ISSN 2278 – 540X FISSN 2278 – 5396

DRUG DISCOVERY

FDA Approved Drugs - December 2013

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Publication History
Received: 12 February 2014
Accepted: 17 March 2014
Published: 02 April 2014

Citation
Vidhya V. FDA Approved Drugs - December 2013. *Drug Discovery*, 2014, 9(20), 10-12

1. ANORO ELLIPTA (UMECLIDINIUM AND VILANTEROL INHALATION POWDER)

1.1. Company
GlaxoSmithKline; Approved by December 2013

1.2. Treatment Area
Chronic obstructive pulmonary disease

1.3. General Information
Anoro Ellipta is specifically indicated for the long-term, once-daily, maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and/or emphysema. It is supplied as a powder formulation for inhalation. The recommended dose is one inhalation of Anoro Ellipta once daily. Anoro Ellipta should be administered at the same time every day. The dose should not exceed one dose every 24 hours.

1.4. Mechanism of Action
Anoro Ellipta is a combination of umeclidinium, an anticholinergic, and vilanterol, a long-acting beta2-adrenergic agonist (LABA).

1.5. Side Effects
Adverse effects associated with the use of Anoro Ellipta includes: pharyngitis, sinusitis, lower respiratory tract infection, constipation, diarrhea, pain in extremity, muscle spasms, neck pain, chest pain

2. SOVALDI (SOFOSBUVIR)

2.1. Company
Gilead Sciences; Approved by December 2013

2.2. Treatment Area
Hepatitis C

2.3. General Information

Sovaldi (sofosbuvir) is a nucleotide analog inhibitor of HCV NS5B polymerase. It is specifically indicated for the treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen. It is supplied as a tablet for oral administration. The recommended dose is one 400 mg tablet taken once daily with or without food. It should be used in combination with ribavirin or in combination with pegylated interferon and ribavirin. Recommended combination therapy and duration is as follows:

Genotype 1 or 4: Sovaldi + peginterferon alfa + ribavirin for 12 weeks

Genotype 2: Sovaldi + ribavirin for 12 weeks

Genotype 3: Sovaldi + ribavirin for 24 weeks.

2.4. Mechanism of Action

Sovaldi (sofosbuvir) is an inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is essential for viral replication. It is a nucleotide prodrug that undergoes intracellular metabolism to form the pharmacologically active uridine analog triphosphate (GS-461203), which can be incorporated into HCV RNA by the NS5B polymerase and acts as a chain terminator.

2.5. Side Effects

Adverse events associated with the use of Solvadi in combination with ribavirin includes: fatigue, headache.

Adverse events associated with the use of Solvadi in combination with peginterferon alfa and ribavirin includes: fatigue, headache, nausea, insomnia, anemia

3. XIAFLEX (COLLAGENASE CLOSTRIDIUM HISTOLYTICUM)

3.1. Company

Auxilium; Approved by December 2013

3.2. Treatment Area

Peyronie's disease

3.3. General Information

Xiaflex is specifically indicated for the treatment of adult men with Peyronie’s disease with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy. It is supplied as a powder for reconstitution into a solution for intralesional injection. The recommended treatment is a follows: Inject 0.58 mg Xiaflex into the target plaque once on each of two days, 1 to 3 days apart, according to the injection procedure. For each plaque causing the curvature deformity, up to four treatment cycles may be administered. Each treatment cycle may be repeated at approximately six-week intervals.

3.4. Mechanism of Action

Xiaflex (collagenase clostridium histolyticum) is an injectable formulation of purified collagenase, an enzyme that causes collagen to degrade within the connective tissue. Peyronie’s disease are caused by a collagen plaque. Injection of Xiaflex into a Peyronie’s plaque, which is comprised mostly of collagen, may result in enzymatic disruption of the plaque. Following this disruption of the plaque, penile curvature deformity and patient bother caused by Peyronie’s disease are reduced.

3.5. Side Effects

Adverse effects associated with the use of Xiaflex for Peyronie's disease includes: penile hematoma, penile swelling, and penile pain.

4. TRETTEN (COAGULATION FACTOR XIII A-SUBUNIT [RECOMBINANT])

4.1. Company

Novo Nordisk; Approved by December 2013

4.2. Treatment Area

Congenital factor XIII (FXIII) A-subunit deficiency

4.3. General Information

Tretten is specifically indicated for the routine prophylaxis of bleeding in people with congenital factor XIII (FXIII) A-subunit deficiency. It is supplied as a solution for infusion. The recommended dose is monthly 35 IU/kg injections.

4.4. Mechanism of Action

Tretten consists of Coagulation Factor XIII A-Subunit (Recombinant). Recombinant human Factor XIII (rFXIII) is integral in the formation of blood clots. In the absence of Factor XIII, loosely formed clots are developed, leading to bleeding complications.

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4.5. Side Effects

Adverse effects associated with the use of Tretten includes: headache, pain in the extremities, injection site pain, D-dimer increase.

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