



SEVEN HILLS TIMES

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In association with Sri Padmavathi Medical
College for Women, Alipiri Road, Tirupati,
Chittoor (Dist.),
Andhra Pradesh, India.

www.shcptirupati.com; shcpdic333@gmail.com

Phone: 7730084513, 7702484513

Editorial Board

Dr.M.Niranjan Babu, Dr.Subhashis Debnath,
Dr.B.Narasimhulu, Mrs.P.Rihana Begum,
Mr.R.Venkatesan.

Student Co-ordinators

T. Charan Teja, E.Suneel Babu,
N.Bhanu, B.Shareef, V.Sai Nelatha.

DRUG PROFILE OF DALFAMPRIDINE

Dr.B.Narasimhulu, Asst. Professor, SHCP, Tirupati

The U.S. Food and Drug Administration (FDA) have approved Oral: Ampyra: 10 mg Improvement of walking in patients with multiple sclerosis (MS). Dalfampridine is a potassium channel blocker. Exactly how it works is not known. It is thought to increase nerve function that will improve walking in patients with MS.

Dosage Forms: Excipient information presented when available (limited, particularly for generics); consult specific product labeling. Tablet Extended Release 12 Hour, Oral: Ampyra: 10 mg

Category: Potassium Channel Blocker

Mechanism of action: Nonspecific potassium channel blocker which improves conduction in focally demyelinated axons by delaying repolarization and prolonging the duration of action potentials. Enhanced neuronal conduction is thought to strengthen skeletal muscle fiber twitch activity, thereby, improving peripheral motor neurologic function.

Pharmacokinetics parameters:

Absorption: Rapid and complete, Distribution: Vd: 2.6 L/kg, Metabolism: Limited metabolism; in vitro data suggests hepatic metabolism to 3-hydroxy-4-aminopyridine occurs primarily via CYP2E1; further conjugated to 3-hydroxy-4-aminopyridine sulfate; metabolites are inactive, Excretion: Urine (96%; 90% of total dose as unchanged drug); feces (0.5%), Time to Peak Plasma: 3-4 hours Half-Life Elimination: 5.2-6.5 hours; prolonged in severe renal impairment (~3 times longer) **Protein Binding:** Negligible; predominantly unbound to plasma proteins.

Use: Labeled Indications: Treatment to improve walking in patients with multiple sclerosis (MS)

Contraindications: Hypersensitivity to Dalfampridine, 4-aminopyridine, or any component of the formulation; history of seizure; moderate or severe renal impairment (CrCl \leq 50 mL/minute Dosing: Adult: Multiple sclerosis: Oral: 10 mg every 12 hours (maximum daily dose: 20 mg); no additional benefit seen with doses $>$ 20 mg daily, Administration: May be administered with or without food. Do not chew, crush, dissolve, or divide tablet. Dietary Considerations: May be taken with or without food. Storage: Store at 25°C (77°F); excursions permitted to 15°C to 30°C (59°F to 86°F).

Drug Interactions: Cimetidine, Metformin, Quinidine.

Adverse Reactions: $>$ 10%: Genitourinary: Urinary tract infection (12%) 1% to 10%, Central nervous system: Insomnia (9%), dizziness (7%), headache (7%), equilibrium disturbance (5%), paresthesia (4%), Gastrointestinal: Nausea (7%), constipation (3%), dyspepsia (2%), Neuromuscular & skeletal: Weakness (7%), back pain (5%), acute exacerbations of multiple sclerosis (4%), Respiratory: Nasopharyngitis (4%), pharyngolaryngeal pain (2%) $<$ 1% (Limited to important or life-threatening).

Warnings/Precautions: Anaphylaxis, Seizures, Urinary tract infection.

Disease-related concerns: Renal impairment: Use in renal impairment is associated with an increased risk of seizure and other adverse events, primarily neurologic effects, due to increased serum concentrations; elimination is predominately via the kidneys as unchanged drug. Monitoring **Parameters:** Renal function (baseline and at least annually thereafter); EEG; walking ability.

Pregnancy Risk Factor: C Pregnancy Considerations: Adverse events have been observed in animal reproduction studies, including decreased growth and death.

Patient Education: Patient may experience nausea, headache, loss of strength and energy, insomnia, back pain, rhinitis, pharyngitis, or constipation. Have patient report immediately to prescriber signs of a urinary tract infection (hematuria, burning or painful urination, polyuria, fever, lower abdominal pain, or pelvic pain), severe dizziness, passing out, severe loss of strength and energy, seizures, change in balance, shortness of breath, or burning or numbness feeling (HCAHPS). Educate patient about signs of a significant reaction (eg, wheezing; chest tightness; fever; itching; bad cough; blue skin color; seizures; or swelling of face, lips, tongue, or throat). Note: This is not a comprehensive list of all side effects. Patient should consult prescriber for additional questions.

References:

1. <https://www.drugs.com/pro/ampyra.html>
2. <http://www.rxlist.com/ampyra-drug/patient-images-side-effects.html>
3. <http://www.webmd.com/drugs/2/drug-153645/dalfampridine-oral/details>

DISEASE KNOWLEDGE ON AUTISM SPECTRUM DISORDER

Mrs.P.Rihana Begum, Asst. Professor, SHCP, Tirupati

Definition: Autism is a brain disorder that often makes it hard to communicate with and relate to others. With autism, the different areas of the brain fail to work together.

Causes: Autism tends to run in families, so experts think it may be something that you inherit. Scientists are trying to find out exactly which genes may be responsible for passing down autism in families. Other studies are looking at whether autism can be caused by other medical problems or by something in your child's surroundings. It's important to make sure that your child gets all childhood vaccines. They help keep your child from getting serious diseases that can cause harm or even death.

Symptoms: Symptoms almost always start before a child is 3 years old. Usually, parents first notice that their toddler has not started talking yet and is not acting like other children the same age. But it is not unusual for a child with autism to start to talk at the same time as other children the same age, then lose his or her language skills.

These are common characteristics children with autism may have, but not everyone will have these characteristics and how severe they are also changes from person to person.



repetitive style of playing



Might not want to look people in the eyes



May prefer to be alone



Might have trouble speaking



Prefers to do things the same way, like following the same routine or eating the same food



May echo words or phrases others say



Might enjoy spinning objects or spinning themselves



May have trouble playing or talking with other children

Always
Unique
Totally
INTERESTING
Sometimes
Mysterious

- A delay in learning to talk, or not talking at all. A child may seem to be deaf, even though hearing tests are normal. Repeated and overused types of behavior, interests, and play. Examples include repeated body rocking, unusual attachments to objects, and getting very upset when routines change.
- There is no "typical" person with autism. People can have many different kinds of behaviors, from mild to severe. Parents often say that their child with autism prefers to play alone and does not make eye contact with other people.

Our Perfect Clicks



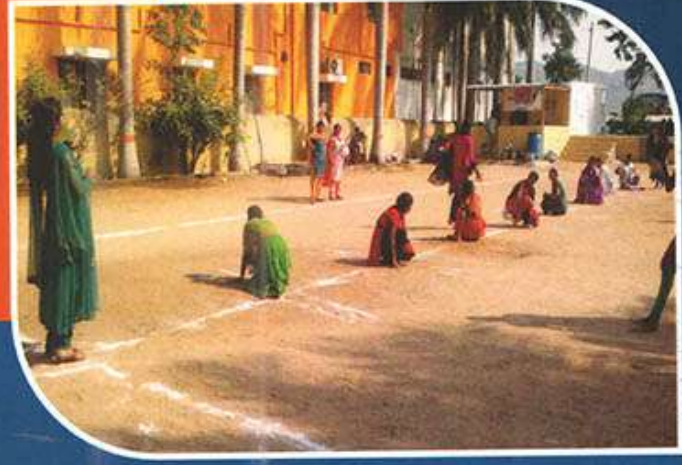
2nd International Conference on Pharmacoeconomics and Outcome Research at Seven Hills College of Pharmacy, Tirupati on 21st & 22nd April 2017



N. Bhanu Receiving Award for the Best Poster Presentation at ISPOR 21st & 22nd April 2017



Pharma Utsav Celebrations at SHCP, Tirupati - 06-08th March 2017



Awareness on World Cancer Day Rally at SHCP - 04th February 2017



World Health Day Celebration's at SHCP - 07th April 2017



We welcome suggestions from the readers.
Drop Your Suggestions at principal.shcp@gmail.com



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Dr. Geisha Merin Varghese

Student Co-ordinators

K. Vamsi, M. Madhurima, T. Muni Kiran

While the virus has
been detected in
breast milk, there
are no reports of
transmission via
breastfeeding



Fig 1: ZIKA Virus

Modes of Transmission

- Through mosquito bites
- From mother to child
- Through sex
- Through blood transfusion
- Through laboratory and healthcare setting exposure

Life style modifications

There is no specific treatment or vaccine to prevent Zika virus, so prevention is key.

- o The best way to prevent diseases spread by mosquitoes is to avoid being bitten altogether.
- o Stay in places with air conditioning or that use window and door screens to keep mosquitoes outside.
- o Remove sources of standing water, which can become a breeding ground for mosquitoes.
- o Remember that mosquitoes that spread Zika virus may be more likely to bite during daytime hours.
- o Apply insect repellents and reapply as directed. Check with your doctor about what kinds of repellents are safe to use in pregnancy.
- o Wear long-sleeved shirts and long pants and tuck your pants into your socks when outdoors.
- o Wear light-colored clothing, since mosquitos are thought to be more attracted to darker colors.
- o Avoid the use of scented skin care products.
- o Sleep under a mosquito net.
- o Understanding prevention now is key, and that means taking the necessary precautions to avoid being bitten.

CLINICAL KNOWLEDGE ON ZIKA VIRUS

A virus transmitted by mosquitoes which typically causes asymptomatic or mild infection (fever and rash) in humans, identified originally in Africa and later in other tropical regions, including South America, where it may be associated with an increased incidence of microcephaly in babies born to mothers infected during pregnancy.

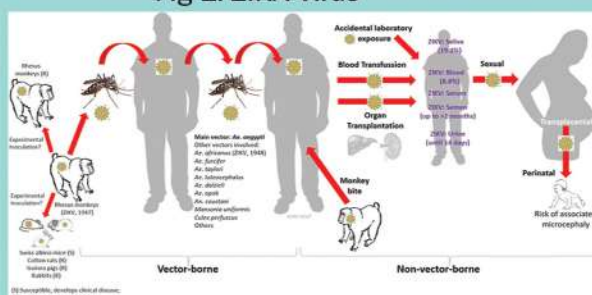
Epidemiology:

Historically, ZIKV spread eastward from equatorial Africa and Asia to the Pacific Islands during the late 2000s to early 2010s, invaded the Caribbean and Central and South America in 2015, and reached North America in 2016.

Etiology:

- ✦ Zika virus is a single-stranded RNA virus of the Flaviviridae family (genus Flavivirus), and is related to the dengue, yellow fever, West Nile, and Japanese encephalitis viruses.
- ✦ Zika virus RNA has been detected in body fluids other than blood and semen, including amniotic fluid, CSF, urine, saliva, vaginal secretions, and ocular fluids; however, transmission via these body fluids has not yet been fully elucidated.
- ✦ The virus may persist for up to 80 days in the blood, and persists in the blood longer than plasma.
- ✦ The virus has been detected in the genital tract of an infected woman, which may have implications for vertical transmission.
- ✦ It has also been detected in fetal tissue.
- ✦ Viremia has been reported in a newborn at least 67 days after birth.

Signs and Symptoms



Lonhala Magnair Approval History

- FDA approved: Yes (First approved December 5th, 2017)
- Brand name: Lonhala Magnair
- Generic name: glycopyrrolate
- Dosage form: Inhalation Solution
- Company: Sunovion Pharmaceuticals Inc.
- Treatment for: COPD

DESCRIPTION

- LONHALA MAGNAIR consists of LONHALA vials and a MAGNAIR nebulization system. LONHALA (glycopyrrolate) Inhalation Solution is a sterile, clear, colorless, aqueous solution for oral inhalation. Glycopyrrolate USP, the active component of LONHALA Inhalation Solution, is chemically described as (3RS)-3-[(2SR)-(2-cyclopentyl-2-hydroxy-2-penylacetyl)oxy]-1,1-dimethylpyrrolidinium bromide. Glycopyrrolate is a synthetic quaternary ammonium compound that acts as a competitive antagonist at muscarinic acetylcholine receptors, also referred to as an anticholinergic. Glycopyrrolate, C₁₉H₂₈BrNO₃, is a white, odorless, crystalline powder that is soluble in water and in alcohol. It has a molecular mass of 398.33.
- The inactive ingredients in LONHALA are: citric acid monohydrate, sodium chloride, sodium hydroxide and water for injection. LONHALA Inhalation Solution is supplied in low-density polyethylene (LDPE) unit dose vials, each containing 1.0 mL of the solution. Each unit-dose vial contains 25 mcg of glycopyrrolate in a sterile, isotonic saline solution, pH-adjusted to 4.0 with citric acid and sodium hydroxide. Like all other nebulized treatments, the amount delivered to the lungs will depend upon patient factors. Under standardized in-vitro testing per USP adult breathing pattern (500 mL tidal volume, 15 breaths per minute, and inhalation: exhalation ratio of 1:1), the mean delivered dose from the mouthpiece was approximately 14.2 mcg of glycopyrrolate (equivalent to 11.4 mcg glycopyrronium and 56.8% label claim). The mass median aerodynamic diameter (MMAD) of the nebulized aerosol particles/droplets is 3.71 µm 95% CI (2.92 - 4.49 µm) as determined using the Next Generation Impactor (NGI) method. The mean nebulization time was approximately 2 to 3 minutes.

COMPOSITION OF DRUG

Lonhala vials & Magnair nebulization system

Active ingredient :Glycopyrrolate

MECHANISM OF ACTION

- Glycopyrrolate is a long-acting muscarinic antagonist, which is often referred to as an anticholinergic. It has similar affinity to the subtypes of muscarinic receptors M1 to M5. In the airways, it exhibits pharmacological effects through inhibition of M3 receptor at the smooth muscle leading to bronchodilation. The competitive and reversible nature of antagonism was shown with human and animal origin receptors and isolated organ preparations. In preclinical in vitro as well as in vivo studies, prevention of methacholine and acetylcholine induced bronchoconstrictive effects was dose-dependent and lasted longer than 24 hours. The clinical relevance of these findings is unknown. The bronchodilation following inhalation of glycopyrrolate is predominantly a site-specific effect.

DRUG INTERACTIONS

Sympathomimetics and Steroids

In clinical studies, concurrent administration of glycopyrrolate and other drugs commonly used in the treatment of COPD including sympathomimetics (long and short-acting beta2 agonists), anticholinergics (short-acting anti-muscarinic antagonists) and oral and inhaled steroids showed no increases in adverse drug reactions.

Anticholinergics

There is a potential for an additive interaction with concomitantly used anticholinergic medications. Therefore, avoid unnecessary co-administration of LONHALA MAGNAIR with other anticholinergic-contain



Lonhala Magnair™
(glycopyrrolate) Inhalation Solution
25 mcg/1 mL

NOW APPROVED
For patients with COPD

LONHALA MAGNAIR™
(glycopyrrolate) Inhalation Solution

**The first and only nebulized LAMA is coming soon,
available in Spring 2018**

LONHALA MAGNAIR is a LAMA indicated for the long-term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

LAMA=long-acting muscarinic antagonist.

ADVERSE REACTIONS

- The following adverse reactions are described in greater detail in other sections:
- Paradoxical bronchospasm
- Immediate hypersensitivity reactions
- Worsening of narrow-angle glaucoma
- Worsening of urinary retention

CONTRAINDICATIONS

- LONHALA MAGNAIR is contraindicated in patients with a hypersensitivity to glycopyrrolate or any of the ingredients.

INDICATIONS AND USAGE

- LONHALA MAGNAIR is indicated for the long-term maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and/or emphysema.

DOSAGE AND ADMINISTRATION

For oral inhalation only. Do not swallow LONHALA solution. LONHALA vials should only be used with MAGNAIR. The recommended dose of LONHALA is the inhalation of the contents of one LONHALA vial twice-daily using MAGNAIR. LONHALA vials should only be administered with MAGNAIR. Patients should be instructed on the correct use of this drug product and device. LONHALA MAGNAIR should be administered at the same time of the day, (1 vial in the morning and 1 vial in the evening), every day. More frequent administration or a greater number of inhalations (more than 1 vial twice daily) of LONHALA MAGNAIR is not recommended. Store LONHALA vials in the foil pouch, and only remove IMMEDIATELY BEFORE USE with MAGNAIR. No dosage adjustment is required for geriatric patients, patients with hepatic impairment, or patients with mild to moderate renal impairment.

PATIENT COUNSELLING

- Not for Acute Symptoms: Inform patients that LONHALA MAGNAIR is not meant to relieve acute symptoms of COPD and extra doses should not be used for that purpose. Advise them to treat acute symptoms with a rescue inhaler such as albuterol. Provide patients with such medicine and instruct them in how it should be used [see Warnings and Precautions (5.1)]. Instruct patients to seek medical attention immediately if they experience any of the following:
Symptoms get worse
- Need for more inhalations than usual of their rescue inhaler
- Patients should not stop therapy with LONHALA MAGNAIR without physician/provider guidance since symptoms may recur after discontinuation

PERFECT CLICK



Freshers Orientation Programme



Teachers Day Celebration conducted by Sambhodhini



Freshers Day Celebration
Chief Guest Narasimha Yadav Garu Chairman TUDA



Freshers Day Celebration



Campus Selection



Medical Camp



Rally conducted during Vigilance Awareness Week



Free Health Awareness Programme conducted at College



Blood Donation Camp



Swacch Bharat

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