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DRUG DISCOVERY

FDA Approved Drugs - November 2013

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1. VARITHENA (POLIDOCANOL INJECTABLE FOAM)

1.1. Company

BTG plc; Approved by November 2013

1.2. Treatment Area

Varicose veins

1.3. General Information

Varithena (polidocanol injectable foam) is a sclerosant and causes fibrosis inside varicose veins, occluding the lumen of the vessel, and reducing the appearance of the varicosity. It is specifically indicated for the treatment of incompetent great saphenous veins, accessory saphenous veins and visible varicosities of the great saphenous vein system above and below the knee. It is supplied as foam for intravenous administration. It should be used under ultrasound guidance only. Use up to 5 ml per injection and 15 ml per treatment session. Treatments sessions should be separated by a minimum of 5 days.

1.4. Mechanism of Action

Varithena (polidocanol injectable foam) is a non-ionic surfactant sclerosing agent. The hydrophobic pole of the polidocanol molecule attaches to the lipid cell membrane of the venous endothelium, resulting in disruption of the osmotic barrier, destruction of the venous endothelium, and vasospasm. Following exposure to polidocanol, the interior surface of the vein becomes thrombogenic, which leads to thrombus formation and venous occlusion. The occluded vein is eventually replaced by fibrous connective tissue. Polidocanol is deactivated upon contact with blood, thus limiting the sclerosant action to the endothelium near the site of injection.

1.5. Side Effects

Adverse effects associated with the use of Varisolve includes: pain/discomfort in extremity, infusion site thrombosis (retained coagulum), injection site hematoma or pain, thrombophlebitis superficial, extravasation

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2. LUZU (LULICONAZOLE) CREAM 1%

2.1. Company

Valeant Pharmaceuticals; Approved by November 2013

2.2. Treatment Area

Interdigital tinea pedis, tinea cruris, and tinea corporis

2.3. General Information

Luzu is specifically indicated for the topical treatment of interdigital tinea pedis, tinea cruris, and tinea corporis caused by the organisms Trichophyton rubrum and Epidermophyton floccosum, in adults 18 years of age and older. It is supplied as a cream for topical administration. The recommended dose is as follows: Interdigital Tinea Pedis:Luzu Cream, 1% should be applied to the affected and immediate surrounding area(s) once a day for two weeks.Tinea Cruris and Tinea Corporis: Luzu Cream, 1% should be applied to the affected skin and immediate surrounding area(s) once a day for one week.

2.4. Mechanism of Action

Luzu (luliconazole) Cream 1% is an antifungal that belongs to the azole class. Although the exact mechanism of action against dermatophytes is unknown, luliconazole appears to inhibit ergosterol synthesis by inhibiting the enzyme lanosterol demethylase. Inhibition of this enzyme's activity by azoles results in decreased amounts of ergosterol, a constituent of fungal cell membranes, and a corresponding accumulation of lanosterol.

2.5. Side Effects

Adverse effects associated with the use of Luzu include: application site reactions

3. OLYSIO (SIMEPREVIR)

3.1. Company

Janssen Therapeutics; Approved by November 2013

3.2. Treatment Area

Hepatitis C

3.3. General Information

Olysio 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 capsule for oral administration. The recommended dose is one 150 mg capsule taken once daily with food. Olysio should be administered with both peginterferon alfa and ribavirin. The recommended treatment duration of Olysio with peginterferon alfa and ribavirin is 12 weeks, followed by either 12 or cc36 additional weeks of peginterferon alfa and ribavirin depending on prior response status.

3.4. Mechanism of Action

Olysio (simeprevir) is a small molecule orally active inhibitor of the NS3/4A protease of hepatitis C virus.

3.5. Side Effects

Adverse effects associated with the use of Olysio includes: rash (including photosensitivity), pruritus, nausea.

4. IMBRUVICA (IBRUTINIB)

4.1. Company

Pharmacyclics; Approved by November 2013

4.2. Treatment Area

Mantle cell lymphoma

4.3. General Information

Imbruvica (ibrutinib) is an orally available, selective inhibitor of Bruton's tyrosine kinase (Btk), a gene that is disrupted in the human disease X-linked agammaglobulenemia (XLA). It is specifically approved for mantle cell lymphoma in patients who have received at least one prior therapy. It is supplied as a capsule for oral administration. The recommended dose is 560 mg taken orally once daily (four 140 mg capsules once daily), taken with water.

4.4. Mechanism of Action

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Imbruvica (ibrutinib) is a selective inhibitor of Bruton's tyrosine kinase (Btk). It forms a covalent bond with a cysteine residue in the BTK active site, leading to inhibition of BTK enzymatic activity. BTK is a signaling molecule of the B-cell antigen receptor (BCR) and cytokine receptor pathways. BTK's crole in signaling through the B-cell surface receptors results in activation of pathways necessary for B-cell trafficking, chemotaxis, and adhesion.

4.5. Side Effects

Adverse events associated with the use of Imbruvica includes: thrombocytopenia, diarrhea, neutropenia, anemia, fatigue, musculoskeletal, pain, peripheral edema, upper respiratory tract infection, nausea, bruising, dyspnea, constipation, rash, abdominal pain, vomiting, decreased appetite.

5. APTIOM (ESLICARBAZEPINE ACETATE)

5.1. Company

Sunovion Pharmaceuticals; Approved by November 2013

5.2. Treatment Area

Partial-onset seizures

5.3. General Information

Aptiom is specifically indicated as adjunctive treatment for partial-onset seizures. It is supplied as a tablet for oral administration. The recommended initial dose is 400 mg once daily. Maximum recommended maintenance dosage is 1200 mg once daily (after a minimum of one week at 800 mg once daily).

5.4. Mechanism of Action

Aptiom (eslicarbazepine acetate) is a voltage-gated sodium channel blocker. The precise mechanism(s) by which eslicarbazepine exerts anticonvulsant activity is unknown.

5.5. Side Effects

Adverse effects associated with the use of Aptiom includes: dizziness, somnolence, nausea, headache, diplopia, vomiting, fatigue, vertigo, ataxia, blurred vision, tremor

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