ISSN 2278 – 540X EISSN 2278 – 5396

DRUG DISCOVERY

# FDA Approved Drugs - February 2014

**Vidhya V**

**Publication History**
Received: 16 February 2014
Accepted: 23 March 2014
Published: 02 April 2014

**Citation**
Vidhya V. FDA Approved Drugs - February 2014. *Drug Discovery*, 2014, 9(20), 15-17

## 1. MYALEPT (METRELEPTIN FOR INJECTION)

### 1.1. Company

Bristol-Myers Squibb; Approved by February 2014

### 1.2. Treatment Area

Lipodystrophy

### 1.3. General Information

Myalept is specifically indicated as an adjunct to diet as replacement therapy to treat the complications of leptin deficiency in patients with congenital or acquired generalized lipodystrophy. It is supplied as a solution for subcutaneous injection. Myalept should be administered as a subcutaneous injection once daily after the lyophilized cake is reconstituted with Bacteriostatic Water for Injection (BWFI) or preservative-free sterile Water for Injection (WFI). The recommended daily dosages in milligrams (mg) per kilogram (kg) of body weight are: Body weight 40 kg or less: starting dose 0.06 mg/kg/day, increase or decrease by 0.02 mg/kg to a maximum daily dose of 0.13 mg/kg. Males greater than 40 kg body weight: starting dose 2.5 mg/day, increase or decrease by 1.25 mg to 2.5 mg/day to a maximum dose of 10 mg/day. Females greater than 40 kg body weight: starting dose 5 mg/day, increase or decrease by 1.25 mg to 2.5 mg/day to a maximum dose of 10 mg/day.

### 1.4. Mechanism of Action

Myalept (metreleptin for injection) is a recombinant human leptin analog for injection that binds to and activates the leptin receptor. Adipocytes store lipids to meet the fuel requirements of non-adipose tissues during fasting. In patients with generalized lipodystrophy, the deficiency of adipose tissue leads to hypertriglyceridemia and ectopic deposition of fat in non-adipose tissues such as liver and muscle, contributing to metabolic abnormalities including insulin resistance. Native leptin is a hormone predominantly secreted by adipose tissue that informs the central nervous system of the status of energy stores in the body. In patients with generalized lipodystrophy, leptin deficiency, resulting from the loss of adipose tissue, contributes to excess caloric intake, which exacerbates the metabolic abnormalities. Myalept exerts its function by binding to and activating the human leptin receptor (ObR), which belongs to the Class I cytokine family of receptors that signals through the JAK/STAT transduction pathway.



Vidhya V,
FDA Approved Drugs - February 2014,
Drug discovery, 2014, 9(20), 15-17,

**1.5. Side Effects**

Adverse events associated with the use of Myalept includes: headache, hypoglycaemia decreased weight, abdominal pain.

## 2. NORTHERA (DROXIDOPA)

**2.1. Company**

Chelsea Therapeutics; Approved by February 2014

**2.2. Treatment Area**

Neurogenic orthostatic hypotension

**2.3. General Information**

Northera (droxidopa) is a synthetic amino acid precursor of norepinephrine. It is specifically indicated for the treatment of orthostatic dizziness or lightheadedness in adult patients with symptomatic neurogenic orthostatic hypotension caused by primary autonomic failure (Parkinson's disease, multiple system atrophy, and pure autonomic failure), dopamine beta-hydroxylase deficiency, and non-diabetic autonomic neuropathy. It is supplied as a capsule for oral administration. The recommended starting dose is 100 mg three times during the day. It may be titrated by 100 mg three times daily, up to a maximum dose of 600 mg three times daily. It should be administered consistently with or without food. To reduce the potential for supine hypertension, elevate the head of the bed and give the last dose at least 3 hours prior to bedtime. The effectiveness of Northera beyond 2 weeks is uncertain, and patients should be evaluated periodically to determine whether Northera is continuing to provide a benefit.

**2.4. Mechanism of Action**

Northera (droxidopa) is a synthetic amino acid analog that is directly metabolized to norepinephrine by dopa-decarboxylase, which is extensively distributed throughout the body. The exact mechanism of action of Northera in the treatment of neurogenic orthostatic hypotension is unknown. Northera is believed to exert its pharmacological effects through norepinephrine and not through the parent molecule or other metabolites. Norepinephrine increases blood pressure by inducing peripheral arterial and venous vasoconstriction.

**2.5. Side Effects**

Adverse events associated with the use of Northera includes: headache, dizziness, nausea, hypertension, fatigue.

## 3. TIVORBEX (INDOMETHACIN)

**3.1. Company**

Iroko Pharmaceuticals; Approved by February 2014

**3.2. Treatment Area**

Acute pain

**3.3. General Information**

Tivorbex is specifically indicated for treatment of mild to moderate acute pain in adults. It is supplied as a capsule for oral administration. The recommended dose is 20 mg orally three times daily or 40 mg orally two or three times daily. Use the lowest effective dose for the shortest duration consistent with individual patient treatment goals.

**3.4. Mechanism of Action**

Tivorbex (indomethacin) is a submicron particle, low dose formulation of indomethacin, a non-steroidal anti-inflammatory drug (NSAID) with analgesic and antipyretic and analgesic properties. The mechanism of action of Tivorbex like that of other NSAIDs, is not completely understood but involves inhibition of cyclooxygenase (COX-1 and COX-2).

**3.5. Side Effects**

Adverse events associated with the use of Tivorbex includes: nausea, post procedural edema, headache, dizziness, vomiting, post procedural hemorrhage, constipation, pruritus, diarrhea, dyspepsia, post procedural swelling, presyncope, rash, abdominal pain (upper), somnolence, pruritus generalized, hyperhidrosis, decreased appetite, hot flush, syncope.

## 4. VIMIZIM (ELOSULFASE ALFA)

**4.1. Company**

BioMarin; Approved by February 2014



Vidhya V,
FDA Approved Drugs - February 2014,
Drug discovery, 2014, 9(20), 15-17,

**4.2. Treatment Area**
Mucopolysaccharidosis type IVA

**4.3. General Information**
Vimizim is an enzyme replacement therapy, presumed to include a recombinant human form of N-acetylgalactosamine-6-sulfatase. It is specifically indicated for Mucopolysaccharidosis type IVA (MPS IVA; Morquio A syndrome). It is supplied as a solution for intravenous administration. The recommended dose is 2 mg per kg given intravenously over a minimum range of 3.5 to 4.5 hours, based on infusion volume, once every week. Pre-treatment with antihistamines with or without antipyretics is recommended 30 to 60 minutes prior to the start of the infusion.

**4.4. Mechanism of Action**
Vimizim is a formulation of elosulfase alfa, which is a purified human enzyme produced by recombinant DNA technology in a Chinese hamster ovary cell line. Mucopolysaccharidoses comprise a group of lysosomal storage disorders caused by the deficiency of specific lysosomal enzymes required for the catabolism of glycosaminoglycans (GAG). Mucopolysaccharidosis IVA (MPS IVA, Morquio A Syndrome) is characterized by the absence or marked reduction in N-acetylgalactosamine-6-sulfatase activity. The sulfatase activity deficiency results in the accumulation of the GAG substrates, KS and C6S, in the lysosomal compartment of cells throughout the body. The accumulation leads to widespread cellular, tissue, and organ dysfunction. It is intended to provide the exogenous enzyme N-acetylgalactosamine-6-sulfatase that will be taken up into the lysosomes and increase the catabolism of the GAGs KS and C6S. Elosulfase alfa uptake by cells into lysosomes is mediated by the binding of mannose-6-phosphate-terminated oligosaccharide chains of elosulfase alfa to mannose-6-phosphate receptors.

**4.5. Side Effects**
Adverse effects associated with the use of Vimizin includes: pyrexia, vomiting, headache, nausea, abdominal pain, chills, fatigue.

## 5. IMBRUVICA (IBRUTINIB)

**5.1. Company**
Pharmacyclics; Approved by February 2014

**5.2. Treatment Area**
Chronic lymphocytic leukemia

**5.3. General Information**
Imbruvica (ibrutinib) is an 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 chronic lymphocytic leukemia in patients who have received at least one prior therapy. It is supplied as a capsule for oral administration. The recommended dose is 420 mg taken orally once daily (three 140 mg capsules once daily). Capsules should be taken orally with a glass of water. Do not open, break, or chew the capsules.

**5.4. Mechanism of Action**
Imbruvica (ibrutinib) is an orally available, selective inhibitor of Bruton's tyrosine kinase (Btk). Ibrutinib 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.

**5.5. Side Effects**
Adverse events associated with the use of Imbruvica for chronic lymphocytic leukemia includes: thrombocytopenia, diarrhea, bruising, neutropenia, anemia, upper respiratory tract infection, fatigue, musculoskeletal pain, rash, pyrexia, constipation, peripheral edema, arthralgia, nausea, stomatitissinusitis, and dizziness.



Vidhya V,
FDA Approved Drugs - February 2014,
Drug discovery, 2014, 9(20), 15-17,