SEVEN HILLS TIMES

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Pharma Therapy News

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DRUG PROFILE - IDELVION

COAGULATION FACTOR IX (RECOMBINANT), ALBUMIN FUSION PROTEIN (RIX-FP)

- T. Charan Teja, V Pharm D, SHCP, Tirupati

Indication: It is indicated in children and adults with hemophilia B (congenital Factor IX deficiency) for: On-demand control and prevention of bleeding episodes, Preoperative management of bleeding, routine prophylaxis to prevent or reduce the frequency of bleeding episodes.

Mechanism of Action: Idelvion is a recombinant protein that temporarily replaces the missing coagulation Factor IX needed for effective hemostasis. Idelvion is comprised of genetically fused recombinant coagulation Factor IX and recombinant albumin. Fusion with recombinant albumin extends the half-life of Factor IX

Adverse Effects: Allergic reactions may occur with idelvion like Rash, itching, tightness of the chest or throat, difficulty breathing, Headache, dizziness, nausea, or decrease in blood pressure.

Dosage Form and Strengths: It is a pale yellow to white lyophilized powder supplied in single-use vials containing nominally 250, 500, 1000, or 2000 IU of factor IX potency. The actual factor IX potency is labeled on each vial and carton.

Contraindication: Idelvion is contraindicated in patients who have had life-threatening hypersensitivity reactions to Idelvion, or its components, including hamster proteins.

Precautions: Hypersensitivity reactions, Neutralizing Antibodies, Thromboembolic Complications, Nephritic Syndrome, Monitor Factor IX plasma level.

Storage: Store Idelvion in its package to protect from light. Store the Idelvion package in the refrigerator or at room temperature 2-25°C (36 to 77°F). Do not freeze. Do not use Idelvion or the Sterilized Water for Injection diluents beyond the expiration date printed on the carton and vial labels.

Patient Counseling Information: Advise patients to read the FDA-approved patient labeling (Patient Information and Instructions for Use). Advise patients to report any adverse reactions or problems following Idelvion administration to their healthcare provider. Inform patients of the early signs and symptoms of hypersensitivity or allergic reactions (including hives, generalized urticaria, chest tightness, wheezing, and hypotension). Instruct patients to discontinue use of Idelvion and contact their healthcare provider and/or seek immediate emergency care if these symptoms occur. Advise patients to contact their healthcare provider or hemophilia treatment center for further treatment and/or assessment if they experience a lack of clinical response to Factor IX replacement therapy, as in some cases this may be a manifestation of an inhibitor.

Source :

http://labeling.cslbehring.com/PI/US/Idelvion/EN/Idelvion-Prescribing Information.

Elimination :

Half-life: 55 hr (Cometriq); 99 hr (Cabometyx) Total body clearance: 4.4 L/hr (Cometriq); 2.2 L/hr (Cabometyx) Excretion: 54% faeces, 27% urine.

Adverse Effects :

Diarrhoea, Hypertension, Increased TSH, Lymphopenia, ALP increased, Hypocalcemia, Stomatitis, Palmar-plantar erythrodysesthesia syndrome, Weight decreased, Appetite decreased, Nausea, Fatigue, Oral pain, Neutropenia, Thrombocytopenia, Dysgeusia Hair color changes, depigmentation, graying, Hypophosphatemia, Constipation, Abdominal pain, Hypobilirubinemia, Vomiting, Asthenia, Dysphonia, Rash Dry skin, Hypomagnesemia Hypokalemia, Headache Alopecia Dizziness Arthralgia Dysphagia Muscle spasms, Dyspepsia Erythema.

Warnings :

1. GI perforations occurred in 3% and fistula formation in 1%
2. Non-GI fistulas (e.g., tracheal, oesophageal) reported in 4%
3. Discontinue if perforation or fistula formation occurs
4. Haemorrhage (Cometriq)

Reference:

1. http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm497483.html
2. http://www.drugs.com/search.php?searchterm = cabozantinib&a=1

Upcoming Events SHCP- 2016

MAY
17World Hypertension Day
31World No Tobacco Day

JUNE
5 World Environment Day
14 World Blood Donor Day
16 Youth Day

JULY
11 World Population Day
28 World Hepatitis Day

AUGUST
6-12 Polio Awareness Week

SEPTEMBER
5-11 Pharmacy Week
26 World Environmental Health Day

OCTOBER
16 World Food Day
17 World Trauma Day
24 World Polio Day

NOVEMBER
2 National Children's Day
14 World Diabetes Day
14-20 National Antibiotic Awareness Week

DECEMBER
1 World AIDS Day
9 World Patient Safety Day

FDA APPROVED DRUGS FROM APRIL- JUNE 2016

S.NO	DRUGS	DISEASE CONDITION
1.	Atezolizumab	Urothelial Carcinoma, Bladder Cancer
2.	Pimavanserin	Hallucinations And Delusions, Parkinson's Disease
3.	Venetoclax	Chronic Lymphocytic Leukemia
4.	Defibrotide sodium	Hepatic Veno-Occlusive Disease, Stem Cell Transplantation
5.	Reslizumab	Severe Asthma
6.	Ixekizumab	Moderate-To-Severe Plaque Psoriasis.
7.	Obiltoxaximab	To Treat Inhalational Anthrax
8.	Brivaracetam	Treat Partial Onset Seizures
9.	Elbasvir and grazoprevir	chronic hepatitis C virus (HCV)

INITIATION & EVALUATION OF DRUG INFORMATION SERVICES IN PRIVATE SECTOR HOSPITAL TIRUPATI

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ABSTRACT

Introduction : Drug information service (DIS) is the service that encompasses the activities of specially trained individuals to provide accurate, unbiased, factual information, primarily in response to patient-oriented problems occurred from the Health care teams. DIS is usually provided by pharmacists in academic institutes and hospitals via face-to-face communication, letter, telephone, fax and e-mail. The background of this study was to extend the DIS to outside Sri Padmavathi Medical College for Women's Hospital, in Tirupati .

Methodology: The aim of this study was to evaluate the quality of drug information services provided in private hospitals Tirupati. The study was planned over all the private primary, secondary & tertiary care hospitals in and around Tirupati it is a Prospective interventional study to extend the drug information services in Sri Padmavathi Medical College for Women's Hospital. The study is planned over a 6 months period from December 2015 to May2016. All the DI queries which are received by direct, telephone & Email or any other mode of communication are included in our study. It excludes poison information and DI queries responded in the Sri Padmavathi Medical College for Women's Hospital. The quality of drug information services provided was assessed both from the receivers' as well as from the providers' perspective using feedback questionnaires and guidelines from the DSE/WHO seminar respectively.

Results & Discussion: Majority of the enquirers were the nurses (39.34%) and physicians (34.34%), from the primary, secondary, tertiary private hospitals. Most of the questions were asked by direct access (92%). Answers to queries were most often needed one day (74%) and in most cases was answered printed material (71.5%). Most frequently asked questions were about adverse drug reactions (50.28%) followed by drug therapy (16.28%) and the purpose of the queries to update the knowledge (49.7%). Assessment of the feedback questionnaire indicated that majority of the enquirers (31.6%) found the quality of the service provided by the centre to be satisfactory.

Conclusion: The study concludes drug information service provided by the centre improves to the need of healthcare professionals towards better patient care and to update knowledge. Upon evaluation of the feedback questionnaires, it was found that the quality of the services provided by the centre was appreciated by majority of its users.

Reference:

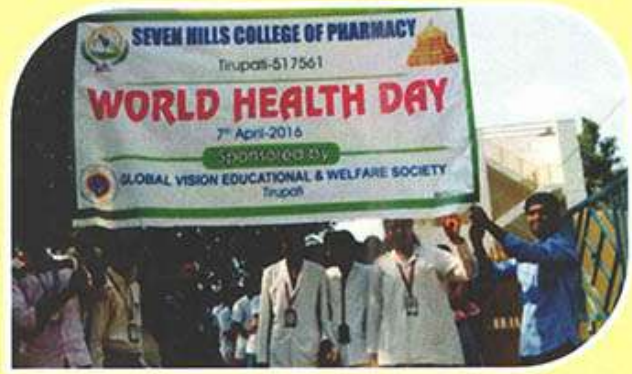
1. Lakshmi PK, Gundu Rao DA, Gore SB, Shyamala B. Drug information services to doctors of Karnataka, India. Ind J Pharmacol, 35, 2003, 245-247.
2. Health Systems Development (HSD) Essential Drugs and Medicines, Drug Information Centres, http://whoindia.org/en/Section2/Section427_1396.htm accessed on 8 Sep, 2011.

Our Perfect Clicks




Best Moments –2nd convention IACP at Coimbatore -2nd&3rd April 2016


M.Harshavardhan, T.Charanteja Receiving Award for the Best Poster Presentation at ISPOR 15th April2016



World Health Day Awareness Rally on 7th April 2016

World No Tobacco Awareness Rally on 31st May 2016

We welcome suggestions from the readers.
Drop Your Suggestions at principal.shcp@gmail.com

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DRUG PROFILE - BYVALSON

(Nebivolol and Valsartan) Tablets

- Dr. B. Narasimhulu, Mr. R. Venkatesan, Assistant Professor, SHCP, Tirupati

The U.S. Food and Drug Administration (FDA) has approved Byvalson (nebivolol and valsartan) 5 mg/80 mg tablets, a fixed-dose combination (FDC) of a beta blocker (BB) and angiotensin II receptor blocker (ARB) for the treatment of hypertension.

Indications and usage :

Treatment of hypertension, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular events, primarily strokes and myocardial infarctions.

Mechanism of action :

Nebivolol is a α-adrenergic receptor blocking agent. In extensive metabolizers (most of the population) and at doses less than or equal to 10 mg, nebivolol is preferentialiy α-1 selective. In poor metabolizers and at higher doses, nebivolol inhibits both α-1 and α-2 adrenergic receptors. Nebivolol lacks intrinsic sympathomimetic and membrane stabilizing activity at therapeutically relevant concentrations.

Pharmacodynamics:

Following oral administration of BYVALSON, peak plasma nebivolol concentrations are reached approximately 1 to 6 hours post-dosing. Peak plasma valsartan concentrations are reached in approximately 2 to 4 hours post-dosing. The rate and extent of absorption of nebivolol and valsartan from BYVALSON are the same as when administered separately. Food had a minor impact on the pharmacokinetics of nebivolol, nebivolol glucuronides and valsartan.

Dosage: BYVALSON is available as a purple, capsule shaped, film-coated tablet with FL1 deposed on one side containing 5 mg of nebivolol and 80 mg of valsartan.

Pharmacokinetics: Absorption and Distribution: Following oral administration of BYVALSON, peak plasma nebivolol concentrations are reached approximately 1 to 6 hours post-dosing. Peak plasma valsartan concentrations are reached in approximately 2 to 4 hours post-dosing. The rate and extent of absorption of nebivolol and valsartan from BYVALSON are the same as when administered separately. Food had a minor impact on the pharmacokinetics of nebivolol, nebivolol glucuronides and valsartan. The in vitro human plasma protein binding of nebivolol is approximately 98%, mostly to albumin, and is independent of nebivolol concentrations. The steady state volume of distribution of valsartan after intravenous administration is 17 L indicating that valsartan does not distribute into tissues extensively. Valsartan is highly bound to serum proteins (95%), mainly serum albumin.

Metabolism and Elimination: Nebivolol is predominantly metabolized via direct glucuronidation of parent and to a lesser extent via N-dealkylation and oxidation via cytochrome P450 2D6. D-Nebivolol has an effective half-life of about 12 hours in CYP2D6 EMs, and 19 hours in PMs and exposure to d-nebivolol is substantially increased in PMs. The difference in d-nebivolol exposure between EMs and PMs is not considered important because nebivolol metabolites, including the hydroxyl metabolite and glucuronides (the prominent circulating metabolites) contribute to the pharmacologic activity. Valsartan, when administered as an oral solution, is primarily recovered in feces (about 83% of dose) and urine (about 13% of dose). Valsartan shows bi-exponential decay kinetics following intravenous administration with an average elimination half-life of about 6 hours. In vitro metabolism studies involving recombinant CYP450 enzymes indicated that the CYP2C9 isozyme is responsible for the formation of valeryl-4-hydroxy valsartan. Following intravenous administration, plasma clearance of valsartan is about 2 L/h and its renal clearance is 0.62 L/h (about 30% of total clearance).
Contraindications : Severe bradycardia , Heart block greater than first degree , Patients with cardiogenic shock, Decompensated cardiac failure , Sick sinus syndrome (unless a permanent pacemaker is in place) ,Patients with severe hepatic impairment (Child-Pugh >B) ,Hypersensitivity to any component of this product .

Warning and Precaution :

Fetal toxicity: Drugs, including BYVALSON, that act directly on the renin-angiotensin system can cause injury and death to the developing fetus.

Acute exacerbation of coronary artery disease upon cessation of therapy: Do not abruptly discontinue

Diabetes: Monitor glucose as ?-blockers may mask symptoms of hypoglycemia. Monitor renal function and potassium in susceptible patients.

Drug Interactions: CYP2D6 enzyme inhibitors, Reserpine or clonidine, Digitalis glycosides, Verapamil (or) diltiazem type of calcium channel blockers, Potassium sparing diuretics, potassium supplements, NSAIDS, Dual inhibition of the renin-angiotensin system, Lithium.

Patient Counselling:

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Fetal Toxicity: Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to notify their healthcare provider with a known or suspected pregnancy

Lactation : Advise women not to breastfeed during treatment with BYVALSON

Symptomatic Hypotension: Advise patients that lightheadedness can occur, especially during the first days of therapy, and that it should be reported to the prescribing physician.

Hyperkalemia: Advise patients not to use salt substitutes containing potassium without consulting their physician.

References: www.BYVALSON.com, www.fda.gov/medwatch

PRE DIABETES

- Mrs.P.Rihana Begum, Assistant Professor, SHCP, Tirupati

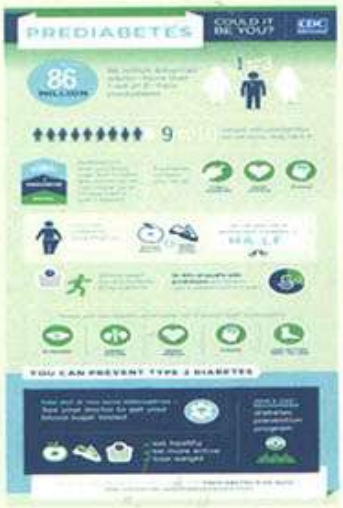
Diabetes is a group of diseases marked by high levels of blood glucose resulting from problems in how insulin is produced, how insulin works, or both. People with diabetes may develop serious complications such as heart disease, stroke, kidney failure, blindness, and premature death.

Type1 Diabetes was previously called insulin-dependent diabetes mellitus or juvenile-onset diabetes. : Children's.

Type 2 Diabetes Was Previously Called Non-Insulin-Dependent Diabetes Mellitus Or Adult-Onset Diabetes

Gestational diabetes is a form of glucose intolerance diagnosed during the second or third trimester of pregnancy.

Prediabetes is a condition in which individuals have high blood glucose or hemoglobin A1C levels but not high enough to be classified as diabetes. People with prediabetes have an increased risk of developing type 2 diabetes, heart disease, and stroke, but not everyone with prediabetes will progress to diabetes.



BLOOD GLUCOSE CHART

Mg/DL	Fasting	After Eating	2-3 hours After Eating
Normal	80-100	170-200	120-140
Impared Glucose	101-125	190-230	140-160
Diabetic	126+	220-300	200 plus

NEW MEDICAL NEWS IN PHARMACY & HEALTH PROFESSION

1. New treatment for allergic response targets mast cells

A new method that stops allergic reactions by removing a key receptor from mast cells and basophils has now been developed by researchers. The work has implications for the treatment of skin allergies and asthma. Mast cells are activated by allergens reacting with IgE bound to IgE receptors on the mast cell surface to trigger the release of histamine and other inflammatory mediators that orchestrate an allergic response including recruitment of inflammatory cells.

Reference: www.sciencedaily.com, November 21, 2016

2. Everyday Pain Relievers May Be Linked to Hearing Loss in Some Women

In a study published in the American Journal of Epidemiology, women using the common pain relievers ibuprofen (Advil, Motrin) or acetaminophen (Tylenol) for six years or longer were at greater risk of hearing loss than if they used the drugs for one year or less. Researcher's analyzed data from more than 54,000 primarily white women aged 48 to 73 from the Nurses' Health Study. Researchers state that assuming causality, roughly 16 percent of hearing loss in these women could be due to ibuprofen or acetaminophen use. The overall magnitude of risk could be substantial given the fact that these pain drugs are widely used throughout the U.S

Referecce: American Journal of Epidemiology, Dec.14 2016

3. Certain high blood pressure drugs block cancer invasion

Researchers at the University of Turku, Finland have identified a new way of blocking the spread of cancer. Calcium channel blockers, which are used to lower blood pressure, block breast and pancreatic cancer invasion by inhibiting cellular structures.

Reference: www.sciencedaily.com, www.community.breastcancer.org, www.medindia.net, December 16, 2016

4. Potential treatment for pregnant women who suffer from preeclampsia found in a vitamin

Scientists in Japan and the US have found that vitamin B3 nicotinamide may help treat pregnant women who suffer from preeclampsia by preventing strokes. In some cases, even stimulating the growth of their fetus

Reference: www.scienceandtechnologyresearchnews.com, December 19, 2016

5.Rubraca Gets Early Accelerated Approval for Ovarian Cancer : In an end-of-year approval, the U.S. Food and Drug Administration (FDA) has cleared Clovis Oncology's Rubraca (rucaparib), over two months early, for the treatment of advanced mutant BRCA ovarian cancer. Rubraca is approved for women who have been treated with two or more chemotherapies and whose tumors have a specific BRCA gene mutation. Rubraca, a poly (ADP-ribose) polymerase (PARP) inhibitor, blocks an enzyme involved in repairing damaged DNA inside the cancerous cells containing the damaged BRCA genes. In studies, 54% of patients who received Rubraca experienced complete or partial shrinkage of their tumors lasting a median of 9.2 months. Common side effects of Rubraca include nausea, fatigue, and vomiting among other reactions

Reference: newdrugapprovals.org, www.drugs.com, Drug update ,December 21, 2016

Our Perfect Clicks

Workshop on Pharmaco Vigilance Conference & ADR Reporting at Tirupati - 8th Dec. 2016

Anti - Corruption Awareness Rally on 5th Dec - 2016

World - Diabetes Day Awareness Rally on 14th Nov. 2016

Best Moments 68th IPC at Vizag - 16th-18th Dec - 2016

Skill Development Program on
Anti-Corruption at SHCP 24th Dec - 2016

We welcome suggestions from the readers.
Drop Your Suggestions at principal.shcp@gmail.com