FARMACIA PRACTIA LETTRE

October – December 2017

News letter from Department of Pharmacy Practice

Principal's Message

It gives me immense pleasure that our department of pharmacy practice, Sri Venkateswara College of Pharmacy is releasing its news letter. I am sure that news letter will motivate Pharm.D students, health care professionals. I this occasion, I congratulate the staff and students of department of pharmacy practice staff, and students for their efforts in bringing this colorful news letter. The clinical pharmacy activity of our pharmacy practice department has gained strength in the last couple of years with the start of Pharm.D programme and our faculty and students are involved in patient services activities in Government Hospital, Chittoor. The college has adequate facilities to train the students, conduct research facilities, consultancy services to obtain job opportunities to the students. This news letter is very much required in present scenario as it educates the health care professionals, students and academicians. I will extend my help and support in making the forcoming newsletter a rand success. I congratulate all the students and staff for bringing this educative news letter.

HIGHLIGHTS OF CURRENT ISSUE

1. **Drug profile**
2. **Disease based information**

MACRILEN

Brand Name: Macrilen
Generic Name: Macimorelin
Drug Class: Diagnostics, Endocrine

Macimorelin is used for diagnosis of adult growth hormone (GH) deficiency.

Macimorelin is available under the following different brand names: Macrilen.

Dosage Forms and Strengths

Granules for Oral Solution: 60mg/packet (0.5mg/mL following reconstitution)

Mechanism of Action

Macrilen is a growth hormone (GH) secretagogue receptor agonist. Macimorelin stimulates GH release by activating growth hormone secretagogue receptors present in the pituitary and hypothalamus.
FDA approved on: 2017-12-01

Dosage Considerations – Should be Given as Follows:

Growth Hormone Deficiency

- Indicated for diagnosis of adult growth hormone (GH) deficiency
- 0.5 mg/kg orally as a single dose after fasting for at least 8 hours
- Avoid concomitant use of with drugs that prolong the QT interval (e.g., antipsychotic medications [e.g., chlorpromazine, haloperidol, thioridazine, ziprasidone]), antibiotics [e.g., moxifloxacin], class 1A antiarrhythmic medications [e.g., quinidine, procainamide]

and class III antiarrhythmic medications [e.g., amiodarone, sotalol], any other medications known to prolong the QT interval)

- Discontinue strong CYP3A4 inducers (e.g., carbamazepine, enzalutamide, mitotane, phenytoin, rifampin, St. John's wort, bosentan, efavirenz, etravirine, modafinil, armodafinil, rufinamide)

Side Effects:

- Changes in taste
- Dizziness
- Headache
- Fatigue
- Nausea
- Hunger
- Diarrhea
- Upper respiratory tract infection
- Feeling hot
- Excessive sweating
- Runny or stuffy nose
- Slow heart rate

Drugs Interactions:

Moderate interactions of macimorelin include:

- cenobamate
- elagolix
- encorafenib
- fedratinib
- stiripentol
- tazemetostat
- tecovirimat

Warnings:

This medication contains macimorelin. Do not take Macrilen if you are allergic to macimorelin or any ingredients contained in this drug.

ERTUGLIFLOZIN

Ertugliflozin is a SGLT2 inhibitor used to treat type 2 diabetes mellitus.

FDA Approval Date: 2017-12-01

Background:
Ertugliflozin belongs to the class of potent and selective inhibitors of the sodium-dependent glucose cotransporters (SGLT), more specifically the type 2 which is responsible for about 90% of the glucose reabsorption from glomerulus. This drug was developed under the collaboration of Merck and Pfizer. It was FDA approved as monotherapy and in combination with sitagliptin or metformin hydrochloride on December 22, 2017
Brand Names: Segluromet, Steglatro, Steglujan
Indications:

Ertugliflozin as a monotherapy is indicated to improve the glycemic control in adult patients with type 2 diabetes.[Label] Ertugliflozin, in combination with metformin hydrochloride, is indicated to improve glycemic control in patients with diabetes type 2 who are not controlled on a regimen of ertugliflozin or metformin or in patients who are already treated with both ertugliflozin and metformin.

Mechanism of Action

Steglatro (ertugliflozin) is a sodium glucose co-transporter 2 (SGLT2) inhibitor. SGLT2 is the predominant transporter responsible for reabsorption of glucose from the glomerular filtrate back into the circulation. By inhibiting SGLT2, ertugliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion.

Indications:

STEGLATRO is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use

- STEGLATRO is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

Dosage and Administration:

The recommended starting dose of STEGLATRO is 5 mg once daily, taken in the morning, with or without food. In patients tolerating STEGLATRO 5 mg once daily, the dose may be increased to a maximum recommended dose of 15 mg once daily if additional glycemic control is needed.

Side effects:

The following important adverse reactions are described elsewhere in the labeling:

- Hypotension
- Ketoacidosis
- Impairment in Renal Function
- Urosepsis and Pyelonephritis
- Lower Limb Amputation
- Hypoglycemia

RHOPRESSA

Rhopressa is a rho kinase inhibitor that was approved by the food and drug administration (FDA) in December 2017. A Rho kinase inhibitor with norepinephrine transport inhibitory activity that reduces production of aqueous

Brand Names: Rhopressa, Rocklatan

Indication:

Netarsudil is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension

Mechanism of action:

The medical condition glaucoma is a leading cause of progressive visual impairment and blindness across the world with primary open-angle glaucoma (POAG) being the major type of glaucoma. Elevated intraocular pressure (IOP) resulting from increased resistance to aqueous humor outflow is considered a major risk for the development and progression of POAG, but various clinical studies have demonstrated that the reduction and tight control of IOP can delay or prevent POAG and the vision loss associated with it. Ordinary physiological IOP results from aqueous humor produced by the ocular ciliary body and its outflow through two main outflow pathways: the conventional (trabecular) and the unconventional (uveoscleral) pathways

Side effects:

- Eye redness
- Eye pain after putting in eye drop
- Blurred vision
- Eyelid redness
- Increased tears
- Decreased vision

XEPI

USFDA approved on 2/11/2017

Description: XEPI contains ozenoxacin, a quinolone antimicrobial. It is intended for topical use only. Xepi is a prescription medicine used to treat the symptoms of Impetigo. Xepi may be used alone or with other medications. Xepi belongs to a class of drugs called Antibacterials,

Side effects:

- hives,
- difficulty breathing
- swelling of your face, lips, tongue, or throat,
- redness of the skin,
- warmth or swelling of the skin, and
- oozing from the skin

Indications:

It is indicated for the topical treatment of impetigo due to Staphylococcus aureus or Streptococcus pyogenes in adult and pediatric patients 2 months of age and older.

Dosage administration:

Apply a thin layer of XEPI topically to the affected area twice daily for five days.

Storage and handling:

XEPI cream, 1% is a pale yellow cream supplied in a 30-gram tube. Each gram of cream contains 10 mg of ozenoxacin.

Stored at 20°C - 25°C (68°F - 77°F); excursions permitted to 15°C to 30°C (59°F - 86°F).

Mechanism of action:

Ozenoxacin is a quinolone antimicrobial drug. The mechanism of action involves the inhibition of bacterial DNA replication enzymes, DNA gyrase A and topoisomerase IV. Ozenoxacin has been shown to be bactericidal against S. aureus and S. pyogenes organisms.

OZEMPIC

USFDA approved on: 12/5/2017

Semaglutide is a glucagon-like peptide 1 receptor agonist used to improve glycemic control in type 2 diabetes mellitus.

Brand Names: Ozempic, Rybelsus, Wegovy

Mechanism of action:

GLP-1 is a physiological hormone that promotes glycemic control via several different mechanisms, including insulin secretion, slowing gastric emptying, and reducing postprandial glucagon secretion. The homeostasis of glucose is dependent on hormones such as insulin and amylin, which are secreted by the beta cells of the pancreas. Semaglutide is 94% similar to human GLP-1. Analogs of this hormone such as semaglutide stimulate the synthesis of insulin[3] by stimulating pancreatic islet cells and reducing glucagon secretion.[3] They directly bind with selectivity to the GLP-1 receptor, causing various beneficial downstream effects that reduce blood glucose in a glucose-dependent fashion.

Adverse effects

Side effects including nausea, vomiting, diarrhea, abdominal pain, and constipation, kidney problems, diabetic retinopathy, allergic reactions, low blood sugar, and pancreatitis.

Indications

It is as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Recommended Dosage

Start OZEMPIC with a 0.25 mg subcutaneous injection once weekly for 4 weeks. The 0.25 mg dose is intended for treatment initiation and is not effective for glycemic control. After 4 weeks on the 0.25 mg dose, increase the dosage to 0.5 mg once weekly.

RHOPRESSA

Rhopressa is a rho kinase inhibitor that was approved by the Food and Drug Administration (FDA) in December 2017.

A Rho kinase inhibitor with norepinephrine transport inhibitory activity that reduces production of aqueous as of December 18, 2017 the FDA approved Aerie Pharmaceutical's Rhopressa (netarsudil ophthalmic solution) 0.02% for the indication of reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Acting as both a rho kinase inhibitor and a norepinephrine transport inhibitor, Netarsudil is a novel glaucoma medication in that it specifically targets the conventional trabecular pathway of aqueous humour outflow to act as an inhibitor to the rho kinase and norepinephrine transporters found there as opposed to affecting protaglandin F2-alpha analog like mechanisms in the unconventional uveoscleral pathway that many other glaucoma medications demonstrate.

Brand Names: Rhopressa, Rocklatan

Indication:

Netarsudil is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension

Mechanism of action:

The medical condition glaucoma is a leading cause of progressive visual impairment and blindness across the world with primary open-angle glaucoma (POAG) being the major type of glaucoma. Elevated intraocular pressure (IOP) resulting from increased resistance to aqueous

humor outflow is considered a major risk for the development and progression of POAG, but various clinical studies have demonstrated that the reduction and tight control of IOP can delay or prevent POAG and the vision loss associated with it. Ordinary physiological IOP results from aqueous humor produced by the ocular ciliary body and its outflow through two main outflow pathways: the conventional (trabecular) and the unconventional (uveoscleral) pathways

Side effects:

- Eye redness
- Eye pain after putting in eye drop
- Blood vessel in the eye(s) breaking
- Blurred vision
- Eyelid redness
- Increased tears

Precautions:

Avoid allowing the tip of the dispensing container to contact the eye or surrounding structures because this could cause the tip to become contaminated by common bacteria known to cause eye infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions. Contact lenses should be removed prior to administration of the solution. Lenses may be reinserted 15 minutes following administration of Rhopressa.

Usage:

Rhopressa comes in solution form and is placed in the affected eye(s) once daily in the evening.

Dosage:

Take this medication exactly as prescribed by your health care professional. The recommended dose of Rhopressa for glaucoma or high blood pressure is one drop in the affected eye(s) once daily in the evening.

Storage:

Store unopened bottle in the refrigerator between 36°F to 46°F (2°C to 8°C) until opened. After opening bottle, Rhopressa bottle can be kept in the refrigerator or at room temperature between 36°F to 77°F (2°C to 25°C) for up to 6 weeks.

XEPI

USFDA approved on 2/11/2017

Description:

XEPI contains ozenoxacin, a quinolone antimicrobial. It is intended for topical use only. Xepi is a prescription medicine used to treat the symptoms of Impetigo. Xepi may be used alone or with other medications.

Side effects:

Difficulty breathing,

Swelling of your face, lips, tongue, or throat,

Redness of the skin,

Warmth

Oozing from the skin

Indications:

It is indicated for the topical treatment of impetigo due *to* Staphylococcus aureus or Streptococcus pyogenes in adult and pediatric patients 2 months of age and older.

Dosage and sdministration:

Apply a thin layer of XEPI topically to the affected area twice daily for five days.

Storage:

Store at 20°C - 25°C (68°F - 77°F); excursions permitted to 15°C to 30°C (59°F - 86°F) [See USP Controlled Room Temperature].

Precautions:

The prolonged use of XEPI may result in overgrowth of non susceptible bacteria and fungi. If such infections occur during therapy, discontinue use and institute appropriate supportive measures.

Mechanism of action:

Ozenoxacin is a quinolone antimicrobial drug. The mechanism of action involves the inhibition of bacterial DNA replication enzymes, DNA gyrase A and topoisomerase IV. Ozenoxacin has been shown to be bactericidal against *S. aureus* and *S. pyogenes* organisms.

Ozempic: semaglutide

USFDA approved on: 12/5/2017

Semaglutide is a glucagon-like peptide 1 receptor agonist used to improve glycemic control in type 2 diabetes mellitus.

Brand Names: Ozempic, Rybelsus, Wegovy

Mechanism of action

GLP-1 is a physiological hormone that promotes glycemic control via several different mechanisms, including insulin secretion, slowing gastric emptying, and reducing postprandial glucagon secretion. The homeostasis of glucose is dependent on hormones such as insulin and amylin, which are secreted by the beta cells of the pancreas. Semaglutide is 94% similar to human GLP-1. Analogs of this hormone such as semaglutide stimulate the synthesis of insulin[3] by stimulating pancreatic islet cells and reducing glucagon secretion.[3] They directly bind with selectivity to the GLP-1 receptor, causing various beneficial downstream effects that reduce blood glucose in a glucose-dependent fashion.

Adverse effects:

Side effects including nausea, vomiting, diarrhea, abdominal pain, and constipation.

Indications:

As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Dosage and Administration:

Start OZEMPIC with a 0.25 mg subcutaneous injection once weekly for 4 weeks. The 0.25 mg dose is intended for treatment initiation and is not effective for glycemic control.

After 4 weeks on the 0.25 mg dose, increase the dosage to 0.5 mg once weekly.

If additional glycemic control is needed after at least 4 weeks on the 0.5 mg dose, the dosage may be increased to 1 mg once weekly. The maximum recommended dosage is 1 mg once weekly.

SAFINAMIDE

A.Charan chandu, Pharm.D V year

Generic Name: Safinamide mesylate

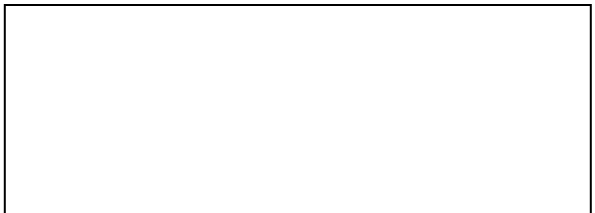
Brand Name: xafinact 50

Approved on: 21/03/2017

Class of Drug: Monoaminooxidase inhibitors (MAO-B)

Category: Antiparkinsonism drug

Manufactured By: Newron pharmaceuticals S.P.A in milan, Italy.



Available doses & strengths:

Tablets: 50mg/100mg, Iv injection: 50mg&100mg

Mechanism of Action:

- The antiparkinsonism mechanism of safinamide is through reversible inhibition of selective MAO-B , as a mesylate salt , thus reducing the degradation of dopamine. It inhibits glutamate release and dopamine reuptake in brain.

Adverse effects:

Swelling of tongue and gums, shortness of breath, rash, hypertension, insomnia, nausea, anxiety, dizziness on standing, rise in ALT and AST levels.

Contra indications:

- Severe diabetic neuropathy
- Severe liver impairment
- Retinitis pigmentosa

Drug interactions:

S.NO	DRUG	SEVERITY	EFFECT
DRUG – DRUG INTERACTIONS			
1.	**verapamil + safinamide**	major	Both the drugs has additive effects so it decreases blood pressure.
2.	**Rosuvastatin+ safinamide**	Moderate	Safinamide may increase the blood levels of rosuvastatin.
S.NO	**DRUGS**	**SEVERITY**	**EFFECT**
3.	**Repaglinide+ safinamide**	Major	.safinamide with diabetic medication may lower the sugar levels.
4.	**Insulin + safinamide**	Major	Safinamide with insulin may cause hypoglycemia.
5.	**Mirtazapine+ safinamide**	Major	Safinamide with mirtazapine may cause serotonin syndrome.
6.	**Atomoxetine+ safinamide**	major	concurrent use of safinamide with atomoxetine may increase cardiovascular side effects like hypertension, increased heart rate.
7.	**Buspirone+ safinamide**	moderate	Concurrent use of buspirone with safinamide may cause serotonin syndrome.
8.	**Amphetamine+ safinamide**	moderate	Concurrent use of amphetamine with safinamide may increase cvs side effects like hypertension, increased heart rate.

Drug- food interaction:

Safinamide with tyramine rich foods may increase blood pressure.

All other interactions are not found:

- ✓ DRUG – ETHANOL
- ✓ DRUG – ALLERGY
- ✓ DRUG – TOBACCO
- ✓ DRUG –PREGNANCY

- ✓ DRUG – LACTATION

STORAGE:

Safinamide is stored at 25°c(77°F); excursions permitted between 15°C to 30°C. Keep away from children.

DISEASE BASED INFORMATION

SYSTEMIC LUPUS ERYTHEMATOSUS

The immune system normally fights off dangerous infections and bacteria to keep the body healthy. An autoimmune disease occurs when the immune system attacks the body because it confuses it for something foreign. There are many autoimmune diseases, including systemic lupus erythematosus (SLE). The term lupus has been used to identify a number of immune diseases that have similar clinical presentations and laboratory features, but SLE is the most common type of lupus.

SLE is a chronic disease that can have phases of worsening symptoms that alternate with periods of mild symptoms. Most people with SLE are able to live a normal life with treatment. According to the Lupus Foundation of America, at least 1.5 million Americans are living with diagnosed lupus. The foundation believes that the number of people who actually have the condition is much higher and that many cases go undiagnosed.

Clinical symptoms:

Symptoms can vary and can change over time. Common symptoms include:

- Severe fatigue
- Joint pain
- Joint swelling
- Headaches
- Rashes on the cheeks and nose, which is called a “butterfly rash”
- Hair loss
- Anemia

- Blood-clotting problems

Genetics

The disease isn’t linked to a certain gene, but people with lupus often have family members with other autoimmune conditions.

Environment

Environmental triggers can include:

- ultraviolet rays
- certain medications
- viruses
- physical or emotional stress
- trauma

Diagnosis:

- blood tests, such as antibody tests and a complete blood count
- a urinalysis
- a chest X-ray

Treatment:

It includes:

- Anti-inflammatory medications for joint pain and stiffness, such as these options available online
- Steroid creams for rashes
- Corticosteroids to minimize the immune response
- Antimalarial drugs for skin and joint problems
- Disease modifying drugs