



New Drug Review

Presented by:

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This program is approved by NCPA for 0.15 CEUs (1.5 contact hours) of continuing education credit. NCPA is approved by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Daniel A. Hussar

Daniel A. Hussar is the Remington Professor of Pharmacy at the Philadelphia College of Pharmacy at University of the Sciences in Philadelphia. He is a member of a number of professional organizations including the American Pharmacists Association, American Society of Health-System Pharmacists, Drug Information Association, Pennsylvania Pharmacists Association, and Pennsylvania Society of Heal-System Pharmacists. He has served as a member of the Board of Trustees of the American Pharmacists Association and is a Past President of the Drug Information Association and the Pennsylvania Pharmacists Association. He currently serves on the Board of Directors of Christian Pharmacists Fellowship International and the Board of Directors of World Vision.

Dr. Hussar teaches the Nonprescription Drug Therapy course and is a participant I the Pharmacotherapeutics and Law and Ethics courses at the Philadelphia College of Pharmacy. He has participated in numerous continuing education programs for practicing pharmacists and other health professionals. His primary interests are in the areas of new drugs, drug interactions, patient compliance, and issues facing the profession of pharmacy, and he has written and spoken extensively on these subjects. For a number of years, he has published articles in several professional journals on the new medications that have been marketed in the United States. He serves as the Author/Editor of The Pharmacist Activist newsletter.

Educational Objectives

Presentation Title: New Drug Review

Name of Presenter: Daniel A. Hussar, Ph.D.

Objectives:

1. After attending this program, the participant will be able to:
2. Identify the indications and routes of administration of the new drugs.
3. Identify the important pharmacokinetic properties and the unique characteristics of the new drugs.
4. Identify the most important adverse effects and precautions of the new drugs.
5. Compare the new drugs to the older therapeutic agents to which they are most similar in activity.
6. Identify information regarding the new drugs that the pharmacist should communicate to the patient.

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New Drug Comparison Rating (NDCR) system

- 5 = important advance (e.g., first drug approved for the indication)
- 4 = significant advantage(s) (e.g., with respect to use/effectiveness, safety, administration)
- 3 = no or minor advantage(s)/disadvantage(s), or advantage(s)/disadvantage(s) of similar importance
- 2 = significant disadvantage(s) (e.g., with respect to use/effectiveness, safety, administration)
- 1 = important disadvantage(s)

Reference: www.pharmacistactivist.com

Tigecycline

Tygacil-Wyeth

a glycylcycline (tetracycline) antibiotic; indicated for intravenous use in adult patients for the treatment of complicated skin and skin structure infections and complicated intra-abdominal infections caused by susceptible aerobic and anaerobic gram-positive and gram-negative bacteria; adverse events include nausea, vomiting, diarrhea, abdominal pain, headache, fever, and local reactions; may cause fetal harm if administered during pregnancy; may cause permanent discoloration of the teeth if administered during the last half of pregnancy or in children less than 8 years of age; must be used with caution in patients with a history of allergy to a tetracycline; should be administered by intravenous infusion over approximately 30 to 60 minutes; usual dosage - 100 mg initially, followed by 50 mg every 12 hours; dosage should be reduced in patients with severe hepatic impairment; vials - 50 mg.

Darunavir

Prezista-Tibotec

an HIV protease inhibitor; is co-administered with 100 mg of ritonavir and with other antiretroviral agents for the treatment of HIV infection in antiretroviral treatment-experienced adult patients, such as those with HIV-1 strains resistant to more than one protease inhibitor; adverse events include diarrhea, nausea, headache, and rash; may increase blood lipid and glucose concentrations, and cause fat redistribution and immune reconstitution syndrome; contains a sulfonamide moiety and must be used with caution in patients with a known sulfonamide allergy; is a CYP3A substrate and CYP3A inhibitor; concurrent use with ergot derivatives, cisapride, pimozide, midazolam, and triazolam is contraindicated; concurrent use with lovastatin,

simvastatin, carbamazepine, phenobarbital, phenytoin, rifampin, and St. John's wort should be avoided; may also interact with numerous other drugs; must be co-administered with ritonavir; should be administered with food; usual dosage - 600 mg with 100 mg of ritonavir twice a day; tablets - 300 mg.

Omega-3-acid ethyl esters

Omacor - Reliant

a lipid regulating agent containing a combination of ethyl esters of eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA); indicated as an adjunct to diet to reduce very high (at least 500 mg/dL) triglyceride levels in adults; adverse events include eructation, infection, flu syndrome, and altered taste; should be used with caution in patients who are allergic to fish; may prolong bleeding time; should be administered with food; usual dosage - 4 grams a day as a single dose or 2 divided doses; capsules - 1 gram.

Ranolazine

Ranexa - CV Therapeutics

a late sodium current inhibitor that exhibits antianginal activity; indicated for the treatment of chronic angina in combination with amlodipine, beta-blockers, or nitrates; use should be reserved for patients who have not achieved an adequate response with other antianginal drugs; may prolong the QT interval and is contraindicated in patients with pre-existing QT prolongation, who are taking other QT-prolonging drugs, who are being treated with a potent or moderately potent CYP3A inhibitor, or in patients with hepatic disease; adverse events include dizziness, headache, constipation, and nausea; may increase the action of digoxin and simvastatin; usual initial dosage - 500 mg twice a day; dosage should not exceed 1000 mg twice a day; extended-release tablets - 500 mg.

Rasagiline

Azilect - Teva

an irreversible monoamine oxidase type B (MAO-B) inhibitor; indicated for the treatment of the signs and symptoms of idiopathic Parkinson's disease as initial monotherapy and as adjunct therapy to levodopa; concurrent use with another MAO inhibitor or meperidine is contraindicated and at least 14 days should elapse between discontinuation of rasagiline and initiation of treatment with one of these agents; concurrent use with a sympathomimetic amine, tramadol, methadone, propoxyphene, dextromethorphan, cyclobenzaprine, mirtazapine, or St. John's wort is contraindicated; concurrent use of a tricyclic, SSRI, or SNRI antidepressant is best avoided and at least 14 days should elapse between the discontinuation of rasagiline and initiation of treatment with one of these antidepressants; use of tyramine - rich foods, beverages, or dietary supplements should be restricted; action may be increased by ciprofloxacin; adverse events include flu syndrome, arthralgia, depression, dyspepsia, falls, and hallucinations; patients should be advised to monitor for melanomas; should not be used in patients with moderate or severe hepatic impairment; usual dosage - 1 mg once a day as monotherapy and 0.5 mg once a day as an adjunct to levodopa; tablets - 0.5, 1 mg.

Pregabalin

Lyrica - Pfizer

structurally related to GABA and gabapentin; indicated for the management of neuropathic pain associated with diabetic peripheral neuropathy and postherpetic neuralgia, and as adjunctive therapy for adult patients with partial onset seizures; adverse events include dizziness, somnolence, peripheral edema, dry mouth, headache, ataxia, blurred vision, and constipation; may cause fluid retention, weight gain, creatine kinase elevations, decreased platelet count, PR interval prolongation, and male-mediated teratogenicity; concurrent use with CNS depressants increases the risk of CNS adverse events; concurrent use with a thiazolidinedione antidiabetic agent may increase the possibility of edema and weight gain; is a schedule V controlled substance; usual dosage - 300 - 600 mg/day divided in 2 or 3 doses; dosage should be reduced in patients with impaired renal function; capsules - 25, 50, 75, 100, 150, 200, 225, 300 mg; treatment should not be abruptly discontinued, and dosage should be tapered gradually over a minimum of 1 week.

Varenicline

Chantix - Pfizer

a partial agonist selective for alpha₄ beta₂ nicotinic acetylcholine receptor subtypes; indicated as an aid to smoking cessation treatment; provides an agonist action that eases withdrawal symptoms and prevents binding of nicotine to receptors that reduces satisfaction if individual resumes smoking; adverse events include nausea, insomnia, and abnormal dreams; individuals should set a date to quit smoking and to initiate treatment one week before the quit date; should be administered after eating and with a full glass of water; usual dosage - 0.5 mg once a day on days 1-3; 0.5 mg twice a day on days 4-7; then 1 mg twice a day on day 8 until the end of treatment (12 weeks); for individuals who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment is recommended; tablets - 0.5, 1 mg.

Abatacept

Orencia - Bristol-Myers Squibb

a selective costimulation modulator that inhibits T cell activation, resulting in inhibition of production of tumor necrosis factor alpha, interferon gamma, and interleukin - 2; produced by recombinant DNA technology; indicated for reducing signs and symptoms, inducing major clinical response, slowing the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more DMARDs, such as methotrexate or TNF antagonists; may be used as monotherapy or concomitantly with DMARDs other than TNF antagonists; adverse events include infections (primarily respiratory), headache, and dizziness; concurrent use with a TNF antagonist or anakinra is not recommended because of an increased risk of infection; patients with COPD are more likely to experience adverse events; patients should be screened for latent TB infection; live vaccines should not be given concurrently or within 3 months following discontinuation of treatment; potential for malignancies should be monitored; administered via intravenous infusion over a period of 30 minutes; usual

dosage - 750 mg initially and then at 2 weeks and 4 weeks following the first dose, and then every 4 weeks thereafter; vials - 250 mg; a silicone - free disposable syringe must be used in reconstituting and diluting the formulation; should be administered using a non-pyrogenic low-protein-binding filter.

Lubiprostone

Amitiza - Sucampo; Takeda

a locally acting chloride channel activator that increases intestinal fluid secretion and motility in the intestine; indicated for the treatment of chronic idiopathic constipation in adults; contraindicated in patients with a history of mechanical GI obstruction; adverse events include nausea, diarrhea, and headache; women who could become pregnant should have a negative pregnancy test prior to beginning therapy; usual dosage - 24 mcg twice a day with food; capsules - 24 mcg.

Insulin glulisine

Apidra - Aventis

a human insulin analog that is produced by recombinant DNA technology; indicated for the treatment of adult patients with diabetes mellitus for the control of hyperglycemia; has a rapid onset of action and short duration of action, and usually should be used in regimens that include a longer-acting insulin or basal insulin analog; adverse events include hypoglycemia and injection site reactions; administered subcutaneously within 15 minutes before a meal or within 20 minutes after starting a meal; may also be infused subcutaneously by external insulin infusion pumps; dosage is individualized; vials - 100 units/ml; cartridges for use in OptiClik insulin delivery device; if mixed with NPH human insulin, insulin glulisine should be drawn into the syringe first - mixture should be injected immediately after mixing.

Insulin detemir

Levemir - Novo Nordisk

a human insulin analog that is produced by recombinant DNA technology; indicated for the treatment of adult and pediatric patients with type 1 diabetes or adult patients with type 2 diabetes who require basal (long-acting) insulin for the control of hyperglycemia; adverse events include hypoglycemia and injection site reactions; administered once a day with the evening meal or at bedtime, or twice a day either with the evening meal, at bedtime, or 12 hours after the morning dose; dosage is individualized; vials, cartridges, pens - 100 units/ml; must not be mixed or diluted with any other insulin preparations.

Sunitinib malate**Sutent - Pfizer**

a multikinase inhibitor that reduces tumor growth; indicated for the treatment of advanced renal cell carcinoma, and for the treatment of gastrointestinal stromal tumor after disease progression or intolerance to imatinib; may cause left ventricular dysfunction, hypertension, and hemorrhagic events; other adverse events include fatigue, diarrhea, abdominal pain, nausea, vomiting, mucositis/stomatitis, anorexia, altered taste, skin discoloration (yellow), asthenia, neutropenia, lymphopenia, thrombocytopenia, anemia, AST/ALT elevation; may cause harm to a fetus and women of childbearing potential should be advised to avoid becoming pregnant; action may be increased by strong CYP3A4 inhibitors (e.g., clarithromycin, itraconazole, HIV protease inhibitors), and decreased by CYP3A4 inducers (e.g., carbamazepine, rifampin, St. John's wort); usual dosage - 50 mg once a day, on a schedule of 4 weeks on treatment followed by 2 weeks off; capsules - 12.5, 25, 50 mg.

Ranibizumab**Lucentis - Genentech**

a humanized monoclonal antibody fragment that binds to and inhibits vascular endothelial growth factor A (VEGF-A); indicated for intravitreal injection for the treatment of patients with neovascular (wet) age-related macular degeneration; adverse events include conjunctival hemorrhage, eye pain, vitreous floaters, increased intraocular pressure, and intraocular inflammation; administered by intravitreal injection; usual dosage - 0.5 mg (0.05 ml) once a month; following the first 4 injections (months), treatment may be continued with one injection every 3 months if monthly injections are not feasible; vials - 2 mg/0.2 ml.

Ecamsule**in Anthelios SX - LaRoche-Posay**

also known as Mexoryl SX; available OTC; a sunscreen that protects against short UVA wavelengths (320-340 nms); used in combination with avobenzone and octocrylene that provide protection against long UVA wavelengths and UVB wavelengths, respectively; used for the prevention of sunburn and for protection against UVA and UVB rays; has a sun protection factor (SPF) of 15%; adverse events include dermatitis, dry skin, eczema, itching, and skin discomfort; cream - 2% ecamsule, 2% avobenzone, 10% octocrylene.

Learning Assessment Questions

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1. Which of the following drug:classification pairings is correct?
 - a. ranolazine:calcium channel blocking agent
 - b. sunitinib:monoclonal antibody
 - c. abatacept:multikinase inhibitor
 - d. lubiprostone:chloride channel activator
2. Which of the following drug:use pairings is correct?
 - a. rasagiline:chronic angina
 - b. darunavir:hepatitis B virus infection
 - c. ranibizumab:age-related macular degeneration
 - d. varenicline:alcohol dependence
3. Which of the following drug:route of administration pairings is correct?
 - a. abatacept:subcutaneous
 - b. ecamsule:topical
 - c. insulin glulisine:inhalation
 - d. sunitinib:intravenous
4. With the use of which of the following agents should the consumption of tyramine-rich foods, beverages, and dietary supplements be restricted?
 - a. ranolazine
 - b. rasagiline
 - c. varenicline
 - d. darunavir
5. Which of the following agents is indicated for the treatment of neuropathic pain associated with diabetic peripheral neuropathy?
 - a. omega-3-acid ethyl esters
 - b. ranolazine
 - c. pregabalin
 - d. tigecycline

Learning Assessment Answers

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Answers:

1. d
2. d
3. b
4. b
5. c