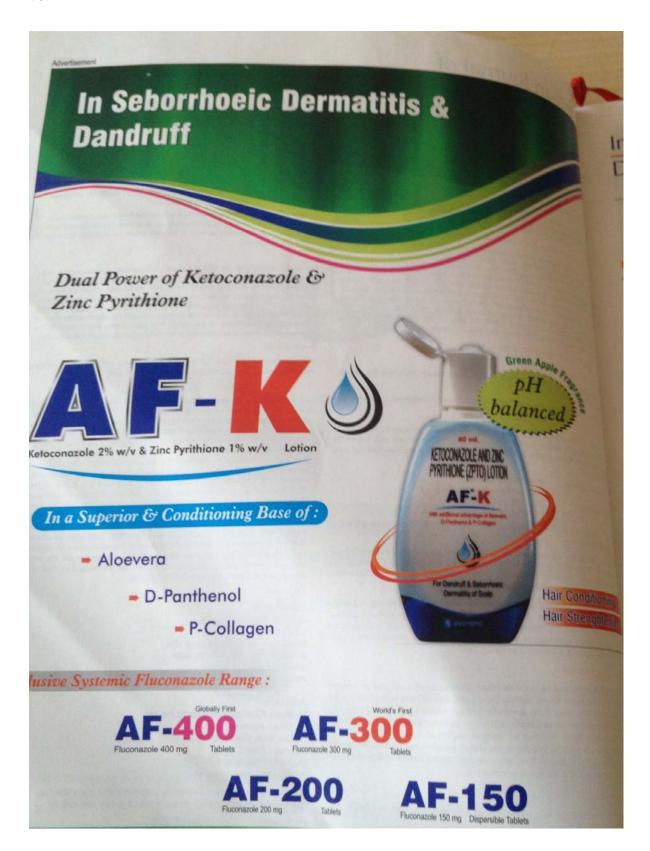
74. Oscicare



75. Venusia



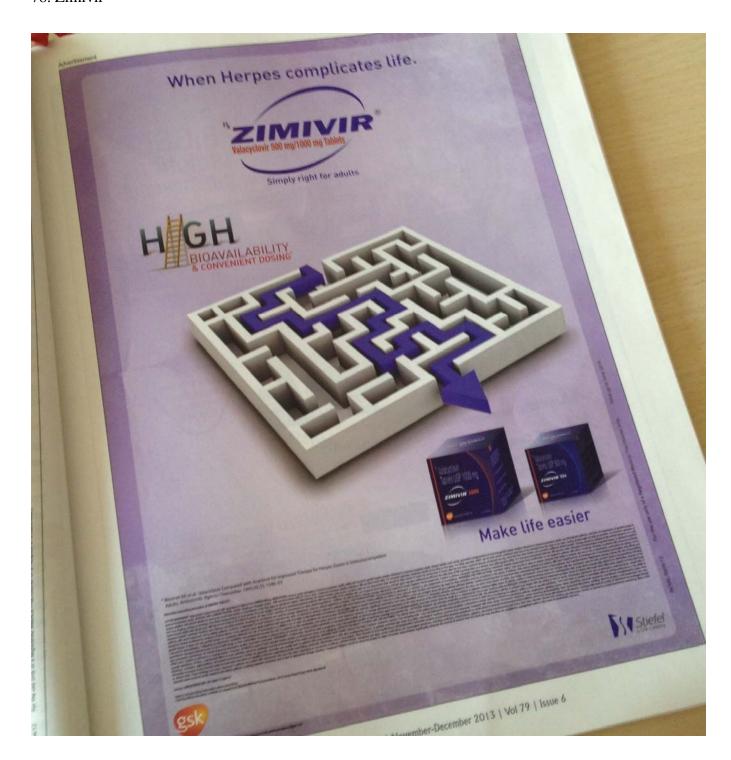
76. AF-K



77. Physiogel



78. Zimivir



79. Momate- XL



80. Triglow – M



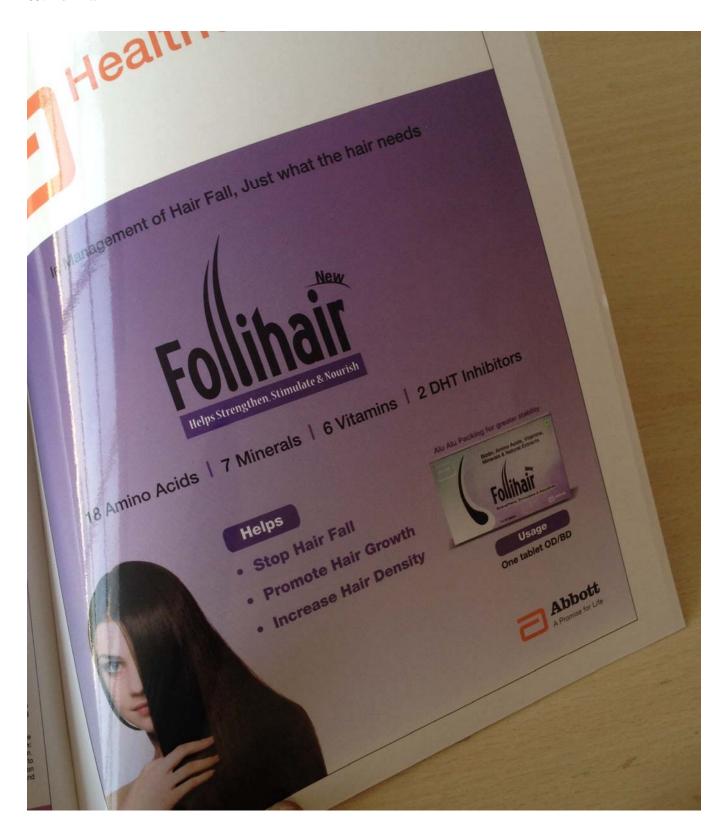
81. Bontress



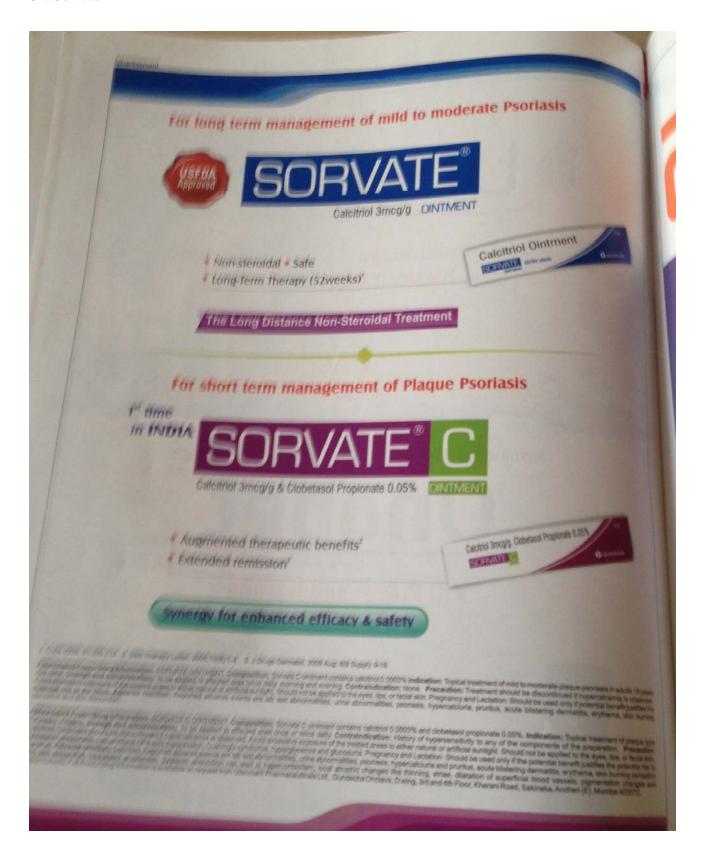
82. Atopiclair



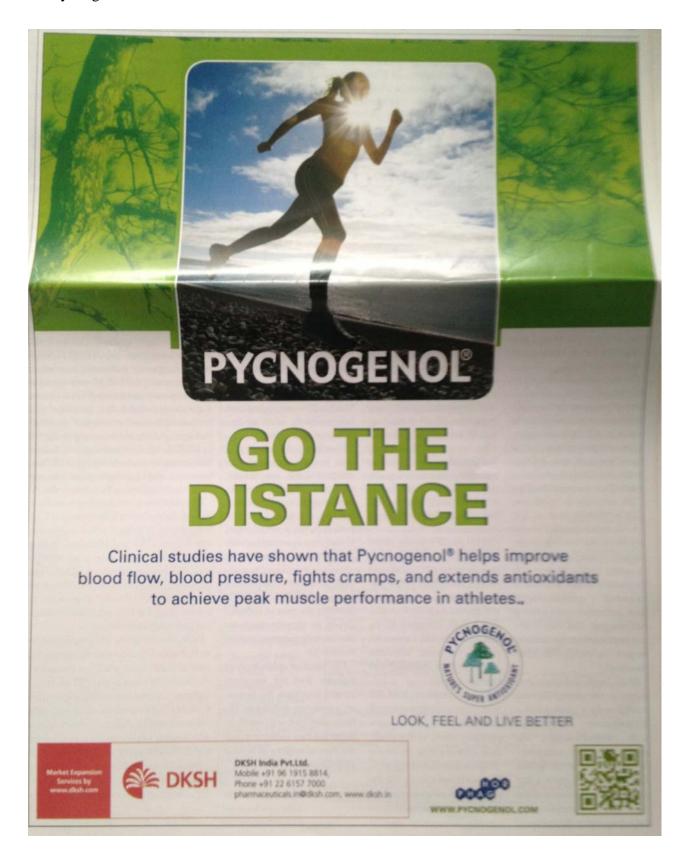
83. Follihair



84. Sorvate



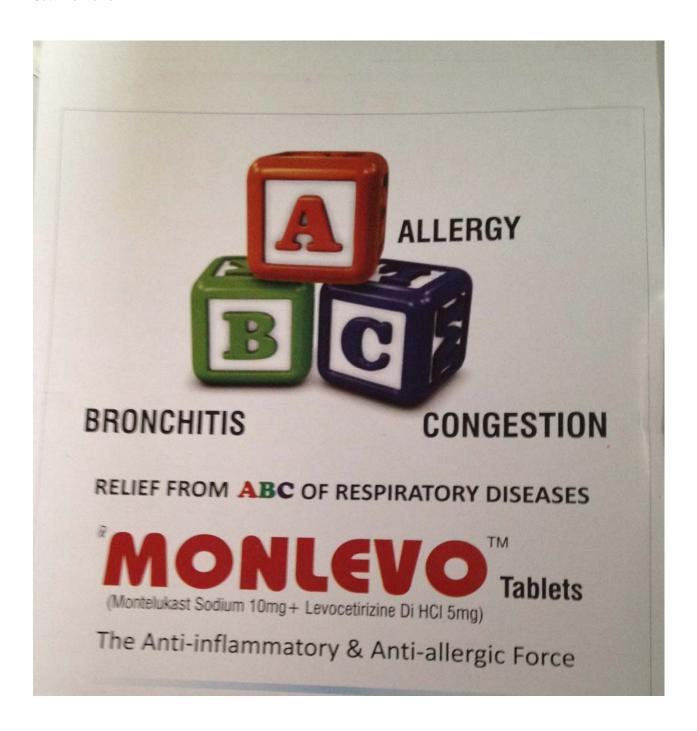
85. Pycnogenol



86. Grilinctus



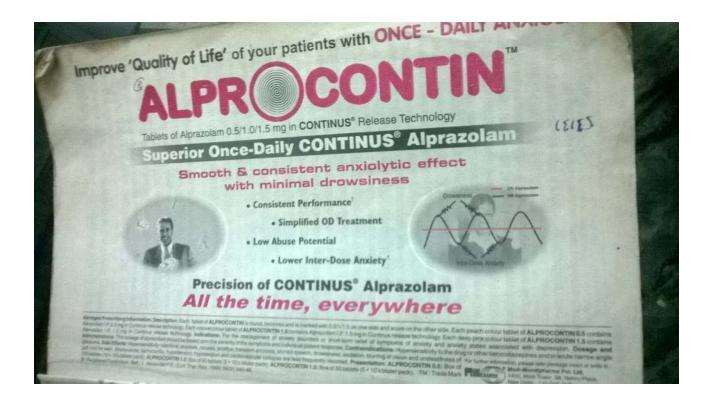
87. Monlevo



88. Divigel



89. Alprocontin



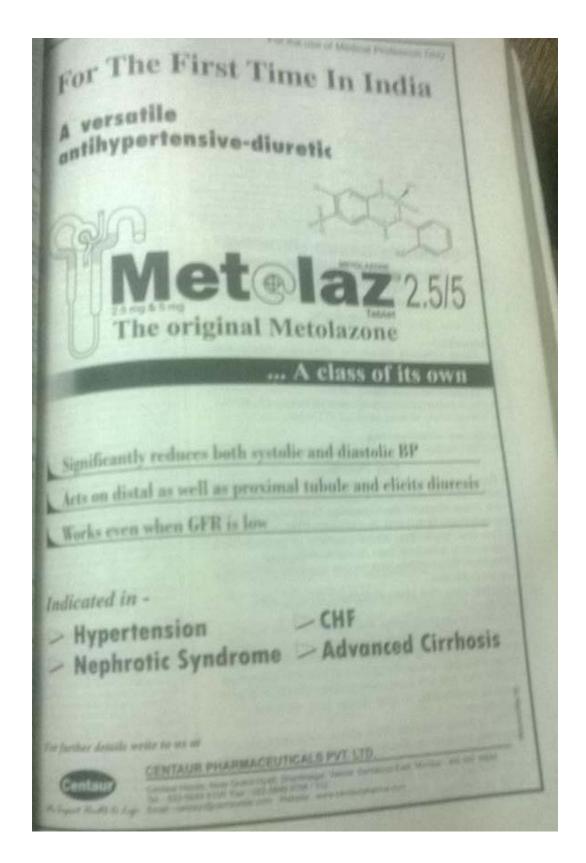
90. Zolam



91. Fenaplus



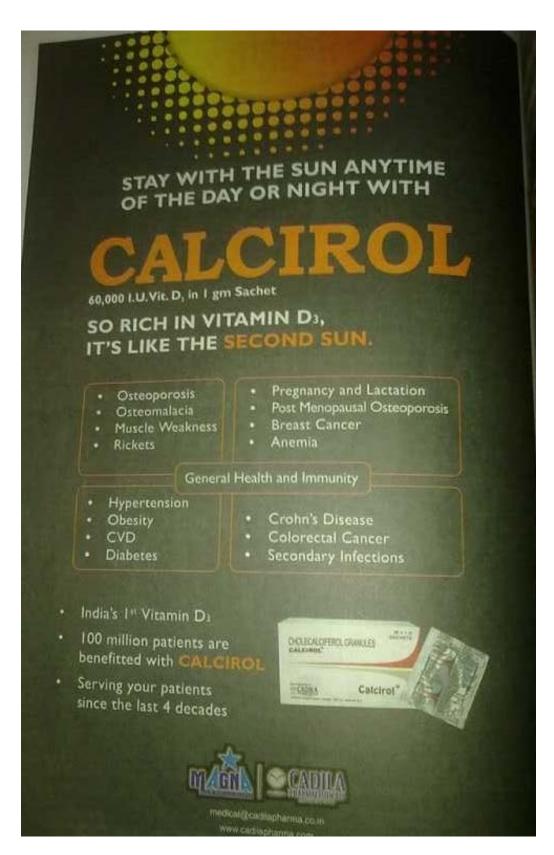
92. Metolaz



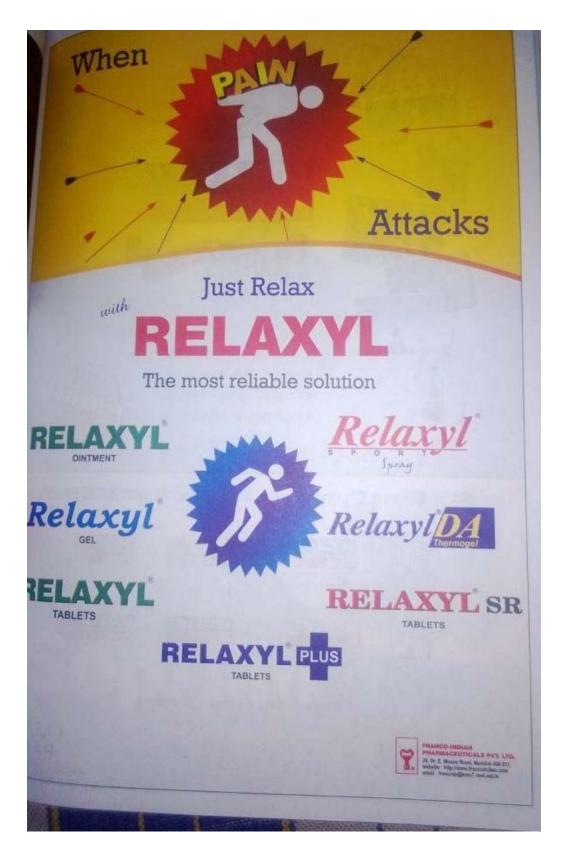
93. GeneVac – B



94. Calcirol



95. Relaxyl

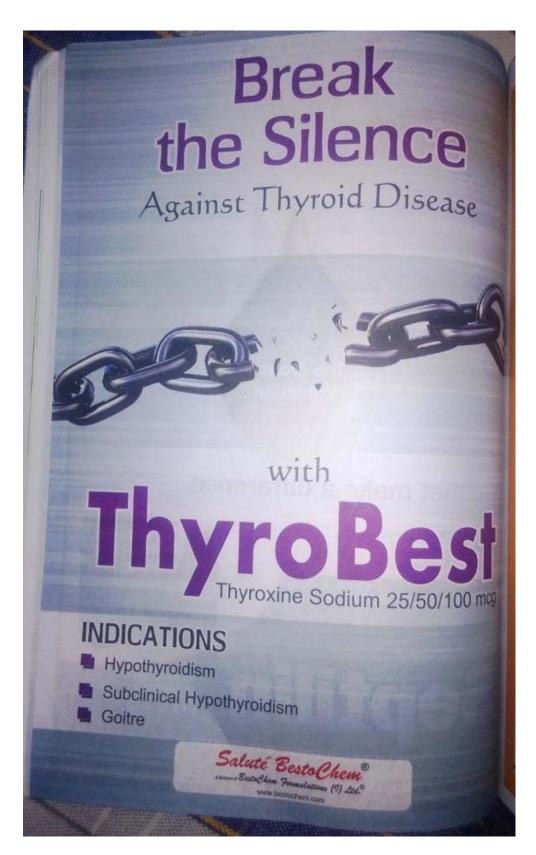


96. Rabipur



97. Scc-4

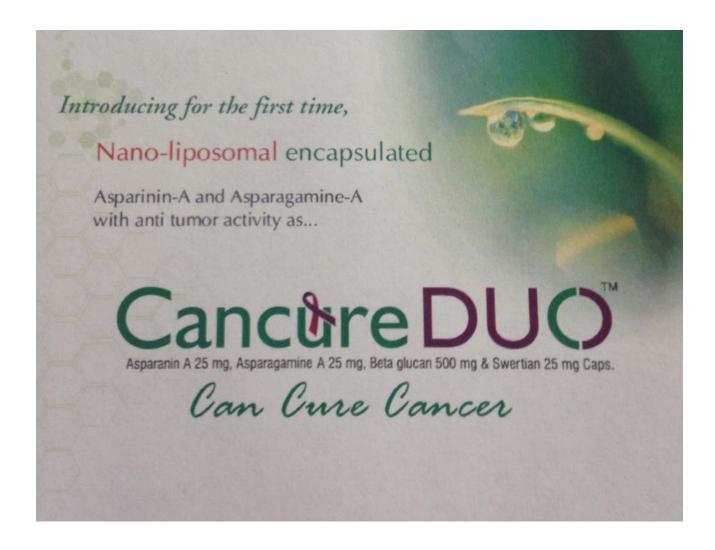




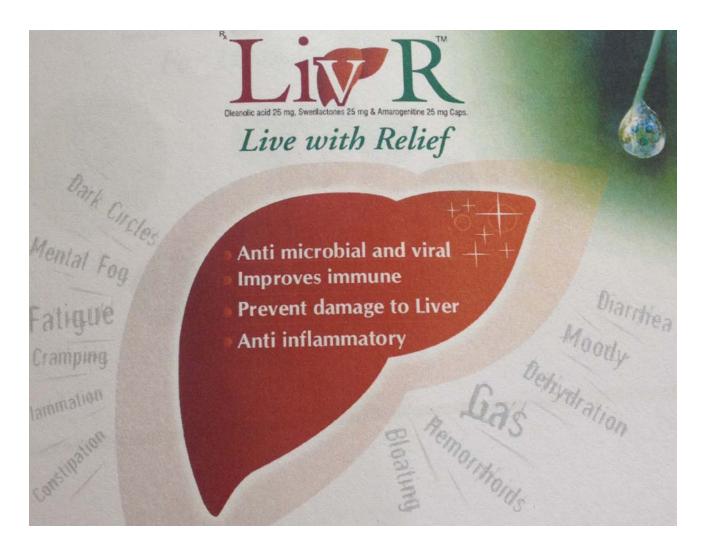
99. Beta s



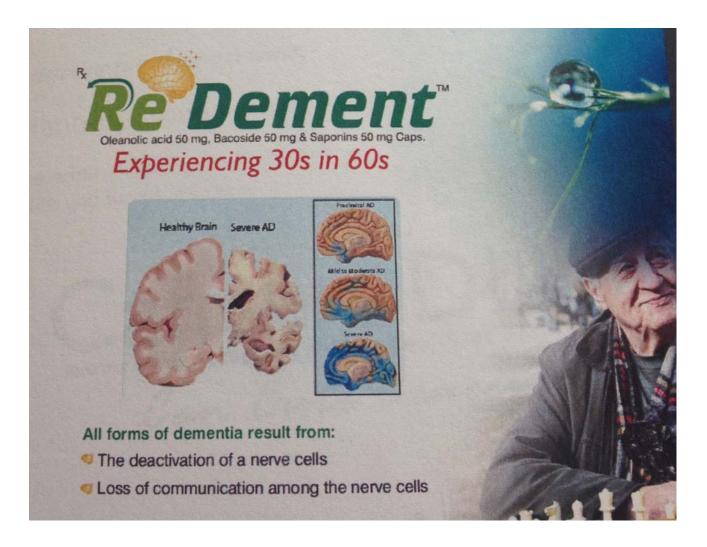
100. Cancure duo



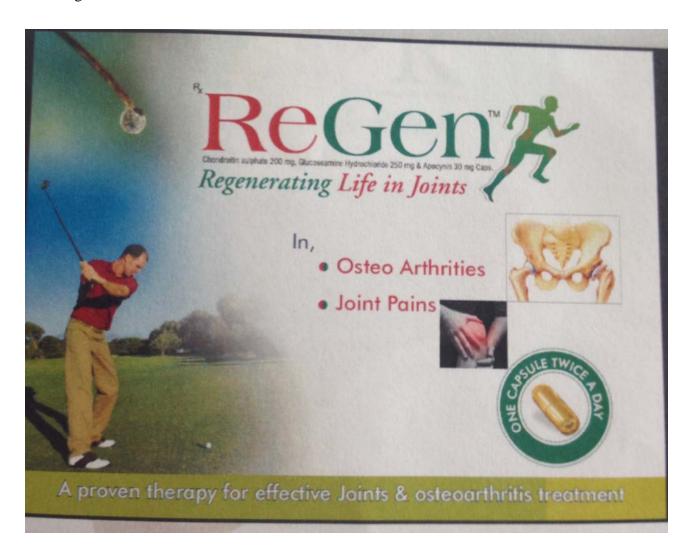
101. Liv R



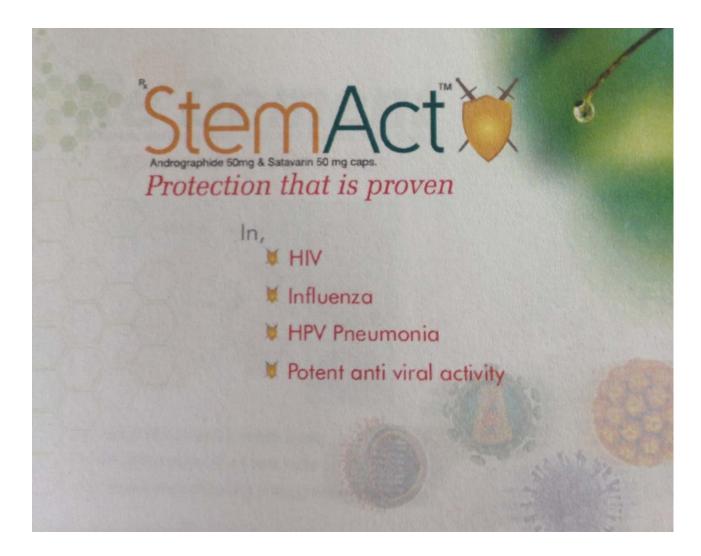
102. ReDement



103. Regen



104. StemAct



DEVIATIONS FROM ETHICAL DRUG PROMOTION