# HYDRYLLIN SYRUP
**(AMINOPHYLLINE PLUS COMPOUND SYRUP)**

**COMPOSITION**
Each 5ml contains:
Aminophylline Ph. Eur. ……..... 32 mg
Diphenhydramine HCl BP …..... 8 mg
Ammonium Chloride Ph. Eur. ….. 30 mg
Menthol BP…… 0.98 mg

**THERAPEUTIC INDICATIONS**

For the oral symptomatic relief of common coughs (such as dry and/or tickly, or troublesome cough) associated with upper respiratory tract congestion.

**DOSAGE AND ADMINISTRATION**

**Adults:**
5 -10 ml (1-2 teaspoons)
Every 4- 6 hours as indicated.

**Children:**
2-6 years
Upto 2.5 ml (1/4 -1/2 teaspoon)
Every 4- 6 hours as indicated.

7-12 years
2.5 ml – 5 ml (1/2 -1 teaspoon)
Every 4- 6 hours as indicated.

If required an additional extra dose may be taken after the first 2 hours.

**Method Of Administration**

Oral

**CONTRAINDICATIONS**

• Hypersensitivity to any of the ingredients

• Patients on monoamine oxidase inhibitor therapy within previous 14 days

**SPECIAL WARNINGS AND PRECAUTIONS FOR USE**

Do not combine with other treatments for coughs and colds.

The Syrup should be used with caution in patients with the following conditions: prostatic hypertrophy, urinary retention, susceptibility to 'closed angle' glaucoma and hepatic disease.

The Syrup may cause drowsiness.

Seek medical advice when suffering from chronic or persistent cough and when suffering from asthma, and acute asthmatic attack or where cough is accompanied by excessive secretions

Keep out of the reach and sight of children.

Should be use with caution if there is a history of hypersensitivity or allergic to aminophylline.

Before using this medication, tell doctor or pharmacist your medical history, especially of:

- stomach/intestinal ulcer
- seizures
- thyroid disease
- heart problems (such as heart failure, irregular heartbeat)
- liver disease
- high blood pressure

If get sick or have a fever while taking this medication, tell the doctor right away. The dose of your medicine may need to be adjusted.

Older adults may be more sensitive to the side effects of this drug, especially fast/irregular heartbeat, or trouble sleeping. Careful monitoring of side effects and drug blood levels is recommended.

Children may be more sensitive to the side effects of this drug. Careful monitoring of side effects and drug blood levels is recommended.under

**DRUG INTERACTIONS**

Additive CNS depressant effects with alcohol and other CNS depressants including barbiturates, hypnotics, opioid analgesics, anxiolytic sedatives and anti-psychotics.

• Additive anti-muscarinic effects with other drugs of similar properties such as atropine and some anti-depressants.

• Not to be taken in patients taking monoamine oxidase inhibitors (MAOIs) or within 14 of stopping treatment as there is a risk of serotonin syndrome.

• Diphenhydramine can inhibit the oxidative metabolism of some drugs.

• Diphenhydramine may enhance the effects of ephedrine.

• Diphenhydramine may mask the response of the skin to allergenic skin tests and also the ototoxic symptoms associated with certain antibiotics.

Aminophylline may interact with:

- riociguat

Other medications can affect the removal of aminophylline from body, which may affect how Aminophylline works. Examples include cimetidine, disulfiram, fluvoxamine, interferon, mexiletine, propranolol, rifampin, drugs used to treat seizures (such as carbamazepine, phenytoin), St. John's wort, ticlopidine, among others.

Cigarette/marijuana (cannabis) smoking decreases blood levels of this medication

Caffeine and alcohol can increase the side effects of this medication. Avoid drinking large amounts of beverages containing alcohol or caffeine (such as coffee, tea, colas), eating large amounts of chocolate, or taking non-prescription products that contain caffeine.

Aminophylline is very similar to theophylline and oxtriphylline. Do not use medications containing Theophylline or oxtriphylline while using Aminophylline.

This medication may interfere with certain laboratory tests (such as blood sugar, cholesterol, uric acid, dipyridamole-thallium imaging tests), possibly causing false test results.

**FERTILITY, PREGNANCY AND LACTATION**

During pregnancy, this should be used only when clearly needed. Discuss the risks and benefits with doctor. Changes in body during the last 3 months of pregnancy may affect the amount of this drug in your blood. Your doctor should carefully monitor the amount of drug in your blood, as well as any side effects, so that your dose may be changed if needed.

This drug passes into breast milk and may have undesirable effects on a nursing infant. Consult the doctor before breast-feeding.

**EFFECTS ON ABILITY TO DRIVE**

The syrup may cause drowsiness. Do not drive or operate machinery. Avoid alcoholic drink.

**ADVERSE DRUG REACTIONS**

The overall percentage of treated patients expected to experience adverse reactions is unknown.

Common side effects include:

CNS effects such as nervous drowsiness (usually diminishes within a few days), paradoxical stimulation, nervous headache, nervous psychomotor impairment.

Anti-muscarinic effects such as urinary retention, dry mouth, blurred vision, gastrointestinal disturbances and thickened respiratory tract secretions.

Rare side effects include:

Hypotension, extrapyramidal effects, dizziness, confusion, depression, sleep disturbances, tremor, convulsions, palpitation, arrhythmia, hypersensitivity reactions, blood disorders and liver dysfunction.

| Organ system Class | Common ADRs<br><br>>1/100, < 1/10 | Uncommon ADRs<br><br>>1/1,000, <1/100 | Rare ADRs<br><br>>1/10,000, <1/1000 |
|---|---|---|---|
| Blood Lymphatic System Disorder | | | Blood Disorders NOS |
| Cardiac Disorder | | | Palpitation, arrhythmia |
| Eye Disorders | Blurred vision | | |
| Gastrointestinal Disorder | Dry mouth, gastrointestinal disturbance | | |
| General Disorder | Paradoxical drug reaction | | |
| Hepatobiliary Disorder | | | Liver Disorder |
| Immune System Disorders | | | Hypersensitivity |
| Nervous System Disorders | Psychomotor skills impairment, drowsiness, headache | | Tremor, convulsions, extrapyramidal disorder, dizziness |
| Psychiatric Disorders | | | Confusion, depression, sleep disturbances |
| Renal and Urinary Disorder | Urinary retention | | |
| Respiratory Disorder | Increased upper airway secretion | | |
| Vascular Disorders | | | Hypotension |

With Aminophylline nausea/vomiting, stomach/abdominal pain, headache, trouble sleeping, diarrhea, irritability, restlessness, nervousness, shaking, or increased urination may occur. If any of these effects last or get worse, tell the doctor or pharmacist promptly.

if have any serious side effects, including:

- nausea/vomiting that doesn't stop
- fast/slow/irregular heartbeat
- muscle cramps
- fainting
- confusion
- dizziness

Get medical help right away if have any very serious side effects, including:

- seizures

A very serious allergic reaction to this drug is rare. However, get medical help right away if notice any symptoms of a serious allergic reaction, including:

- rash
- itching/swelling (especially of the face/tongue/throat)
- severe dizziness
- trouble breathing

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via pv@searlecompany.com

**OVERDOSAGE**

Symptoms of overdosage include those due to diphenhydramine or menthol (drowsiness, dizziness, ataxia, anti-cholinergic effects, pyrexia, headaches, convulsions, hallucinations, excitement and respiratory depression).

Treatment consists of gastric lavage and aspiration. Administration of activated charcoal may help. Other symptomatic and supportive measures should be provided.

**PHARMACOLOGICAL PROPERTIES**

**Pharmacodynamic properties**

**Pharmacotherapeutic group:** Antihistamines for systemic use

**ATC code:** R06AA52

**Pharmacodynamics**

*Diphenhydramine* possesses antitussive, antihistaminic, and anticholinergic properties and suppresses the urge to cough. It also dries up secretions in the nose and chest. Experiments have shown that the antitussive effect is discrete from its sedative effect. Taken at night will assist sleeping

*Ammonium Chloride* "Traditional" Expectorant.

*Menthol* Subjective relief of upper respiratory congestion, it has mild local anaesthetic and cooling effect.

Aminophylline It is a bronchodilator that relax the muscles in the bronchial tubes (air passages) of the lungs.

oral solution is a thick demulcent, which in the buccal cavity and throat forms a soothing film over the mucous membrane. This brings it into contact with the sensitive nerve endings of the throat lining.

**Pharmacokinetic properties**

***Diphenhydramine***

Is a histamine receptor antagonist Main site of metabolic transformation is the liver. Oral availability - 50%, Plasma bound - 80%, Half-life - 4 hours

***Ammonium Chloride***

Effectively absorbed from GI tract. Ammonium Ion converted to urea by the liver.

Acid ion released gives mild metabolic acidosis.

***Menthol***

After absorption menthol is excreted in the urine and bile as a glucuronide.

**Aminophylline**

Aminophylline does not undergo any appreciable pre-systemic elimination, distributes freely into fat-free tissues and is extensively metabolized in the liver.

**Pharmacokinetics in special populations**

No data available

**PRECLINICAL SAFETY DATA**

There are no preclinical data of relevance, within are additional to those already included in other sections of the leaf insert

**PRESENTATION**

Hydryllin Syrup is available in a bottle of 120ml syrup.

**INSTRUCTIONS**

- Store in cool, dry, dark place away from direct sunlight, heat and moisture.
- Do not store & transport above 30ºC.
- Keep the cap tightly closed & store in original packaging.
- Keep out of the reach of the children.
- Do not refrigerate.
- Avoid freezing.

**REGISTRATION NUMBER: 000016**

***Mfg. Searle Specs.***
**Manufactured by**:
The Searle Company Limited
32-Km, Multan Road, Lahore-Pakistan.

1012006339-001

**DATE OF PUBLICATION**

**July 2021**

**DATE OF REVISION**

**August 2025**

**SPL/SPC-HYD./825-000(002)**