

FDA approved drugs – August 2015

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FDA APPROVED DRUGS – AUGUST 2015

1. Drug Name: Repatha (evolocumab)

Company: Amgen

Approval Status: Approved by August 2015

Therapeutic Areas: Cardiology/Vascular Diseases

General Information

Repatha (evolocumab) is a fully human monoclonal antibody to Proprotein Convertase Subtilisin/Kexin Type 9 (PCSK9), a negative regulator of low density lipoprotein receptor (LDLR). It is specifically indicated for the following:

- 1) As an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia (HeFH) or clinical atherosclerotic cardiovascular disease (CVD), who require additional lowering of low density lipoprotein cholesterol (LDL-C).
- 2) As an adjunct to diet and other LDL-lowering therapies (e.g., statins, ezetimibe, LDL apheresis) for the treatment of patients with homozygous familial hypercholesterolemia (HoFH) who require additional lowering of LDL-C.

It is supplied as an injection for subcutaneous administration. The recommended subcutaneous dosage in patients with HeFH or patients with primary hyperlipidemia with established clinical atherosclerotic CVD is either 140 mg every 2 weeks OR 420 mg once monthly. The recommended subcutaneous dosage in patients with HoFH is 420 mg once monthly. In patients with HoFH, measure LDL-C levels 4 to 8 weeks after starting Repatha, since response to therapy will depend on the degree of LDL-receptor function.

Mechanism of Action

Repatha (evolocumab) is a human monoclonal IgG2 directed against human proprotein convertase subtilisin kexin 9 (PCSK9). Evolocumab binds to PCSK9 and inhibits circulating PCSK9 from binding to the low density lipoprotein (LDL) receptor (LDLR), preventing PCSK9-mediated LDLR degradation and permitting LDLR to recycle back to the liver cell surface. By inhibiting the binding of PCSK9 to LDLR, evolocumab increases the number of LDLRs available to clear LDL from the blood, thereby lowering LDL-C levels.

Side Effects

Adverse effects associated with the use of Repatha may include: nasopharyngitis, upper respiratory tract infection, influenza, back pain, injection site reactions

2. Drug Name: Addyi (flibanserin)

Company: Sprout Pharmaceuticals

Approval Status: Approved by August 2015

Therapeutic Areas: Endocrinology/Obstetrics/Gynecology (Women's Health)

General Information

Addyi is specifically indicated for the treatment of premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty. It is supplied as a tablet for oral administration. The recommended dosage is 100 mg taken once daily at bedtime. It should be dosed at bedtime because administration during waking hours increases risks of hypotension, syncope, accidental injury, and central nervous system (CNS) depression. Discontinue treatment after 8 weeks if no improvement is observed.

Mechanism of Action

Addyi (flibanserin) is a serotonin 1A receptor agonist and a serotonin 2A receptor antagonist, but the mechanism by which the drug improves sexual desire and related distress is not known.

Side Effects

Adverse effects associated with the use of Addyi may include: dizziness, somnolence, nausea, fatigue, insomnia, dry mouth

3. Drug Name: Synjardy (empagliflozin and metformin hydrochloride)

Company: Boehringer Ingelheim

Approval Status: Approved by August 2015

Therapeutic Areas: Endocrinology

General Information

Synjardy is a combination of empagliflozin and metformin, two medicines with complementary mechanisms of action. Empagliflozin, a sodium glucose co-transporter-2 (SGLT2) inhibitor, removes excess glucose through the urine by blocking glucose re-absorption in the kidney. Metformin lowers glucose production by the liver and its absorption in the intestine. It is specifically indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are not adequately controlled on a regimen containing empagliflozin or metformin, or in patients already being treated with both empagliflozin and metformin. It is supplied as a tablet for oral administration. Synjardy comes in the following dose strengths:

5 mg empagliflozin/500 mg metformin hydrochloride

5 mg empagliflozin/1000 mg metformin hydrochloride

12.5 mg empagliflozin/500 mg metformin hydrochloride

12.5 mg empagliflozin/1000 mg metformin hydrochloride

Individualize the starting dose of Synjardy based on the patient's current regimen:

In patients on metformin, switch to Synjardy containing empagliflozin 5 mg with a similar total daily dose of metformin;

In patients on empagliflozin, switch to Synjardy containing metformin 500 mg with a similar total daily dose of empagliflozin;

In patients already treated with empagliflozin and metformin, switch to Synjardy containing the same total daily doses of each component.

Take Synjardy twice daily with meals; with gradual dose escalation to reduce the gastrointestinal side effects due to metformin.

In patients with volume depletion not previously treated with empagliflozin, correct this condition before initiating Synjardy.

Adjust dosing based on effectiveness and tolerability while not exceeding the maximum recommended daily dose of metformin 2000 mg and empagliflozin 25 mg

Mechanism of Action

Synjardy is a combination of empagliflozin, a sodium-glucose co-transporter 2 (SGLT2) inhibitor and metformin, a biguanide. Empagliflozin: Sodium-glucose co-transporter 2 (SGLT2) is the predominant transporter responsible for reabsorption of glucose from the glomerular filtrate back into the circulation. Empagliflozin is an inhibitor of SGLT2. By inhibiting SGLT2, empagliflozin reduces renal reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion. Metformin hydrochloride: Metformin is an antihyperglycemic agent which improves glucose tolerance in patients with type 2 diabetes mellitus, lowering both basal and postprandial plasma glucose. It is not chemically or pharmacologically related to any other classes of oral antihyperglycemic agents. Metformin decreases hepatic glucose production, decreases intestinal absorption of glucose, and improves insulin sensitivity by increasing peripheral glucose uptake and utilization. Unlike SUs, metformin does not produce hypoglycemia in either patients with type 2 diabetes mellitus or normal subjects (except in special circumstances) and does not cause hyperinsulinemia. With metformin therapy, insulin secretion remains unchanged while fasting insulin levels and day-long plasma insulin response may actually decrease.

Side Effects

Adverse effects associated with the use of Synjardy may include:

Most common adverse reactions associated with empagliflozin: urinary tract infection, female genital mycotic infections.

Most common adverse reactions associated with metformin: diarrhea, nausea/vomiting, flatulence, abdominal discomfort, indigestion, asthenia, headache