HIMACHAL PRADESH STATE PHARMACY COUNCIL

H.P. STATE PHARMACY COUNCIL

DRUG INFORMATION CENTER

DRUG AND THERAPY BULLETIN

November, 2017

Contact us
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Editorial

Advisory Board:

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DRUG UPDATES

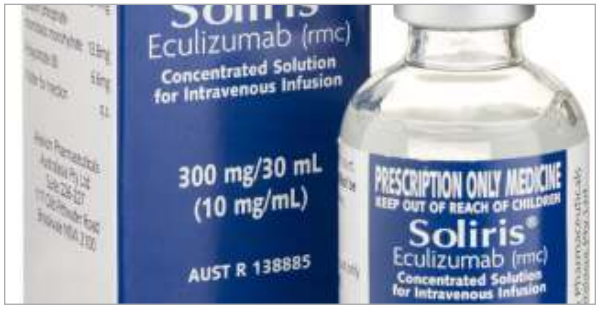
New IV Varubi

On October 25, 2017, the US FDA approved Varubi(R) (rolapitant) IV emulsion in combination with other antiemetic agents in adult patients to prevent delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy. Varubi, which is already marketed as an oral tablet formulation, IV emulsion will be available in single-dose, ready-to-use vials.

Prescribing information can be found at: http://www.varubirx.com/download_file/view/13/152.

Soliris now for GMG

On October 23, 2017, the US FDA approved a new indication for Soliris(R) (eculizumab) IV injection for the treatment of adult patients with generalized myasthenia gravis (gMG). Soliris, which is already approved for paroxysmal nocturnal hemoglobinuria and atypical hemolytic uremic syndrome, was approved for gMG based on data from the REGAIN clinical trial.



Prescribing information can be found at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/125166s422lbl.pdf.

Bydureon BCise Injectable suspension

On October 23, 2017, the US FDA approved Bydureon(R) BCise(TM) (exenatide) subQ extended-release suspension as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus. Bydureon BCise, a new formulation providing patients with a once-weekly option presented in a single-dose autoinjector, carries a boxed warning for risk of thyroid C-cell tumors.

Prescribing information can be found at: https://www.azpicentral.com/bydureon_bcise/bydureon_bcise_pi.pdf.

Simponi aria for PsA and AS

On October 20, 2017, the US FDA approved 2 new indications for Simponi Aria(R) (golimumab) IV injection for treatment of adult patients with active psoriatic arthritis (PsA) or ankylosing spondylitis (AS). The efficacy of golimumab for PsA and AS was demonstrated in 2 clinical trials in which a higher percentage of patients treated with golimumab showed symptom improvement compared with those treated with placebo. Simponi Aria is already indicated to treat adult patients with moderate to severe rheumatoid arthritis.

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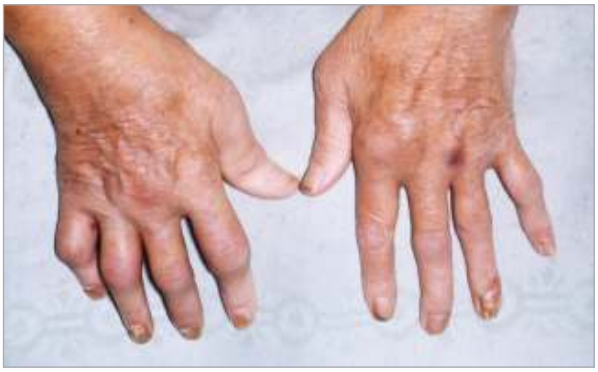
Prescribing information can be found at: http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SIMPONI+ARIA-pi.pdf.

Yescarta for lymphoma

On October 18, 2017, the US FDA approved Yescarta(TM) (axicabtagene ciloleucel) IV suspension indicated to treat adult patients with relapsed or refractory large B-cell lymphoma after 2 or more lines of systemic therapies, including



diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma. Yescarta, a chimeric antigen receptor (CAR) T cell therapy and the second gene therapy to gain FDA approval, carries a boxed warning for cytokine release syndrome and neurologic toxicities.

Prescribing information can be found at: https://www.yescarta.com/wp-content/uploads/yescarta-pi.pdf.

Stelara for pediatric psoriasis

On October 13, 2017, the US FDA approved an expanded indication for Stelara(R) (ustekinumab) injection to include treatment of pediatric patients 12 years of age or older with moderate to severe plaque psoriasis. Stelara, which is already approved to treat adult patients with psoriasis, psoriatic arthritis and Crohn disease, was approved for adolescent psoriasis based on data from a clinical trial in which patients 12 years of age or older responded to treatment with a Physician's Global Assessment score indicating cleared or minimal psoriasis at the week 12 primary endpoint.

Prescribing information can be found at: https://www.stelarahcp.com/sites/www.stelarahcp.com/files/prescribing-information-stelara.pdf?v=11.

Botox cosmetic for forehead lines

On October 3, 2017, the US FDA approved a new indication for Botox(R) Cosmetic (onabotulinumtoxinA) IM injection for temporary improvement in the appearance of moderate to severe forehead lines associated with frontalis muscle activity in adult patients. The efficacy of Botox Cosmetic, the first neurotoxin indicated for 3 facial treatment areas, was demonstrated in clinical trials in which there was decreased forehead lines severity as assessed by both the investigators and the patients at treatment day 30.

Prescribing information can be found at: http://www.allergan.com/assets/pdf/botox_cosmetic_pi.pdf.

Fiasp fast acting insulin

On September 29, 2017, the US FDA approved Fiasp(R) (insulin aspart, recombinant) subQ or IV injection to improve glycemic control in adults with diabetes mellitus. Fiasp, a fast-acting mealtime insulin developed to closely mimic mealtime glycemic response in a patient without diabetes, is formulated with 2 excipients: niacinamide (vitamin B3) to increase the rate of absorption and L-arginine for stability.

Prescribing information can be found at: http://www.novo-pi.com/fiasp.pdf.

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DRUGS – NON-STANDARD QUALITY

List of Drugs declared (by CDSCO) as not of Standard Quality, for the month of September 2017

Sr. No.	Drug Name	Batch No./Date of Mfg./Date of Expiry/Name of manufacturer	Reason for failure
1	Cefoclox –XL Tablets.	B. No. UTCCLA524, Mfg date: 10/2015, Exp. Date: 09/2017, Mfd by: Khandelwal Laboratories Pvt Ltd. Uttarakhand.	Disintegration
2	Diazepam Tablet IP 1mg	B. No. DZT411, Mfg date: 12/2016, Exp. Date: 11/2018, Mfd by: Unicure India Ltd. Gautam Budh Nagar. UP.	Related substances and related decomposition
3	CLOP Cream 30gm (Clobetasol Cream IP 05%w/w	B. No. BFT118, Mfg date: 02/2017, Exp. Date: 01/2019, Mfd by: Cadila Healthcare Ltd. Ahmedabad	Assay
4	Oxyline 250 (Oxytetracyclin Capsules IP250mg)	B. No. OXC-105, Mfg date: 05/2017, Exp. Date: 04/2018, Mfd by: Alco formulations. Faridabad.	Uniformity of weight and loss on drying
5	Ceemox 250 DT (Amoxicillin Trihydrate Dispersible Tablets	B. No. AT7094, Mfg date: 02/2017, Exp. Date: 01/2019, Mfd by: Anrose Pharma. Brotiwala, HP.	Uniformity of dispersion
6	Diaset 2 (Glimepiride tablet 2 mg IP)	B. No. L33L11, Mfg date: 03/2017, Exp. Date: 02/2020, Mfd by: Stadmed Pvt. Ltd. Lucknow.	Dissolution

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List of Drugs not of Standard Quality, for the month of September 2017 (*Continued*)

Sr. No.	Drug Name	Batch No./Date of Mfg./Date of Expiry/Name of manufacturer	Reason for failure
7	ELCITAPAM S-10 (Escitalopram oxalate tablets IP)	B. No. AP7076, Mfg date: 02/2017, Exp. Date: 01/2019, Mfd by: Affy Parentrals, Baddi. HP.	Assay
8	Ceequin Injection (Chloroquine Phosphate injection IP)	B. No. PC-03, Mfg date: 07/2016, Exp. Date: 06/2018, Mfd by: Bio-Medica laboratories Pvt Ltd. Indore.	Extractable volume
9	Pantoprazole Tablets IP 40mg	B. No. PRJT 1001, Mfg date: 11/2016, Exp. Date: 10/2018, Mfd by: Wings Biotech Industrial area, Baddi. HP.	Dissolution
10	Ramil 5 (Ramipril Tablets IP)	B. No. T 10694, Mfg date: 01/2016, Exp. Date: 12/2017, Mfd by: Jacksons Laboratories Pvt Ltd. Amritsar.	Dissolution and assay
11	Laxsum 40mg (Frusemide Tablets IP 40mg)	B. No. T-9737, Mfg date: 01/2017, Exp. Date: 12/2018, Mfd by: Karnani Pharmaceuticals Pvt. Ltd. Dehradun.	Dissolution.
12	AARPIK-20 Tablets (Atorvastatin Tablets IP)	B. No. STN-170055, Mfg date: 04/2017, Exp. Date: 03/2019, Mfd by: Terrace Pharmaceutical Pvt. Ltd. Sansarpur Terrace. HP.	Dissolution
13	Ispaghula Husk Granules BP (CREMADIET)	B. No. TPC0195, Mfg date: 05/2017, Exp. Date: 04/2019, Mfd by: Tirupati Medicare Ltd. Paonta Sahib. HP.	Swelling Index

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List of Drugs not of Standard Quality, for the month of September 2017 (*Continued*)

Sr. No.	Drug Name	Batch No./Date of Mfg./Date of Expiry/Name of manufacturer	Reason for failure
14	Enteric Coated Rabeprazole Sodium and Domperidone sustained release capsules (RABETEL DSR CAPSULES)	B. No. C-4516, Mfg date: 06/2017, Exp. Date: 05/2018, Mfd by: Senate Laboratories, Roorkee. UK.	Assay of Rabeprazole
15	Diclofenac Sodium, Chlorpheniramine Maleate, Paracetamol and magnesium trisilicate Tablets. (Common Tablets)	B. No. TL-16085, Mfg date: 12/2016, Exp. Date: 05/2019, Mfd by: Horizone Bioceuticals Pvt Ltd. Sirmour HP.	Assay of Chlorpheniramine maleate
16	Rabeprazole Tablet IP (RABSOL 20 TABLETS)	B. No. BT-86, Mfg date: 04/2017, Exp. Date: 03/2019, Mfd by: Boffine Biotech Private Ltd. Sirmour HP.	Dissolution
17	Tizanidine Hydrochloride Tablets IP 2mg (Tizapol Tablets)	B. No. TT-030, Mfg date: 04/2016, Exp. Date: 03/2018, Mfd by: Medipol Pharmaceutical India Pvt Ltd. Baddi. HP	Description
18	Aceclofenac, Paracetamol Tablets (OSEO-AP TABLETS)	B. No. NT-1604, Mfg date: 03/2016, Exp. Date: 02/2018, Mfd by: H.L. Heathcare Pvt. Ltd. Gagret. HP.	Identification and assay of aceclofenac.
19	Amlodipine and Atenolol Tablets (AMTAS-AT 25 TABLETS)	B. No. KT-1192, Mfg date: 05/2016, Exp. Date: 04/2019, Mfd by: Intas Pharmaceutical Ltd. East Sikkim.	Assay of Amlodipine Besylate calculated as Amlodipine.
20	Silver Sulphadiazine cream IP.	B. No. S7116, Mfg date: 06/2017, Exp. Date: 05/2019, Mfd by: Scott Edil Pharmacia Ltd. Jharmajri, Baddi. HP.	Assay

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PHARMA NEWS

Torrent to acquire branded business of India and Nepal from Unichem

Torrent Pharmaceuticals Limited and Unichem Laboratories Limited announced that Torrent has entered into a definitive binding agreement with Unichem to acquire its branded business of India and Nepal ("India business") for a consideration of Rs.3600 Crores (Three Thousand Six Hundred Crores only), pursuant to the approval from the Board of Directors of the company.

Fibrinogen prevents repair in brain

In many diseases of the nervous system, such as multiple sclerosis (MS), spinal cord injuries, stroke, neonatal brain injuries, and even Alzheimer's disease, the nerve fibers in the brain lose their protective coating, called myelin, and become extremely vulnerable. This leaves the nerve cells exposed to their environment and reduces their ability to transmit signals quickly, resulting in impaired cognition, sensation, and movement. In disease, the brain seems to activate mechanisms to repair myelin, but cannot complete the process. They found that when fibrinogen (a blood-clotting protein) leaks into the central nervous system, it stops brain cells from producing myelin and, as a result, prevents repair.

New obesity drug completes phase-1 clinical trial

Gila Therapeutics, recently took a big step toward FDA approval for its new weight control treatment, completing its Phase I clinical trial in August. Gila is developing a novel intra-oral delivery of PYY, a well-known satiety hormone, to help patients reduce caloric intake and lose weight. Previous attempts to use PYY for this purpose have run into issues associated with systemic side effects of nausea and vomiting.

Vedanta biosciences to advance cancer immunotherapy

Vedanta Biosciences, an affiliate of PureTech Health developing a new category of therapies for immune and infectious diseases based on rationally designed consortia of human microbiome-derived bacteria, announced that it has exclusively sub-licensed key intellectual property from JSR Corporation to develop and commercialize microbiome-derived cancer immunotherapies based on live biotherapeutics. These live biotherapeutics have been shown to activate CD8+ T cells, a type of white blood cell that is the predominant effector in cancer immunotherapy. The sub-licensed intellectual property is based on the pioneering research of Dr. Kenya Honda, Professor, of Keio University School of Medicine and his collaborators in the University of Tokyo in Japan. An IND filing for the lead product candidate is planned in 2018.

New gene signature expression assay can enhance lymphoma management

Diffuse large B-cell lymphoma (DLBCL) is an aggressive cancer and the most frequently diagnosed non-Hodgkin lymphoma worldwide (nearly 40% of cases). Recent advancements indicate that both the prognosis and choice of treatment of DLBCL may depend on identifying its molecular subtype. In a report in the Journal of Molecular Diagnostics, researchers describe their development of a reliable, accessible, rapid, and

cost-effective new gene expression signature assay that can enhance lymphoma management by helping to match tumors with the appropriate targeted therapy. DLBCLs are heterogeneous, with three major subtypes associated with different outcomes. According to the recent update of the World Health Organization (WHO) classification, this information should therefore be systematically provided at diagnosis. Moreover, many targeted therapies are under clinical evaluation and being able to distinguish these diseases routinely and accurately should soon become a major goal," explained lead author Victor Bobée, PharmD, of the Henri Becquerel Cancer Treatment Center, INSERM U1245 (Rouen, France).

FDA identified the deficiencies in testosterone of Antaras pharma

Antares Pharma, Inc. announced that, the Company received a letter from the U.S. Food and Drug Administration (FDA) stating that, as part of their ongoing review of the Company's New Drug Application (NDA) for XYOSTED™ (testosterone enanthate) injection, they have identified deficiencies that preclude the continuation of the discussion of labeling and postmarketing requirements/commitments at this time.

Note

If anyone would like to publish his/her article in the monthly bulletin of Drug Information Center regarding Pharma updates, they can send their articles with their full address and professional status on the following reference before 25th of the every month.

Mail ID: hpspcdic@gmail.com

Toll Free: 18001210443, Tel: 9218428042,
Whatsapp: 9459220253

Which kind of queries can be asked from Drug Information Center... ?

It is the matter of pride for all the population of Himachal Pradesh that there is **Drug Information Center** (DIC) in the state which is giving the services to promote the rational drug use. Maximum population of state knows that there is DIC, but they are unaware about the services of the DIC. They all are confused that which kind of queries they can ask.

There is no any restriction to take the drug query information by any one. Any person (physician, pharmacist, nurse, patient, people of community, old persons, students, researchers etc.) can come in or call in the DIC office to take drug information.

Following kinds of queries regarding drugs can be asked from DIC:

- If patient is administering two medicines at the same time then he/she before administering the medicine, can confirm from DIC that this combination is safe or not safe. If combination will be not safe then it may also be life threatening.
- If patient is administering a medicine then he/she can confirm which kinds of foods have to be avoided.
- Someone can confirm that use of any specific medicine in particular condition (like as pregnancy/ lactation) is safe or not safe.
- General information about drug identification can also be taken from the DIC, like as use and side/adverse effects, time of administration, duration of administration, dose in different age groups etc. about any drug.
- Information about substituted drugs with different prices can also be provided by DIC.
- Any updation about medicines can be confirmed from DIC.

DIC will provide the accurate information on request without any fear and favor.

In short, it can be say that DIC can provide any kind of information about any medicine to any one without any cost.

Personnel can assess directly, can call in the DIC office, sent the query by post, by E-mail on following address:

Drug Information Center, Run by Himachal Pradesh State Pharmacy council at Laureate Institute of Pharmacy Kathog, jwala ji, Distt. Kangra HP 177101

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