PHARMACIST'S OATH

- I swear by the code of Ethics of Pharmacy Council of India in relation to the community and shall act as an integral part of health care team.
- I shall uphold the laws and standards governing my profession.
- I shall strive to perfect and enlarge my knowledge to contribute to the advancement of pharmacy and the public health.
- I shall follow the system which I consider best for pharmaceutical care and counseling of patients.
- I shall Endeavour to discover and manufacture drugs of quality to alleviate sufferings of humanity.
- I shall hold in confidence the knowledge gained about the patients in connection with my professional practice and never divulge unless compelled to do so by the law.
- I shall associate with organizations having their objectives for betterment of the Profession of Pharmacy and make contribution to carry out the work of those organizations.
- While I continue to keep this oath unviolated, may it be granted to me to enjoy life and the practice of pharmacy respected by all, at all times!
- Should I trespass and violate this oath may the reverse be my lot!

Editor: Mrs. Saili S. Masal

Editorial Board:

1. Shri. J.S. Shinde, President, MSCDA, Mumbai

2. Dr.S. G. Deshpande, Ex. Chairman, AICTE

3. Dr. Urmila Thatte, Head of Clinical Pharmacology, Seth G.S. Medical college & KEM Hospital, Mumbai

4. Dr. Suresh Sarvedekar, Asst. Director,Ministary of Medical Education & Health, Maharashtra

5. Dr. Mrs. M. N. Nagarsenkar, Professsor of Pharmaceutics, Bombay College of Pharmacy, Mumbai

6. Mr. Jayendra Pandya, Arihant Distributors (Pharma), Mumbai

7. Mrs. Zarine Khety, Chief Pharmacist, Saifee Hospital, Mumbai

Technical Contribution: Vibhavari Lathi Incharge, Drug Information Centre

Editorial Assistant: Mrs. Supriya Patil

Printed & Published by Registrar on behalf of **Maharashtra State Pharmacy Council,**
E.S.I.S. Hospital Compound, L.B.S. Marg, Mulund (West), Mumbai - 400080
Phone No. 25930607 / 25684291
Printed at

April'2011 - No.

Price Rs. 20/-

(Annual Subscription for four quarterly issues is Rs. 100/-)

Maharashtra State Pharmacy Council's Drug Information Bulletin April-June 2011

INSIDE THIS ISSUE:

Only about seventy years ago was chemistry, like a grain of seed from a ripe fruit, separated from the other physical sciences. With Black, Cavendish and Priestley, its new era began. Medicine, pharmacy, and the useful arts, had prepared the soil upon which this seed was to germinate and to flourish.

MAHARASHTRA STATE PHARMACY COUNCIL

(Constituted under the Pharmacy Act,1948)

E.S.I.S. Hospital Compound, Lal Bahadur Shastri Marg,

Mulund (W), Mumbai – 400 080 Tel.No. 25684291/25684418

E-mail :- mspc1@vsnl.net Website :- www.mspcindia.org

From the Registrar's Desk :

Dear pharmacists,

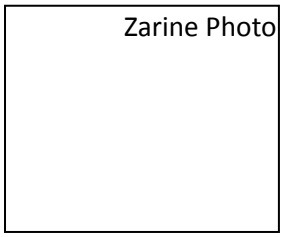
Regards,

Saili S Masal

Registrar

From Editorial Board Member

Pharmacy management and Medication Therapy Management – A Winning Combination



Pharmacy in the early 20th Century was termed a 'Marginal' profession. The principal function of the pharmacist was 'Daily handling and preparing of remedies in common use.' Pharmacists or 'Apothecaries' were engaged in wholesale manufacturing and distribution of Medicinal products. Hence pharmacists had little choice, but to have sharp business acumen to survive. They had to have a keen sense of manufacturing aspects, management of inventories of chemicals and formulations they made and dispensed. Pharmacy practice has evolved since then. Management perspective in pharmacy Practice abounds.

Pharmacist is now a recognized healthcare professional globally.

Lack of time and poor communication are primary obstacles in delivering pharmacy care services. Continuous education in healthcare systems and pharmacotherapeutics is greatly helpful to a practicing pharmacist.

Morbidity and mortality arising from medication errors are a recognized public health problem hence the concept of medication therapy management has been accepted. Clinically this approach helps patients maximize the benefits of drug therapy. But to obtain perfection in medication therapy management, pharmacists must design efficient distribution systems, select and train staff, have systems which disseminate knowledge on new drugs and technology and document measurable controls.

Evidence suggests that the need for a management perspective in pharmacy is very important and is mandatory. A series of studies wherein the use of strategic planning by community and hospital pharmacy settings saw higher sales volume and profitability compared to those who did not. Pharmacies owned by strategic planners were also found to be more proactive in offering clinical or value added services than others.

There are many things that a Pharmacist can do to improve quality. First they can promote a "systems view" culture within the organization.

Second focus on important systems change like medication safety. E.g. Fast moving drugs, narrow therapeutic index medications and medications available in multiple strengths.

Intervention and analysis of prescriptions can help improvement in quality patient care.

The rational of a good pharmacy practice lies in the fact that a pharmacist has the requisite managerial skills together with enough clinical drug associated knowledge. Thus good business and good patient care are not mutually exclusive and good patient care with implementation of clinical services can be made possible.

Domains of Pharmaceutical Care Practice in a Hospital

1. *Risk Management – System of data collection*

- Obtain History of patient
- Adverse drug reactions
- Be knowledgeable about Drug – Drug interactions

2. *Patient Advocacy*

- Counsel patients on drugs in treatment
- Promote patient wellness
- Maintain caring, friendly relationship with patients.

3. *Disease Management*

- Provide information to patients on how to manage their disease state/ condition.
- Maintain a proper inventory of products necessary for patients with chronic disease e.g. inhalers, Nebulizers, glucose monitors, etc. in the pharmacy at all times.

4. *Pharmaceutical care services marketing.*

- Meet the prescribers i.e. doctors
- Identify and use software which helps patient care activities.
- Good inventory and stock management.

5. Utilize organized pharmacist services for proper distribution of drugs at all levels viz. outpatient, Inpatient etc.

Authored by: Zarine Khety,
Senior Chief Pharmacist, Saifee Hospital

संपादकीय लेख .....

फार्मसी व्यवस्थापन व औषधोपचार पध्दतीचे व्यवस्थापन - एक प्रभावी संयोग

विसाव्या शतकाच्या पूर्वीच्या काळात फार्मसी हा "मामुली " व्यवसाय मानला जात असे. दैनंदिन हाताळणी करुन नेहमीच्या वापरासाठी उपाययोजना तयार करणे हे औषध व्यावसायिकांचे मुख्य काम होते. औषध व्यावसायिक किंवा अपोथेकॅरीज (Apothecaries) हे औषधांची घाऊक निर्मिती व विक्री या कामात व्यस्त असत. त्यामुळे औषध व्यावसायिकांना या व्यवसायात फार थोडी संधी उपलब्ध होती पण उपजिविकेसाठी या व्यवसायाचा योग्य दृष्टीकोन आवश्यक होता. निर्मितीचे स्वरुप, रसायनांच्या साठयाचे व्यवस्थापन व औषधांची मांडणी करुन ते तयार करुन देणे या सर्व बाबींचे सखोल ज्ञान आवश्यक होते. तेव्हापासून फार्मसी प्रॅक्टीस विकसित झाली. फार्मसी प्रॅक्टीस मध्ये व्यवस्थापन हा महत्वाचा भाग बनला.

औषध व्यावसायिक हा आता जगभर आरोग्याशी निगडीत व्यावसायिक म्हणून ओळखला जातो.

वेळेची कमतरता व परस्पर संवादाची कमी हे औषधांची सेवा देण्यातील मूळ अडथळे आहेत. औषध व्यवसाय करणा-यांसाठी आरोग्यविषयक प्रणाली व फार्माकोथेअरप्युटिक्स मध्ये सतत शिक्षण हे अतिशय उपयुक्त ठरु शकते.

औषधोचारातील चुकांमुळे रोगांचे बळी व मृत्यु ही सार्वजनिक आरोग्याची समस्या म्हणून ओळखली गेली आणि म्हणून औषधोपचार पध्दतीचे व्यवस्थापन ही संकल्पना स्विकारली गेली. या संकल्पनेचा औषधोपचार पध्दतीत जास्तीत जास्त लाभ रुग्णास घेता येऊ लागला. औषधोपचार पध्दतीच्या व्यवस्थापनात परिपूर्णता आणण्यासाठी औषध व्यावसायिकाने औषधांची कार्यक्षम वितरण पध्दत बनविणे, कर्मचा-यांची निवड करुन प्रशिक्षण देणे व अशी पध्दत विकसित करणे जेणेकरुन नवीन औषधे व तंत्रज्ञान याविषयीच्या माहितीचा प्रसार करीता येऊ शकेल व आवश्यक माहिती योग्य प्रकारे संग्रहित होऊ शकेल.

औषध व्यवसायात व्यवस्थापन संकल्पनेची गरज निर्माण झाली आहे असा निरीक्षणाअंती निष्कर्ष काढला असून व ते अनिवार्य आहे. याविषयीच्या अभ्यास मालिका घेतल्यानंतर असे आढळून आले आहे की, कम्युनिटी व रुग्णालयीन फार्मसी मध्ये तंत्रशुध्द नियोजन अवलंबिले असता जास्त विक्री व नफा दिसून आला. तंत्रशुध्द नियोजन करणा-या औषधी दुकानांचे मालक औषध व आरोग्य विषयक जागरुकता व तत्सम सेवा देण्यामध्ये इतरांपेक्षा जास्त क्रियाशील आढळले.

दर्जा वाढविण्याच्या दृष्टीने औषध व्यावसायिक ब-याच गोष्टी करु शकतो. प्रथमतः त्यांच्या आस्थापनेमध्ये सिस्टीम्स् व्हयू ही संकल्पना जोपासली पाहिजे.

त्यानंतर महत्वाच्या पध्दतीत बदल जसे की औषधोपचारातील सुरक्षितता उदाहरणार्थ जास्त खप असलेली औषधे, नॅरो थिअराप्टीकल इंडेक्स मेडिकेशन्स व वेगवेगळया तीव्रतेमध्ये उपलब्ध असलेली औषधे.

औषधपत्रांचे विश्लेषण व त्यामध्ये योग्य प्रकारे हस्तक्षेप (intervention) झाल्यास रुग्णसेवेच्या दर्जात सुधारणा होईल.

चांगली फार्मसी प्रॅक्टीस याचा अर्थ औषध व्यावसायिकास व्यवस्थापकीय कसब यासोबत औषधांविषयी सखोल माहिती व तांत्रिक ज्ञान असेल हा होईल. चांगला धंदा व रुग्णांना चांगली सेवा हे एकमेकासापेक्ष आहे व चांगली रुग्ण देखरेख सेवा व क्लिनीकल सर्व्हिसेस देणे शक्य होऊ शकते.

रुग्णालयात औषधविषयक सावधगिरी बाळगण्यासाठी क्षेत्र :-

1. **जोखीम व्यवस्थापन - माहिती संग्रहित करण्याची पध्दत**

- रुग्णाचा इतिहास मिळविणे
- औषधांचे घातक परिणाम
- औषधांच्या परस्पर प्रक्रियेविषयी माहिती असणे

2. **रुग्ण समर्थन**

- उपचारामध्ये औषधांविषयी रुग्णास समुपदेशन करणे
- रुग्ण बरा होण्यासाठी प्रयत्न करणे
- रुग्णांची देखरेख व त्यांच्यासोबत मित्रत्वाचे नाते प्रस्थापित करणे.

3. **रोग व्यवस्थापन**

- रुग्णास त्यांच्या आजारामध्ये कसे जमवून घ्यावे याबाबत माहिती देणे
- वारंवार होणा-या आजारांमध्ये रुग्णास आवश्यक साहित्याचा योग्य साठा बाळगणे उदा.इनहेलर्स, नेब्युलायझर्स, ग्लुकोज मॉनिटर्स इ.

4. **औषधविषयक देखरेख सेवा विपणन**

- औषधपत्र देणारे म्हणजेच डॉक्टर्सना भेटणे
- रुग्णांच्या काळजी संदर्भात असलेली संगणक प्रणाली शोधणे व त्याचा वापर करणे
- औषधांचा साठा व्यवस्थापन

5. औषधांचे योग्य वितरण सर्व स्तरावर जसेकी, बाहय रुग्ण/ आंतर रुग्ण येथे होण्याच्या दृष्टीने औषध व्यवसायींच्या सेवेचे योग्य आयोजन करणे

New PUBLICATION of MSPC's DIC:

Recently MSPC's DIC launched a new publication to help pharmacists while counselling a patient. *The book is entitled as*

"GUIDE TO PATIENT COUNSELING - A reference booklet for Essential Drugs in India"

To avail your copy, contact Drug Information Center.

Contact Details:

Incharge- Drug Information Center

Contact No. 022- 25930607,

e- Mail ID: dicmspc@gmail.com

QUERY OF THE QUARTER

Que: Which are the drugs recently banned by DCGI and why?

Ans: The decision to ban or withdraw a drug by the regulatory authorities is normally based on the risk assessment process, which is influenced by a number of factors such as disease pattern in a country, indications and dosages of the drug permitted, varying reactions of certain ethnic groups in a given population, availability of safer substitutes and overall safety profile of the drug. These conditions are different for different countries. It is for this reason that a drug banned / restricted in one country may continue to be marketed in other countries. Following is the list of drugs that have been prohibited for manufacture and sale through gazette notifications under section 26a of drugs & cosmetics act 1940 by the ministry of health and family welfare in the New Year.

- Nimesulide formulations for human use in children below 12 years of age.
- Cisapride and its formulations for human use.
- Phenylpropanolamine and its formulation for human use.
- Human Placental Extract and its formulations for human use.
- Sibutramine and its formulations for human use
- R-Sibutramine and its formulations for human use.
- Gatifloxacin formulation for systemic use in human by any route including oral and injectable
- Tegaserod and its formulation for human use.

1. Nimesulide formulations for human use in children below 12 years of age: Nimesulide is an NSAID that is being used as an anti-pyretic in children on a vast scale in India. Nimesulide is banned due to concerns over liver toxicity. Use of nimesulide is involved with concerns of both increased frequency and severity of hepatic lesions as compared with other NSAIDs. The mechanism appears idiosyncratic and not dose related Finland's National Agency for Medicines reports a total of 66 cases of hepatic toxicity (from a total of 109 adverse reaction reports) involving nimesulide. Developing symptoms such as general malaise, nausea, jaundice or abdominal pain while taking nimesulide should be immediate cause for concern and evaluation. .

2. Cisapride and its formulations for human use:
Cisapride, a drug which increases motility in the upper gastrointestinal tract, has been either withdrawn from the market or had its indications limited in many countries due to its side effects. Serious cardiac arrhythmias including ventricular tachycardia, ventricular fibrillation, torsades de pointes and QT prolongation have been reported in patients taking cisapride.

3. Phenylpropanolamine and its formulation for human use: **Phenylpropanolamine** may have the risk of hemorrhagic stroke associated with its use. The United States Food and Drug Administration (FDA) removed this drug from US market in November 2000.

4. Human Placental Extract and its formulations for human use:

Similar is the case with use of placenta extraction. According to reports, all products containing extract of human placenta have been banned by the US FDA since they can transit diseases and pose serious health hazards to consumers. Placenta extract was never permitted for use as medicine in the western countries such as US, UK, Australia, Canada and European Union states due to lack of efficacy and safety data.
However, some companies in US were importing products containing human placenta as dietary supplements. However, on April 14, 2008, all products containing human placenta extracts even for use as cosmetics have been banned by the US government.
But in India, human placenta extract sold as Placentrex lotion, gel, and injection is being actively promoted as a remedy for a variety of unrelated disorders such as vitiligo, wound dressing, prevention of adverse effects due to radiotherapy, fallopian tube blockage, female infertility, scarring, post-phlebitis ulcers, scars due to acne, etc., but now this product is banned as no significant efficacy or effect is observed on humans after using this medicine,

5. Sibutramine and its formulations for human use:
Increase concern over cardiovascular and stroke risk. Sibutramine is an appetite suppressant structurally related to amphetamine. Although initial data indicate that the drug may be useful in the treatment of obesity, long-term safety related to its effects on blood pressure and heart rate are needed. According to a study done by Abbott laboratories, it was found that cardiovascular risks outweigh modest weight loss benefits. (For more information refer Drug Information Bulletin, Oct- Dec 2010 issue)

6. R-Sibutramine and its formulations for human use:
It is banned in India due to increase concern over cardiovascular and stroke risk.
7. Gatifloxacin formulation for systemic use in human by any route including oral and injectable:
Gatifloxacin has been associated with both hypoglycemia and hyperglycemia. Use of gatifloxacin in oral & intravenous form is contraindicated diabetes mellitus; disturbances in blood glucose homeostasis, but now systemic use are banned in all patients and only topical preparations can be used. According to a study entitled as "Outpatient Gatifloxacin Therapy and Dysglycemia in Older Adults", it was found that As compared with the use of other broad-spectrum oral antibiotics, including other fluoroquinolones, the use of gatifloxacin among outpatients is associated with an increased risk of in-hospital treatment for both hypoglycemia and hyperglycemia.

8. Tegaserod and its formulation for human use:

Tegaserod is a drug used to cure irritable bowel syndrome and constipation, can be responsible for increased risks of heart attack or stroke, Tegaserod maleate was withdrawn by the USFDA on March 30, 2007, following results of a safety analysis that found a higher risk of heart attack, stroke, and worsening heart chest pain in patients treated with tegaserod compared to placebo-treated patients. Clinicians prescribing tegaserod are advised to transition their patients to other therapies as clinically appropriate.

Reference:

1. http://www.pharmexcil.org/data/media_files/DCGItobannimesu_media_file_1573.pdf
2. MICROMEDEX(R) Healthcare Series Vol. 147

3. Laura Y. Park-Wyllie, David N. Juurlink, Alexander Kopp, Baiju R. Shah, Therese A. Stukel, Carmine Stumpo, Linda Dresse., Donald E. Low, and Muhammad M. Mamdani; Outpatient Gatifloxacin Therapy and Dysglycemia in Older Adults; N Engl J Med 2006;354:1352-61.
4. James W., & et.al. Effect of Sibutramine on Cardiovascular Outcomes in Overweight and Obese Subjects. N Engl J Med 2010; 363:905-917

तिमाहीतील प्रश्न:

प्रश्न : अलिकडेच DCGI ने बहिष्कृत केलेली औषधे कोणती व का ?

उत्तर :- एखादे औषध बहिष्कृत करावे वा ते औषधांच्या बाजारातून काढून घ्यावे हा निर्णय विनियामक प्राधिकरणाचा असतो वा तो सर्वसाधारणपणे त्या औषधामुळे उद्भभणा-या धोक्याचे परिक्षण करुन धेतला जातो. हे परिक्षण त्या देशातील रोगांचे प्रकार, औषधाच्या वापराचे कारण, त्या औषधांची संमत केलेली मात्रा, एखाद्या प्रदेशातील काही जमातीतील लोकांच्या त्यावरील प्रतिक्रिया इतर काही सुरक्षित औषधांचा उपलब्ध असलेला पर्याय व त्या औषधाची सर्वांगिण सुरक्षिततेची रुपरेखा यावर अवलंबून असते. ही स्थिती वेगवेगळया देशात वेगवेगळी असते. याच कारणासाठी एखाद्या देशात बहिष्कृत केलेले अथवा काही कारणासाठी वापरात असलेले औषध दुस-या देशात वापरले जाऊ शकते वा विक्रीसाठी उपलब्ध होऊ शकेल. औषधे व सौंदर्य प्रसाधन कायदा 1940 व त्या खालील कलम 26 अ अंतर्गत आरोग्य व जनकल्याण विभागाने या नवीन वर्षात राजपत्राव्दारे खालील औषधांची निर्मिती व विक्री यावर निर्बंध धातले आहेत.

मानव वापरासाठी असलेले निमेस्युलाईड औषध 12 वर्षाखालील वयोगटासाठी

मानवासाठी असलेले सिसाप्राईड

मानवासाठी असलेले फिनेलप्रोपॅनोलाइमाईन

मानवासाठी असलेले प्लेसेंटल एक्सट्रक्ट

मानवासाठी असलेले सिब्युट्रामाईन

मानवासाठी असलेले आर-सिब्युट्रामाईन

मानवाकडून तोंडावाटे व इंजेक्शनव्दारे गटीप्लॉक्ससीन चा योग्य वापर

मानवाच्या वापरासाठी असलेले टेगासिरोड

1. मानवासाठी असलेले निमेस्युलाईड औषधाच्या 12 वर्षाखालील वयोगटासाठी वापर (Nimesulide formulations for human use in children below 12 years of age)

निमेस्युलाईड हे NSAID या गटात येते व भारतात अतिशय मोठया प्रमाणावर मुलांमध्ये तापासाठी दिले जाते. यकृत्तावर असणा-या घातक परिणामामुळे निमेस्युलाईडला बहिष्कृत केले आहे. इतर NASID च्या तुलनेने निमेस्युलाईडमुळे यकृतामधील छेद वाढण्याच्या क्रियेची वारंवरता व तीव्रता यामुळे निमेस्युलाईडचा वापर

करण्याविषयी विचार करावा लागला. निमेस्युलाईडच्यामुळे घातक परिणाम हे त्याच्या मात्रेशी निगडीत नसल्याचे आढळून आले आहे. मानवासाठी वापर करण्यात आलेल्या निमेस्युलाईडमुळे आतापर्यंत एकूण 109 औषधांचे घातक परिणाम (Adverse Drug Reaction) पैकी 66 प्रकरणे ही निमेस्युलाईडमुळे उद्भवणारे यकृतावर घातक परिणाम म्हणून घोषीत केली आहे. सर्वसाधारण आळस, मळमळ, कावीळ अथवा पोटदुखी अशी लक्षणे निमेस्युलाईड घेताना आढळल्यास त्वरीत याची छाननी करणे अत्यंत महत्वाचे ठरते.

2. मानवासाठी असलेले सिसाप्राईड (Cisapride and its formulations for human use)

सिसाप्राईड हे औषध चयापचय संस्थेतील वरच्या भागात हालचाल वाढवण्याचे काम करते. अनेक देशांमधून हे औषध बहिष्कृत केले आहे अथवा फक्त काहीच कारणासाठी त्याचा वापर करण्यास परवानगी आहे. याचे कारण म्हणजे त्याचे विपरीत परिणाम होय. हृदयाच्या गतीमध्ये अनियमितता, हृदयाच्या अकुंचन प्रसरण क्रियेमध्ये अनियमितता. अशा प्रकारचे धोकादायक दष्परिणाम सिसाप्राईड घेणा-या रुग्णांमध्ये आढळून आला आहे.

3. मानवासाठी असलेले फिनेलप्रोपॅनोलाइमाईन (Phenylpropanolamine and its formulation for human use).

फिनेलप्रोपॅनोलाइमाईन याचा वापर करताना , रुग्णांनमध्ये रक्तस्त्रावासोबत झटका असे दुष्पपरिणाम आढळून आला आहे. अमेरिकन अन्न व औषध खात्याकडून सदर औषध नोव्हेंबर 2000 पासून अमेरिकेने बहिष्कृत केले आहे.

4. मानवासाठी असलेले हयुमन प्लेसेंटल एक्सट्रक्ट व त्याची मांडणी (Human Placental Extract and its formulations for human use).

अनेक अहवालानुसार ज्या उत्पादनामध्ये Human Placental Extract आहेत अशी उत्पादने अमेरिकन अन्न व औषध प्रशासनाने बहिष्कृत केले आहे. याचे कारण म्हणजे अशी उत्पादने अनेक रोगांचे संक्रमण करु शकतात व सामान्य ग्राहकांच्या आरोग्यास घातक धोके निर्माण करु शकतात प्लेसेंटल एक्सट्रक्ट चा वापर अमेरिका, इंग्लंड, ऑस्ट्रेलिया, कॅनडा, युरोपियन अशा पाश्चात्य देशात कधीही केला गेला नाही कारण याच्या उपयुक्तेविषयी व सुरक्षिततेविषयी माहिती उपलब्ध नाही.

परंतु पूर्वी अमेरिकेतील काही कंम्न्या हयुमन प्लेसेंटल एक्सट्रक्ट या उत्पादनाचे आहारविषयक पुरवणी या अंतर्गत आयात करीत असत पण अमेरिकन सरकारने 14 नोव्हेंबर 2008 पासून हयुमन प्लेसेंटल असणारी सर्व उत्पादने अगदी सौदर्यप्रसाधने म्हणून वापर असणारी सुध्दा बहिष्कृत केली आहे.

परंतु भारतात मात्र हयुमन प्लेसेंटल एक्सट्रक्ट लोशन, जेल, व इंजेक्शन स्वरुपात वापर होत असे. त्याचावापर अनेक असंबंध वापरासाठी होत असे जसे की, जखमाची मलमपट्टी, रेडीओथिरपीचे घातक परिणामाच्या प्रतिबंधासाठी, स्त्रियामधील वंध्यता, मुरुमांचे व्रण इत्यादीसाठी, पण या औषधाचा वापर मानवामध्ये केल्यानंतर काही विशेष सुयोग्य परिणाम न आढळल्यामुळे सदर औषध बहिष्कृत केले आहे.

5. मानवासाठी असलेले सिब्युट्रामाईन (Sibutramine and its formulations for human use)

सिब्युट्रामाईन हे औषध भूक कमी करण्यासाठी दिले जाते. याबाबत सुरुवातीची माहिती असे दर्शविते की सदर औषध स्थूलतेसाठी उपयुक्त ठरु शकेल परंतु या औषधामुळे रक्तदाबावर व ह्रदयाच्या गतीशी संबंधित होणा-या दुष्परिणामाविषयी माहिती मिळवणे आवश्यक आहे व त्या अनुषंगाने सदर औषधाचा मानवी शरीरावर सुरक्षिततेची माहिती मिळणे आवश्यक आहे. ॲबॉट लॅबने केलेल्या अभ्यासातून असे सिध्द झाले आहे की, या औषधामुळे हृदयावर होणारे दुष्पपरिणाम हे या औषधाच्या वजन घटवणा-या परिणामापेक्षा अधिक महत्वाचे आहेत.

6. मानवासाठी असलेले आर-सिब्युट्रामाईन (R-Sibutramine and its formulations for human use)

आर-सिब्युट्रामाईन या औषधामुळे हृदयरोगाचा धोका उद्भवतो हा दुष्परिणाम असल्याने भारतात बहिष्कृत केले आहे.

7. मानवासाठी तोंडावाटे व इंजेक्शनव्दारे गॅटीप्लॉक्ससीनचा वापर (Gatifloxacin formulation for systemic use in human by any route including oral and injectable)

गॅटीप्लॉक्ससीन मुळे रक्तातील शर्करेचे प्रमाण आवश्यकतेपेक्षा कमी अथवा अधिक होते, मधुमेहाच्या रुग्णांमध्ये गटीप्लॉक्ससीन चा तोंडाव्दारे व आय. व्हि. व्दारे वापर करु नये असे निर्देश आहेत पण आता आय. व्ही. व्दारे गटीप्लॉक्ससीन

चा वापर सर्व रुग्णांमध्ये बहिष्कृत केला असून फक्त त्वचेवर वरुन लावण्यासाठी याचा वापर करण्यास अनुमती आहे. इतर फलोरोक्विनोलोन प्रतिजैविकाच्या तुलनेत गॅटीप्लॉक्ससीन चा वापर केल्यास रुग्णांमध्ये रक्तातील शर्करचे प्रमाण कमी अथवा जास्त आढळून येऊन त्यांना इस्पितळात दाखल करण्याच्या धोका अधिक आहे असे एका अभ्यासातून निदर्शनास आले आहे.

8. मानवाच्या वापरासाठी असलेले टेगासिरोड (Tegaserod and its formulation for human use)

टेगासिरोड हे औषध मलावरोध व इरिटेबल बाऊल सेंड्रोम या आजारावर इलाज करण्यासाठी दिले जाते हृदयविकाराचा झटका येण्याचा धोका हा दुष्परिणाम औषधाशी निगडीत आहे. अमेरिकन अन्न व औषध प्रशासनाने 30 मार्च 2000 रोजी सदर औषधामुळे हृदयविकाराचा झटका येण्याचा धोका असल्याने व रुग्णांमध्ये हृदय व छातीमध्ये तीव्र वेदना निर्माण होत असल्याने बहिष्कृत केले आहे. ज्या डॉक्टरांनी रुग्णांना टेगासिरोड दिले आहे त्याचा आपल्या रुग्णांना या औषधाऐवजी इतर योग्य औषधोपचार करण्याचा सल्ला दिला आहे.

Down Syndrome

Down syndrome (DS) is a genetic condition in which a person has 47 chromosomes instead of the usual 46. In most cases, Down syndrome occurs when there is an extra copy of chromosome 21. This form of Down syndrome is called Trisomy 21. The extra chromosome causes problems with the way the body and brain develop. Normally, at the time of conception a baby inherits genetic information from its parents in the form of 46 chromosomes: 23 from the mother and 23 from the father. In most cases of Down syndrome, a child gets an extra chromosome 21 — for a total of 47 chromosomes instead of

46. It's this extra genetic material that causes the physical features and developmental delays associated with DS. The only well known risk factor for conceiving a child with Down syndrome is advanced maternal age.

21 st March is celebrated as World Down Syndrome day.

Symptoms

Down syndrome symptoms vary from person to person and can range from mild to severe. However, children with Down syndrome have a widely recognized appearance.

The head may be smaller than normal and abnormally shaped. For example, the head may be round with a flat area on the back. The inner corner of the eyes may be rounded instead of pointed.

Common physical signs include:

- Decreased muscle tone at birth
- Excess skin at the nape of the neck
- Flattened nose
- Separated joints between the bones of the skull (sutures)
- Single crease in the palm of the hand
- Small ears
- Small mouth
- Upward slanting eyes
- Wide, short hands with short fingers
- White spots on the coloured part of the eye (Brushfield spots)

Physical development is often slower than normal. Most children with Down syndrome never reach their average adult height.

Children may also have delayed mental and social development. Common problems may include:

Many different medical conditions are seen in people with Down syndrome, including:

- Birth defects involving the heart, such as an atrial septal defect or ventricular septal defect
- Dementia may be seen. Individuals with Down syndrome are at a high risk for developing dementia and early-onset Alzheimer's disease.
- Eye problems, such as cataracts (most children with Down syndrome need glasses)
- Early and massive vomiting, which may be a sign of a gastrointestinal blockage, such as esophageal atresia and duodenal atresia
- Hearing problems, probably caused by regular ear infections
- Hip problems and risk of dislocation

- Long-term (chronic) constipation problems
- Sleep apnea (because the mouth, throat, and airway are narrowed in children with Down syndrome
- Teeth that appear later than normal and in a location that may cause problems with chewing
- Underactive thyroid (hypothyroidism)

Diagnosis:

The diagnosis of Down syndrome can be made before birth using one of several diagnostic tests. These tests carry a small risk of miscarriage.

Prenatal screening tests currently available include the expanded alpha-fetoprotein (AFP) screening test, the nuchal translucency test, and additional ultrasound screens which look for changes in certain anatomical features of the fetus. While these screening tests can assess the risk for Down syndrome, they cannot confirm Down syndrome with certainty.

The most widely used screening test is the AFP. Between weeks 15 and 20 of pregnancy, a small blood sample is taken from the mother and examined. The levels of AFP and three hormones called unconjugated estriol, human chorionic gonadotropin, and inhibin-A are measured in the blood sample. If the AFP and hormone levels are altered, Down syndrome can be suspected, but not confirmed. Likewise, a normal test result does not rule out Down syndrome.

The nuchal translucency test measures the thickness of the fold in the neck via ultrasound. This test can be done between 11 and 13 weeks of pregnancy. In combination with the mother's age, this test identifies about 80% of Down syndrome fetuses.

Women considered at high risk (advanced maternal age, positive AFP test, or a history of a previous child with Down syndrome) may benefit from additional ultrasound scans between 18 and 22 weeks of pregnancy. When certain anatomical features are altered, absent, or present in a fetus, it may indicate Down syndrome. Some of the markers that are examined include:

- the length of the long arm (humerus) or leg bone (femur),
- the length of the nasal bridge,
- the size of the renal pelvis (hypoplasia, pyelectasis),
- small bright spots in the heart (echogenic intracardiac foci),
- small middle section of the little finger (hypoplastic fifth digit),
- a large gap between the first and second toe,
- increased brightness of the bowel (echogenic bowel), and
- Pelvic bone angle (widened iliac angle).

If Down syndrome is suspected after a child is born, a diagnosis can be made via chromosome analysis.

Amniocentesis is performed between 16 and 20 weeks of pregnancy. During this procedure, a thin needle is inserted through the abdominal wall and a small sample of amniotic fluid is taken. The sample is analyzed for chromosome anomalies.

Chorionic villus sampling (CVS) is done between 11 and 12 weeks of pregnancy. It involves the collection a chorionic villus cell sample from the placenta either through insertion of a needle in the abdominal wall or through a catheter in the vagina. The chromosomes in CVS are analyzed for deviations.

For percutaneous umbilical blood sampling (PUB), fetal blood is taken from the umbilical cord using a needle inserted through the abdominal wall. The blood sample is examined for chromosome abnormalities. It is usually performed after week 18.

Complications

- Airway blockage during sleep
- Compression injury of the spinal cord
- Endocarditis
- Eye problems
- Frequent ear infections and increased risk of other infections
- Hearing loss
- Heart problems
- Gastrointestinal blockage
- Weakness of the back bones at the top of the neck

Prevention

- Experts recommend genetic counseling for persons with a family history of Down syndrome who wish to have a baby.

- A woman's risk of having a child with Down syndrome increases as she gets older. The risk is significantly higher among women age 35 and older.

- Couples who already have a baby with Down syndrome have an increased risk of having another baby with the condition.

- Tests such as nuchal translucency ultrasound, amniocentesis, or chorionic villus sampling can be done on a fetus during the first few months of pregnancy to check for Down syndrome. The American College of Obstetricians and Gynecologists recommends offering Down syndrome screening tests to all pregnant women, regardless of age.

References:

- http://www.medicinenet.com

- http://www.ncbi.nlm.nih.gov

• Practical Oral Care for People with Down syndrome U.S. department of health and human services, National Institutes of Health, National Institute of Dental and Craniofacial Research.

[2] डाऊन सेंड्रोम (Down Syndrome (DS))

डाऊन सेंड्रोम DS ही एक प्रकारची मानवाची उत्पत्ती व वाढ संबंधात (gentic) अशी स्थिती आहे, की ज्यामध्ये एका व्यक्तिमध्ये सामान्यपणे आढळणा-या 46 गुणसुत्राएंवजी 47 गुणसुत्रे असतात. ज्यावेळी 21 व्या गुणसुत्रांची अतिरिक्त प्रत उपलब्ध असते त्यावेळेस डाऊन सेंड्रोम DS हा आजार होतो. अशा प्रकारच्या डाऊन सेंड्रोम DS ला "ट्रायसॉमी 21" असे म्हणतात. ज्या पध्दतीने शरीराची व मेंदूची सामान्यपणे वाढ होणे अपेक्षित असते त्यामध्ये हे अतिरिक्त गुणसूत्र बाधा उत्पन्न करतो. सर्वसाधारणपणे गर्भ, हा गर्भधारणेच्या वेळेस आपल्या पालकाकडून म्हणजेच आईकडून 23 व वडिलाकडून 23 गुणसुत्रे प्राप्त करतो. बहूतेक डाऊन सेंड्रोम DS च्या रुग्णांमध्ये बाळाला "अतिरिक्त गुणसुत्र 21" प्राप्त होतो व त्यामुळे एकूण गुणसुत्र सामान्यपणे 46 ऐवजी 47 होतात या अतिरिक्त गुणसुत्रामुळे बाहय रुप व वाढ या क्रिया प्रलंबित होतात. डाऊन सेंड्रोम DS चा आजार असलेल्या गर्भाची गर्भधारणा होण्यामागे एक धोका निगडीत असतो तो म्हणजे गर्भधारणेच्या वेळेस मातेचे वय नियमित वयापेक्षा जास्त असणे होय.

21 मार्च हा जागतिक डाऊन सेंड्रोम DS दिन म्हणून साजरा केला जातो.

लक्षणे :-

डाऊन सेंड्रोम DS ची लक्षणे व्यक्तिनुरुप बदलतात काहींमध्ये ती सौम्य तर काहींमध्ये तीव्र आढळतात. परंतु डाऊन सेंड्रोम DS असलेली मुले त्वरीत ओळखून येतात.

डोक्याचा आधार नेहमीपेक्षा लहान व बेढब असू शकतो . उदा. डोके गोल असते परंतु पाठच्या बाजूला सपाट असते. डोळयाच्या आतील कोपरा तीक्ष्ण असण्याऐवजी गोल असू शकतो.

काही सर्वसाधारण आढळणारी शाररिक लक्षणे :-

- जन्माच्यावेळी कमी स्नायूंची लवचिकता.
- मानेच्या येथे जास्त लोंबणारी त्वचा
- पसरट नाक
- तळहातावर एकच रेष.
- छोटे कान
- छोटे तोंड
- वरच्या बाजूला झुकलेले डोके
- पसरट लहान बोटे असलेले आखूड हात
- डोळयाच्या रंगीत भागावर पांढरे टिपके (ब्रशफिल्ड स्पॉटस्)

सामान्य मुलांपेक्षा शारिरिक वाढ बहुधा मंद गतीने होते. डाऊन सेंड्रोम DS आजार असणारी बहुतेक मुलांची उंची सरासरी मोठया माणसाच्या उंचीइतकी कधीच होत नाही.

लहान मुलांची बौध्दिक व सामाजिक प्रगती मंदगतीने होते. सर्वसाधारणपणे खालील अडचणी उद्भवतात.

- जन्मजात दोषांमध्ये हृदयामधील ॲट्रील सेप्टल डिफेक्ट (Atrial septal Defect) अथवा व्हेंट्रीक्युलर सेप्टल डिफेक्ट (Vrnytricular Septal Defect)
- विस्मरण होऊ शकते. डाऊन सेंड्रोम DS असलेल्या व्यक्तिमध्ये विस्मरण होण्याचा धोका जास्त असतो व स्मृतीभ्रशाचा आजाराची सुरुवात लवकर होऊ शकते.
- नेत्रदोष - मोतीबिंदू (डाऊन सेंड्रोम DS असणा-या मुलांना बहुधा चष्मा लावावा लागतो)
- खुप उलटया - चयापचय संस्थेत अडथळयाचे चिन्ह
- नियमित कानाच्या विकारांमुळे श्रवणदोष
- अनेक दिवसापासून असलेला मलावरोध स्लीप अपेनिया (Sleep apnea)
- अनेकवेळा दात उशीराने व अयोग्य जागी येतात त्यामुळे चर्वणक्रियेत अडचणी
- थायरॉईड ग्रंथी सामान्य कार्यक्षमेतेपेक्षा कमी कार्यक्षम.

निदान :-

या रोगाचे निदान होण्यासाठी बाळाला जन्म देण्यापूर्वी अनेक चाचण्या उपलब्ध आहेत या चाचण्यामुळे गर्भपातचा धोका अगदी कमी असतो.

जन्मापूर्वी चाचण्यांमध्ये (AFP) अल्ट्रसाऊंड स्क्रीन टेस्ट उपलब्ध आहे. या चाचण्यांव्दारे गर्भामध्ये काही अनियमितता असेल तर डाऊन सेंड्रोम DS चे निदान घेण्याची शक्यता असते पण खात्रीलायक सांगता येत नाही.

AFP चाचणी ही मुख्यत्वेकरुन केली जाते. गर्भधारणेनंतर 15-20 आठवडयामध्ये ही चाचणी केली जाते. आईकडून रक्ताचा लहानसा नमुना घेऊन तपासला जातो. रक्तातील AFP ची पातळी व 3 हार्मोन्सची पातळी मोजली जाते. जर AFP व हार्मोन्सच्या पातळीत बदल झाला तर डाऊन सेंड्रोम DS ची शक्यता वर्तवली जाते पण खात्रीलायक सांगता येत नाही.

न्युचल ट्रान्सलुसन्सी टेस्ट व्दारे गर्भाच्या मानेच्या त्वचेची जाडी अल्ट्रासाऊंडव्दारे मोजता येते ही चाचणी 11-13 व्या आठवडयात करता येते.

18-22 व्या गर्भधारणेच्या आठवडयात अतिरिक्त अल्ट्रासाऊंड स्क्रीन चाचणी केल्यास डाऊन सेंड्रोम DS आजाराचा धोका असलेल्या गर्भवती महिलांना त्याचा फायदा होऊ शकतो. गर्भामधील शारिरीक फिचर्स(Features) मध्ये बदल अथवा ती असणे वा नसणे यावरुन डाऊन सेंड्रोम DS असू शकतो ही शक्यता वर्तवली जाऊ शकते. खालील गोष्टींची चाचणी केली जाते.

1) नाकाच्या हाडाची लांबी
2) हृदयामधील लहान तेजस्वी टिपके.
3) करंगळी मधील लहान मधला भाग
4) पहिल्या व दुस-या पायाच्या बोटांमधील मोठी जागा (Gap)

जर मुल जन्मल्यानंतर डाऊन सेंड्रोम DS ची शंका आली तर गुणसुत्रांच्या परिक्षणाव्दारे डाऊन सेंड्रोम DS चे निदान करता येते.

गर्भधारणेनंतर 16-20 आठवडयात अमीनोसेंटेसीट ही चाचणी करता येते. एक लहान सुई पोटामधून खूपसून गर्भजलाचा लहान नमुना घेतला जातो. त्याचे गुणसुत्रांच्या अनियमिततेसाठी परिक्षण केले जाते.

तसेच गर्भाला जोडणा-या नाळेतून PUB चा नमूना वरील पध्दतीने घेतला जातो. ज्याव्दारे गर्भाच्या रक्ताचे परिक्षण केले जाते. ही चाचणी साधारणपणे गर्भधारणेच्या 18 व्या आठवडयानंतर केली जाते.

समस्या :-

1) झोपेत श्वसनक्रियेत अडथळा
2) पाठीच्या मणक्याची दबून दुखापत
3) डोळयांना त्रास
4) वारंवार उद्भवणारे कानाचे विकार व इतर विकार
5) बहिरेपणा
6) हदयरोग
7) चयापचय क्रियेत व्यत्यय
8) पाठीच्या हाडामध्ये मानेच्या वरच्या बाजूच्या हाडांमध्ये अशक्तपणा

प्रतिबंध (Prevention) :-

- ज्या व्यक्तिंच्या पिढयांमध्ये डाऊन सेंड्रोम DS आजार होता, अशा व्यक्ती जर मुलाला जन्म देऊ इच्छित असतील तर त्यांना गुणसुत्र विषयक समुपदेशन करणे गरजेचे आहे असे तज्ञ लोक सुचवतात.
- जसजसे स्त्रिचे वय वाढते तसतसे मुलाला डाऊन सेंड्रोम DS होण्याचा धोका वाटतो. 35 वर्षापेक्षा अधिक वय असलेल्या स्त्रियामध्ये धोका अधिक.
- ज्या जोडप्यांना डाऊन सेंड्रोम DS असलेले मूल असेल तर पुढच्या मुलामध्ये डाऊन सेंड्रोम DS असण्याची शक्यता वाटते.
- गर्भवती महिलांच्या पहिल्या काही महिन्यात डाऊन सेंड्रोम DS चे निदान करण्यासाठी उपलब्ध चाचण्या करुन घ्याव्यात. अमेरिकन कॉलेज ऑफ ऑबस्टेस्ट्रीशियन ॲन्ड गायनॉकॉलॉजिस्टस् (American College of Obstetricians and Gynecologists) यांच्या सल्यानुसार डाऊन सेंड्रोम DS निदान चाचण्या सर्व महिलांमध्ये त्यांचा गर्भधरणेच्यावेळी वयोगट कोणताही असेल तरी कराव्यात.

आयपीएच्या राष्ट्रीय फार्मास्युटीकल परिषदेत कम्युनिटी फार्मासिस्टच्या शोधप्रतिबंधास प्रथम पुरस्कार

इंदोर येथे नुकत्याच पार पडलेल्या तिस-या इंडियन फार्मास्युटीकल असोसिएशन (आयपीए) च्या नॅशनल कनव्हेंशन-2011 मध्ये कम्युनिटी फार्मासिस्ट सागर कुलकर्णी आणि प्रा. सुनिल चव्हाण यांनी सादर केलेल्या शोध निबंधास प्रथम पारितोषिक मिळाले. सागर कुलकर्णी यांनी 60 कम्युनिटी फार्मसीचा सर्व्हे केला होता. त्याआधारे Use or Misuse of Erectile

Dysfunction Pills- Survey of Community Pharmacies' हा पेपर तयार करुन या परिषदेत सादर केला. कम्युनिटी फार्मसी विभागात देशाच्या विविध भागातील फार्मसी संस्थानी एकूण 43 पेपर्स सादर केले होते, या सर्वामध्ये सागर कुलकर्णीच्या पेपरने प्रथम पारितोषिक मिळविले . या पेपरसाठी प्रि. के. एम. कुंदनानी फार्मसी पॉलिटेक्निकच्या उपप्राचार्या मंजिरी घरत, प्राध्यापक सुनिल चव्हाण आणि कल्याण केमिस्टस व ड्रगिस्टस असोसिएशनचे अध्यक्ष श्री. राज हलवाई यांनी मोलाचे सहकार्य व मार्गदर्शन केले.

Drug of the Quarter:

Pramipexole Di Hcl monohydrate is approved for the treatment of the sign and symptoms of idiopathic Parkinson's disease in March 2010 by CDSCO.

How does this drug work as Antiparkinsonian agent?

Pramipexole dihydrochloride is a nonergot dopamine agonist whose exact mechanism of action as a treatment for Parkinson's disease and restless leg syndrome is unknown. Pramipexole has full intrinsic activity at the D (2) subfamily of dopamine receptors, and has a higher affinity to the D (3) receptors than the D (2) or D (4) receptors.

Is this drug safe to be used in pregnancy?

According to USFDA Pregnancy Category, Pramipexole Di HCl monohydrate comes under Category C which means either studies in animals have revealed adverse effects on the fetus (teratogenic or embryocidal or other) and there are no controlled studies in women or studies in women and animals are not available. Drugs should be given only if the potential benefit justifies the potential risk to the fetus.

Which drugs can interact with Pramipexole Di Hcl monohydrate when taken together?
Following drugs can interact with Pramipexole Di Hcl monohydrate:
Cimetidine: Concurrent use of cimetidine and pramipexole may result in an increase in the area under the concentration-time curve (AUC) and half-life of pramipexole.
Monitor patients for excessive pramipexole adverse effects (orthostatic hypotension, drowsiness, dizziness, insomnia).
Amantadine: Alteration of oral clearance of pramipexole is unlikely
Antipsychotic agents (e.g., phenothiazines, butyrophenones, thioxanthenes): Dopamine antagonist activity of the antipsychotic agent may diminish effectiveness of Pramipexole.
CNS depressants (e.g., alcohol, antidepressants, antipsychotics, benzodiazepines): Possible additive sedative effects.
Diltiazem: Diltiazem is secreted by the cationic transport system and may decrease oral clearance of Pramipexole.
Levodopa: Additive therapeutic and/or adverse (e.g., dyskinesia) effects; peak plasma levodopa concentration may be higher and occur sooner after administration, but extent of levodopa absorption is not altered. Consider a reduction in levodopa dosage when pramipexole is added to levodopa therapy

Metoclopramide: Dopamine antagonist activity of metoclopramide may diminish effectiveness of Pramipexole.
Probenecid: No appreciable alteration of pramipexole pharmacokinetics
Quinidine and Quinine: Quinidine and quinine are secreted by the cationic transport system and may decrease oral clearance of Pramipexole.
Ranitidine: Ranitidine is secreted by the cationic transport system and may decrease oral clearance of Pramipexole.
Triamterene: Triamterene is secreted by the cationic transport system and may decrease oral clearance of Pramipexole.
Verapamil: Verapamil is secreted by the cationic transport system and may decrease oral clearance of Pramipexole.

What are its adverse effects?

Most common adverse effects experienced with this agent are: Orthostatic hypotension, Constipation, Nausea, Amnesia, Asthenia, Confusion, Dizziness, Dream disorder, Dyskinesia, Extrapyramidal movements, Headache, Insomnia, Somnolence, Hallucinations

SERIOUS adverse events are:

Malignant melanoma, Sleep attack, malignant melanoma.

When to contact doctor in case of any effect experienced after using this medicine?

Contact doctor right away if any of these side effects experienced:

- Allergic reaction: Itching or hives, swelling in your face or hands, swelling or tingling in your mouth or throat, chest tightness, trouble breathing.
- Change in how much or how often you urinate, or painful urination. Changes in vision.
- Chest pain. Extreme sleepiness or drowsiness.
- Fever, chills, cough, sore throat, and body aches.
- Lightheadedness, dizziness, or fainting. Muscle pain, stiffness, tenderness, or weakness.
- Problems with balance or walking.
- Seeing, hearing, or feeling things that are not really there.
- Swelling in your hands, ankles, or feet.
- Tremors.
- Trouble breathing.
- Twitching or muscle movements you cannot control.
- Unusual tiredness or weakness.

What precautions need to be taken while using this medicine?

1. Avoid driving, using machines, or doing anything else that could be dangerous if you are not alert. You may also feel lightheaded when standing suddenly from a sitting or lying position, so get up slowly.

2. Some people who have used this medicine had hallucinations or unusual changes in their behavior, such as having problems with gambling, increased sex drive, or compulsive eating. Talk with your doctor if this is a concern for you.
3. Your doctor will need to check your progress at regular visits while you are using this medicine. Your doctor may also need to check your skin regularly. Be sure to keep all appointments.

4. Avoid alcohol

5. Pramipexole may be taken with or without food; however, taking the drug with food may reduce the occurrence of nausea.

Reference:
MICROMEDEX(R) Healthcare Series Vol. 148
http://cdsco.nic.in/LIST%20OF%20APPROVED%20DRUG%20FROM%2001.htm
http://www.drugs.com/monograph/pramipexole-dihydrochloride.html

[3] तिमाहितील औषध :-

प्रॉमिपेक्सॉल डाय हायड्रोक्लोराईड मोनोडायहाड्रेट या औषधास पार्किन्सन् डिसिजच्या लक्षणांवर उपचारासाठी मार्च 2010 मध्ये CDSCO ने मान्यता दिली आहे.

हे औषध कशा प्रकारे काम करते ?

प्रॉमिपेक्सॉल डाय हायड्रोक्लोराईड मोनोडायहाड्रेट हे औषध नॉन एर्गाट या प्रकारात मोडते व हे औषध तंतोतंत कसे काम करते या विषयी माहिती उपलब्ध नाही. पण सदर औषध D(2) व D(4) या रिसेप्टर ऐवजी D(3) या रिसेप्टर कडे जास्त आकर्षित होते.

हे औषध गर्भवती महिलांसाठी सुरक्षित आहे का ?

अमेरिकन अन्न व औषध प्रशासनाकडून सदर औषध "C" या वर्गात मोडले जाते. म्हणजेच प्राण्यावरील चाचण्यामध्ये गर्भावर विपरित परिणाम दर्शवतात व स्त्रियांमध्ये याचा अभ्यास Controlled Study व्दारे केला गेला नाही. जर या औषधाचा फायदा गर्भारपणातील या औषधामुळे होणा-या विपरित परिणामांपेक्षा अधिक असेल तरच हे औषध गर्भावस्थेत द्यावे.

कोणती इतर औषधे प्रॉमिपेक्सॉल डाय हायड्रोक्लोराईड मोनोडायहाड्रेट सोबत घेतल्यास त्यांचे ऐकमेकांसोबत क्रिया प्रक्रिया होऊ शकतात ?

1) सिमेटीडीन व प्रॉमिपेक्सॉल एकत्र घेतल्यास प्रॉमिपेक्सॉल या औषधाचा हाफ लाईफ पिरिअड वाटतो व सदर औषधाचे रक्तातील प्रमाण वाटते.
2) फिनोथायाजिन्स, ब्युटायरोफिनोन्स थायोक्सॅन्सीनसाठी सारखी मानसिक आजारावर असणारी औषधासोबत घेतल्यास प्रॉमिपेक्सॉल ची प्रभावीपणा कमी होतो.
3) मद्य व इतर मानसिक आजारांवर देण्यात येणारी ओषधासोबत घेतल्यास जास्त झोप / गुंगी येऊ शकते.
4) लिव्होडोपा सोबत घेतल्यास प्रभाविपणा वाढू शकतो अथवा विपरीत परिणाम होऊ शकतो, म्हणून लिव्होडोपाची मात्रा प्रॉमिपेक्सॉल सोबत देताना कमी करण्याचा विचार होऊ शकतो.
5) मोटोक्लोप्रामाईड - प्रॉमिपेक्सॉल प्रभावीपणा कमी होऊ शकतो.
6) प्रोबेनिसिड - प्रॉमिपेक्सॉल कार्यामध्ये विशेष फरक पडत नाही.
7) रॅनिटीडीन, क्विनिडीनीन व क्विनिन - प्रॉमिपेक्सॉल चा ओरल क्लिअरन्स कमी होऊ शकतो.
8) ट्रायअमिट्रीन - प्रॉमिपेक्सॉल चा ओरल क्लिअरन्स कमी होऊ शकतो.
9) व्हेरापॅमिल - प्रॉमिपेक्सॉल चा क्लिअरन्स कमी होऊ शकतो.

प्रॉमिपेक्सॉल चे सामान्यपणे आढळणारे विपरित परिणाम

कमी रक्तदाब, मलावरोध, मळमळ, विस्मरण, संभ्रम, सुस्ती, स्वप्नामध्ये विपरित परिणाम, डोकेदुखी, स्मृतीभ्रंश, आभास होणे.

धोकादायक विपरित परिणाम

मॅलिग्नन्ट मिलॅयनोना, वारंवार झोप / गुंगी येणे.

सदर औषध घेतल्यानंतर खालील गोष्टी रुग्णांमध्ये आढळल्यास आपल्या डॉक्टरशी संपर्क साधा.

1) ॲलर्जिक रिॲक्शन - खाज सुटणे, उचक्या लागणे, तोंड व हातावर सूज, तोंडात सूज अथवा खाज, छाती भरुन येणे, श्वासोच्छवासात त्रास.
2) मूत्र विसर्जन कितीवेळा व किती प्रमाणात होते यामध्ये बदल, मूत्र विसर्जनात त्रास, दृष्टीमध्ये बदल.
3) छातीमध्ये दुखणे, झोप येणे अथवा चक्करणे
4) ताप, थंडी, कफ, घसा धरणे अथवा सुस्ती.
5) डोके गरगरणे, सुस्ती अथवा चक्कर येणे, स्नायुदुखी, स्नायूमध्ये कडकपणा किंचा शिथिलता, अथवा स्नायूंमध्ये कमजोरी.
6) चालण्यात अथवा शरीराच्या संतुलनात अडचण.
7) ज्या गोष्टी नाहित त्या बघणे, ऐकणे अथवा जाणवणे.
8) थरथर / कंपन
9) श्वसनात अडचण
10) स्नायूंची रोखू शकत नाहीत अशी हलचाल
11) प्रमाणपेक्षा अधिक दमणे अथवा थकवा जाणवणे

हे औषध घेताना कोणती काळजी घेणे आवश्यक आहे ?

1) गाडी चालवणे ,यंत्र चालवणे अथवा अशी कुठलीही कृती जेथे तुम्ही सतर्क राहणे आवश्यक आहे ती करणे टाळा. ब-याचवेळेस झोपेतून अथवा बसले असताना अचानक उठल्यास डोके गरगरण्याची शक्यता आहे म्हणन सावकाश उठा.
2) जे लोक हे औषध घेतात त्यांना अभास होणे किंवा त्यांच्या सर्वसाधारण वागण्यात बदल जाणवतात जसे जास्त संभोगाची इच्छा, जास्त खाणे, जर आपणासाठी ही महत्वाची गोष्ट असेल तर आपल्या डॉक्टरांशी या विषयी बोला.
3) हे औषध घेताना आपल्या डॉक्टरांना नियमित काळानंतर आपली प्रगती तपासणे हे आवश्यक आहे.
4) आपले डॉक्टर आपली त्वचा सुध्दा नियमितपणे तपासतील. डॉक्टरांची वेळेत भेट घ्या.
5) मद्यपान करु नका.
6) प्रॉमिपेक्सॉल हे अन्नासोबत अथवा अनाशेपोटी घेऊ शकता. परंतु सदर औषध अन्नासोबत घेतल्यास मळमळ कमी जाणवेल.

World Head Injury Awareness Day

Injuries are a major public health problem in India. India is passing through a major sociodemographic, epidemiological, technological and media transition. The political, economic and social changes have altered the health scenario. In the past two decades, India has witnessed rapid urbanization, motorization, industrialization and migration of people resulting from socioeconomic growth and development. With mechanization and revolution in technology, traditional ways of living and working are being altered.

Head injuries can occur at any time and at any age. The victim could be a baby who has fallen from a crib, a child hit by a baseball bat, a teenager beaten by his notorious classmates, an adult who met with an accident or an old person who has fallen down the staircase. The reasons could be many but the affected organ is always the brain.

Brain injury is an impairment of normal brain functions that cause altered cognitive functioning.

World Head Injury Awareness Day, which is observed on 20th March, is a reminder of simple yet forgotten day to day actions. Head injury is much more painful than short term amnesia or a bandaged-covered head as usually shown in our daily soaps. We all know that prevention is better than cure, and sometimes it is true because some health disorders do not have a cure.

The brain is the center of the nervous system in a human being. The nervous system is responsible for numerous bodily functions that keep a man alive. The smallest damage to the brain makes a huge impact on one's health. Therefore, it is very crucial to take care of this system as we are concerned about other systems in our body. A slight case of vertigo could lead to bigger damage if failed to be treated on time

A head injury is any trauma that leads to injury of the scalp, skull, or brain. The injuries can range from a minor bump on the skull to serious brain injury. Head injury is classified as either closed or open (penetrating).

- A closed head injury means you received a hard blow to the head from striking an object, but the object did not break the skull.
- An open, or penetrating, head injury means you were hit with an object that broke the skull and entered the brain. This usually happens when you move at high speed, such as going through the windshield during a car accident. It can also happen from a gunshot to the head.

Causes

Common causes of head injury include traffic accidents, falls, physical assault, and accidents at home, work, outdoors, or while playing sports.

Some head injuries result in prolonged or nonreversible brain damage. This can occur as a result of bleeding inside the brain or forces that damage the brain directly. These more serious head injuries may cause:

- Coma
- Chronic headaches
- Loss of or change in sensation, hearing, vision, taste, or smell
- Paralysis
- Seizures
- Speech and language problems

Symptoms

The symptoms of a head injury can occur immediately or develop slowly over several hours or days. Even if the skull is not fractured, the brain can bang against the inside of the skull and be bruised. The head may look fine, but complications could result from bleeding or swelling inside the skull.

The following symptoms suggest a more serious head injury and require emergency medical treatment:

- Changes in, or unequal size of pupils
- Convulsions
- Distorted features of the face
- Fluid draining from nose, mouth, or ears (may be clear or bloody)
- Fracture in the skull or face, bruising of the face, swelling at the site of the injury, or scalp wound
- Impaired hearing, smell, taste, or vision
- Inability to move one or more limbs
- Irritability (especially in children), personality changes, or unusual behavior
- Loss of consciousness, confusion, or drowsiness
- Low breathing rate or drop in blood pressure
- Restlessness, clumsiness, or lack of coordination
- Severe headache
- Slurred speech or blurred vision
- Stiff neck or vomiting
- Symptoms improve, and then suddenly get worse (change in consciousness)

First Aid……

Get medical help immediately if the person:

- Becomes unusually drowsy
- Behaves abnormally
- Develops a severe headache or stiff neck
- Loses consciousness, even briefly
- Vomits more than once

For a moderate to severe head injury, take the following steps:

1. Check the person's airway, breathing, and circulation. If necessary, begin rescue breathing and cardiopulmonary resuscitation (CPR).
2. If the person's breathing and heart rate are normal but the person is unconscious, treat as if there is a spinal injury. Stabilize the head and neck by placing your hands on both sides of the person's head, keeping the head in line with the spine and preventing movement. Wait for medical help.
3. Stop any bleeding by firmly pressing a clean cloth on the wound. If the injury is serious, be careful not to move the person's head. If blood soaks through the cloth, do not remove it. Place another cloth over the first one.
4. If you suspect a skull fracture, do not apply direct pressure to the bleeding site, and do not remove any debris from the wound. Cover the wound with sterile gauze dressing.
5. If the person is vomiting, roll the head, neck, and body as one unit to prevent choking. This still protects the spine, which you must always assume is injured in the case of a head injury.
6. Apply ice packs to swollen areas.

Over-the-counter pain medicine, such as acetaminophen, may be used for a mild headache. Do not take aspirin, ibuprofen, or other anti-inflammatory medications because they can increase the risk of bleeding.

Do…….

- Always use safety equipment during activities that could result in head injury. These include seat belts, bicycle or motorcycle helmets, and hard hats.
- Obey traffic signals when riding a bicycle. Be predictable so that other drivers will be able to determine your course.
- Make sure that children have a safe area in which to play.
- Supervise children of any age.
- If you have kids or senior citizens at home then use rails on an adequately lighted stairway, place grillwork on windows and balconies, make sure there are no obstacles in the pathways, and if you have any ammunition at home make sure they are locked safely.

DO NOT……..

- Wash a head wound that is deep or bleeding a lot.
- Remove any object sticking out of a wound.
- Move the person unless absolutely necessary.
- Shake the person if he or she seems dazed.
- Remove a helmet if you suspect a serious head injury.
- Pick up a fallen child with any sign of head injury.
- Drink alcohol within 48 hours of a serious head injury.
- Ride a bicycle at night unless you wear bright, reflective clothing and have proper headlamps and flashers.

References:

1. Gururaj G., Injuries in India: A national perspective; NCMH Background Papers· Burden of Disease in India.
2. http://www.emedicinehealth.com
3. http://www.medicinenet.com

BANNED DRUGS IN INDIA

1 LIST OF DRUGS PROHIBITED FOR MANUFACTURE AND SALE THROUGH GAZETTE NOTIFICATIONS UNDER SECTION 26A OF DRUGS & COSMETICS ACT 1940 BY THE MINISTRY OF HEALTH AND FAMILY WELFARE

- DRUGS PROHIBITED FROM THE DATE OF NOTIFICATION
- 1. Amidopyrine.
- 2. Fixed dose combinations of vitamins with anti-inflammatory agents and tranquilizers.
- 3. Fixed dose combinations of Atropine in Analgesics and Antipyretics.
- 4. Fixed dose combinations of Strychnine and Caffeine in tonics.
- 5. Fixed dose combinations of Yohimbine and Strychnine with Testosterone and Vitamins.
- 6. Fixed dose combinations of Iron with Strychnine, Arsenic and Yohimbine.
- 7. Fixed dose combinations of Sodium Bromide/chloral hydrate with other drugs.
- 8. Phenacetin.
- 9. Fixed dose combinations of antihistaminic with anti-diarrhoeals.
- 10. Fixed dose combinations of Penicillin with Sulphonamides.
- 11. Fixed dose combinations of Vitamins with Analgesics.
- B 12.Fixed dose combinations of any other Tetracycline with Vitamin C.
- E 13.Fixed dose combinations of Hydroxyquinoline group of drugs with any other drug except for preparations meant for external use.
- ccc 14. Fixed dose combinations of Corticosteroids with any other drug for internal use.
- ccc 15. Fixed dose combinations of Chloramphenicol with any other drug for internal use.
- 16.Fixed dose combinations of crude Ergot preparations except those containing Ergotamine, Caffeine, analgesics, antihistamines for the treatment of migraine, headaches.
- 17. Fixed dose combinations of Vitamins with Anti TB drugs except combination of Isoniazid with Pyridoxine Hydrochloride (Vitamin B6).
- 18. Penicillin skin/eye Ointment.
- 19. Tetracycline Liquid Oral preparations.
- 20. Nialamide.
- 21. Practolol.
- 22. Methapyrilene, its salts.
- c 23. Methaqualone. &
- 24. Oxytetracycline Liquid Oral preparations. &
- 25. Demeclocycline Liquid Oral preparations.
- T 26. Combination of anabolic Steroids with other drugs.
- cc 27.Fixed dose combination of Oestrogen and Progestin (other than oral contraceptive) containing per tablet estrogen content of more than 50 mcg (equivalent to Ethinyl Estradiol) and progestin content of more than 3 mg (equivalent toNorethisterone Acetate) and all fixed dose combination injectable preparations containing synthetic Oestrogen and Progesterone. (Subs. By Noti. No. 743 (E) dt 10-08-1989)
- * 28.Fixed dose combination of Sedatives/ hypnotics/anxiolytics with analgesics-antipyretics.
- J* 29.Fixed dose combination of Rifampicin, isoniazid and Pyrazinamide, except those which provide daily adult dose given below:

Drugs	Minimum	Maximum

Rifampicin	450 mg	600 mg
Isoniazid	300 mg	400 mg
Pyrazinamide	1000mg	1500 mg

- 30. Fixed dose combination of Histamine H-2 receptor antagonists with antacids except for those combinations approved by Drugs Controller, India.
- 31.The patent and proprietary medicines of fixed dose combinations of essential oils with alcohol having percentage higher than 20% proof except preparations given in the Indian Pharmacopoeia.
- * 32. All Pharmaceutical preparations containing Chloroform exceeding 0.5% w/w or v/v whichever is appropriate.
- ** 33.Fixed dose combination of Ethambutol with INH other than the following: INH Ethambutol 200 mg. 600 mg. 300 mg. 800 mg.
- ** 34. Fixed dose combination containing more than one antihistamine.
- B**35.Fixed dose combination of any anthelmintic with cathartic/purgative except for piperazine/Santonim.
- J **36. Fixed dose combination of Salbutamol or any other drug having primarily bronchodilatory activity with centrally acting anti-tussive and/or antihistamine.
- ** 37.Fixed dose combination of laxatives and/or anti-spasmodic drugs in enzyme preparations.
- G** 38.Fixed dose combination of Metoclopramide with systemically absorbed drugs except fixed dose combination of metoclopramide with aspirin/paracetamol
- ** 39.Fixed dose combination of centrally acting, antitussive with antihistamine, having high atropine like activity in expectorants.
- ** 40.Preparations claiming to combat cough associated with asthma containing centrally acting antitussive and/ or an antihistamine.
- ** 41.Liquid oral tonic preparations containing glycerophosphates and/or other phosphates and / or central nervous system stimulant and such preparations containing alcohol more than 20% proof.
- ** 42.Fixed dose combination containing Pectin and/or Kaolin with any drug which is systemically absorbed from GI tract except for combinations of Pectin and/or Kaolin with drugs not systemically absorbed.
- *** 43. Chloral Hydrate as a drug.
- b 44. Dovers Powder I.P.
- b 45. Dover's Powder Tablets I.P.
- A 46.Antidiarrhoeal formulations containing Kaolin or Pectin or Attapulgite or Activated Charcoal.
- A 47.Antidiarrhoeal formulations
  containing Phthalyl Sulphathiazole or Sulphaguanidine or Succinyl Sulphathiazole.
- A 48.Antidiarrhoeal formulations containing Neomycin or Streptomycin or Dihydrostreptomycin including their respective salts or esters.
- A 49.Liquid Oral antidiarrhoeals or any other dosage form for pediatric use containing Diphenoxylate Lorloperamide or Atropine or Belladona including their salts or esters or metabolites Hyoscyamine or their extracts or their alkaloids.
- A 50.Liquid Oral antidiarrhoeals or any other dosage form for pediatric use containing halogenated hydroxyquinolines.
- A 51. Fixed dose combination of antidiarrhoeals with electrolytes.
- C 52. Patent and Proprietary Oral Rehydration Salts other than those conforming to the
- D 53. Fixed dose combination of Oxyphenbutazone or Phenylbutazone with any other drug.
- H.D54. Fixed dose combination of Analgin with any other drug.

- D 55. Fixed dose combination of dextropropoxyphene with any other drug other than anti-spasmodics and/or non-steriodal anti-inflammatory drugs (NSAIDS).
- D 56. Fixed dose combination of a drug, standards of which are prescribed in the Second Schedule to the said Act with an Ayurvedic, Siddha or Unani drug.
- F 57. Mepacrine Hydrochloride (Quinacrine and its salts) in any dosage form for use for female sterilization or contraception.
- F 58. Fenfluramine and Dexfenfluramine.
- I 59. Fixed dose combination of Diazepam and Diphenhydramine Hydrochloride .
- K 60. Rimonabant.
- **LIST OF DRUGS PROHIBITED FOR IMPORT**
- Nialamide
- Practolol
- Amidopyrine
- Phenacetin
- Methapyrilene and its salts
- a 6. Methaqualone
- b 7. Chloral Hydrate as a drug
- c 8. Mepacrine Hydrochloride (Quinacrine and its Salts) in any dosage form for use for female sterilization or contraception.
- 9. Fenfluramine and Dexfenfluramine]
- d 10. Rimonabant
- **DRUGS PROHIBITED FOR MANUFACTURE , SALE AND DISTRIBUTION FROM SUBSEQUENT DATE**

Drugs Formulation	Effective date	Notifica
Cosmetics Licensed as toothpaste/tooth powder containing tobacco.	With immediate effect	GSR dt.30.4.9
Parenteal Preparations fixed dose combination of streptomycin with Pencillin	Jan 1,1998	GSR dt.25.2.9
Fixed dose combination of Vitamin B1, Vitamin B6 and Vitamin B12 for humanuse	Jan 1,2001	GSR dt.14.10
Fixed dose combination of haemoglobin in any form (natural or synthetic).	Sep 1,2000	GSR dt.16.12
Fixed dose combination of Pancreatin or Pancrelipase containing amylase, protease and lipase with any other enzyme.	Sept. 1,2000	GSR dt.16.12
Fixed dose combination of Nitrofurantoin and trimethoprim.	Jan 1,2002	GSR dt.12.3.0

Fixed dose combination of Phenobarbitone with any anti-asthmatic drugs.	Jan 1,2002	GRS 170(E)
Fixed dose combination of Phenobarbitone with with Hyoscin and/or Hyoscyamine	Jan 1,2002	GRS 170(E)
Fixed dose combination of Phenobarbitone with with Ergotamine and/or Belladona	Jan 1,2002	GRS 170(E)
Fixed dose combination of Haloperidol with any anti-cholinergic agent including Propantheline Bromide.	Jan 1,2002	GRS 170(E)
Fixed dose combination of Nalidixic Acid with anyanti-amoebic including Metronidazole.	Jan 1,2002	GSR dt.12.3.0
Fixed dose combination of Loperamide Hydrochloride with Furazolidone	Jan 1,2002	GSR dt.12.3.0
Fixed dose combination of Cyproheptadine with Lysine or Peptone	Jan 1,2003	GSR dt.12.3.0
Astemizole	Apr.1,2003	GSR dt.5.3.03
Terfinadine	Apr.1,2003	GSR dt.5.3.03
Fenformin	Oct.1,2003	GSR dt.1.10.0
Rafecoxib	Dec 13,2004	GSR dt. 13.12
Valdecoxib and it's formulation	July 25,2005	GSR dt. 25.07
Diclofenac and its formulations for animal use	July 4,2008	GSR dt.4.07.0

-
- **Reference:** http://www.cdsco.nic.in/html/Drugsbanned.html

MAHARASHTRA STATE PHARMACY COUNCIL'S DRUG INFORMATION CENTRE

NOTIFICATION OF SUSPECTED ADVERSE DRUG REACTION

Patients Name : ---------- Age : ---------- Sex : ----------

Address & Contact Number :----------

Prescriber :----------

Suspected drug (s) :----------

Date of drug Started :----------

Date of adverse reaction Started :----------

Brief description of the reaction :----------

Name of the reporting Community Pharmacist :---------- ---------

Address & Contact No.:----------

Signature :---------- Date :----------

Please return this filled form to MSPC's Drug Information Centre, E.S.I.S. Hospital Compound, L.B.S. Marg, Mulund (W), Mumbai-400 080 Tel:25930607 Telefax: 25684291

Do you want to Subscribe Council's DRUG INFORMATION BULLETIN?

If yes, send us following information

Name.....

Address.....

Phone..... Fax..... E-mail.....

Qualification..... Reg.No.....dt. ....

Signature. (Applicant)

Send additional Rs.100/- so total of Rs.200/- to receive five more WHO booklets viz.*Drug Interaction Manual, Drugs Harmful In Pregnancy, Essential Drug List for Children*, *Drugs Harmful in Hepatic and Renal Impairment (Injury), & Guide to Patient Counseling* with bulletin.

Note:- Demand Draft should be sent in favour of " Maharashtra State Pharmacy Council-DIC", E.S.I.S Hospital Compound, L.B.S. Marg, Mulund (West), Mumbai-400 080, Maharashtra"*[Cheques are not acceptable]*

OfficeTime:10.30am to 3.00pm (Mon-Fri) 10.30am to 1pm (Sat)

You can pay Rs.500/- as DD or cash to Council and get 6 years Bulletin subscription started!! Hurry and Subscribe today!