

## COMPOUNDED AMLEXANOX: NOVEL USES FOR AN OLD DRUG

Do you have patients with chronic inflammatory conditions, autoimmune diseases, metabolic dysregulation and other chronic conditions who are treatment-refractory? They may be good candidates for compounded amlexanox.

### What Is Compounded Amlexanox?

Amlexanox, a novel antiallergic and anti-inflammatory drug, has recently been found to have a much broader list of applications, ranging from metabolic disease and mast cell stabilization to immunomodulation and correction

of gene expression.<sup>1</sup> Previously branded as Apthasol<sup>®</sup> oral paste, amlexanox was originally used topically to treat recurrent aphthous ulcers in the mouth.<sup>2</sup> No longer available in the U.S. as a commercially available product, amlexanox is available only as a compounded product and comes in an oral capsule formulation at Physicians Preference Pharmacy.

In other countries, such as Japan, amlexanox is still being used to successfully treat asthma, allergic rhinitis and conjunctivitis.<sup>3</sup> Due to its structural similarity to sodium cromoglycate, an antihistaminic mast cell stabilizer, amlexanox functions as a sister compound to products such as Cromolyn<sup>®</sup>, Nasalcrom<sup>®</sup> and Gastrocrom<sup>®</sup>. Amlexanox has been found to be clinically effective for atopic conditions as well, but most importantly, it plays a strong role in balancing the immune system and improving inflammatory conditions in difficult-to-treat patients.

### BENEFITS/USES OF AMLEXANOX

<b>Mast cell stabilizer:</b>	Reduces release of histamine and leukotriene mediators in mast cells, neutrophils and monocytes.
<b>Cancer:</b>	Inhibits Th17 cells but not Th1 cells.
<b>Longevity and inflammation:</b>	Promotes cellular autophagy via the mTOR pathway and induces apoptosis.
<b>Metabolic disease, obesity and diabetes:</b>	Stimulates lipolysis via AMPK and reduces insulin resistance, stimulates the mitochondria, and lowers cholesterol. If obesity is caused by Th17-driven inflammation, visceral fat tissue may become resistant to lipolysis, leading to obesity, insulin resistance and metabolic syndrome. Amlexanox helps lower Th17 inflammation, sensitizing the fat cells to lipolysis and leading to fatty acid oxidation and reduction in fat volume. <sup>4</sup>

### HOW TO ORDER

#### Call or fax your prescriptions:

 Fax 281.828.9669

 Tel 281.828.9088

### NEED SUPPLIES?

For Rx sheets, product catalogs, and supportive materials, please call or email us:

 281.828.9088

 [pharmacy@physicianspreferencrx.com](mailto:pharmacy@physicianspreferencrx.com)

 [physicianspreferencrx.com](http://physicianspreferencrx.com)

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### ACCREDITED

*Physicians Preference Pharmacy is a Houston-based, PCAB-accredited compounding pharmacy serving physicians and patients since 2001. We are licensed to work with and ship to doctors and patients in 48 states (excludes NV, AL). Our standards are more stringent than those of the United States Pharmacopeia (USP). Physicians Preference Pharmacy ranks first in Houston for the number of samples sent for potency testing and in the top 8% of pharmacies nationwide.*

## BENEFITS/USES OF AMLEXANOX continued

<b>Immunomodulator:</b>	Modulates macrophages, balances Th1 and Th2 cells and regulates T cell function.
<b>Genetics:</b>	May correct gene expression in cystic fibrosis, specifically the nonsense gene mutation which leads to the characteristic malfunctioning chloride channel present in the disease. In Duchenne muscular dystrophy (progressive muscle degeneration due to protein dysfunction), amlexanox overrides stop codons to restore appropriate gene function.
<b>Asthma, allergies and bronchodilator:</b>	Inhibits phosphodiesterase and cAMP, leading to bronchodilation and reduction of inflammation. Amlexanox decreases allergic responses by inhibiting histamine release from mast cells. <sup>5</sup>
<b>Neurodegeneration:</b>	Decreases inflammation and oxidative stress.
<b>Psoriasis:</b>	Reduces inflammation and balances Th1 and Th2 cells.
<b>Erectile dysfunction:</b>	Promotes maintenance of an erection due to PDE-5 inhibition.
<b>Vasodilation:</b>	Reduces blood pressure and improves circulation.
<b>Non-alcoholic fatty liver disease (NAFLD) and liver cirrhosis:</b>	Activates AMPK and reduces inflammation.
<b>Long-haul syndrome/mast cell activation:</b>	Reduces brain fog, improves oxygen delivery to the lungs, reduces histamine release and associated inflammation and inhibits IgE-mediated degranulation of mast cells. <sup>6</sup>
<b>Antifibrotic:</b>	Binds to fibroblast growth factor 1 (FGF-1), useful in atherosclerosis (a type of fibrosis), liver cirrhosis, NAFLD and fibrotic tissues and diseases.

### Dosing and Safety

Amlexanox is compounded in 40mg oral capsules. No side effects have been currently reported. Amlexanox 40 mg is recommended as once-daily dosing to achieve the benefits listed above.

Patients considered to be good candidates for compounded amlexanox tend to be those with chronic inflammatory conditions, autoimmune conditions, treatment-refractory disease, mast cell activation syndrome and metabolic dysregulation.

### To Learn More

For more information on amlexanox or to speak to a pharmacist about this versatile compounded medication, please contact Physicians Preference Pharmacy at 281-828-9088.

### REFERENCES

- <sup>1</sup> National Center for Biotechnology Information (2023). PubChem Compound Summary for CID 2161, Amlexanox. <https://pubchem.ncbi.nlm.nih.gov/compound/Amlexanox>.
- <sup>2</sup> Khandwala A, Van Inwegen RG, Alfano MC. 5% amlexanox oral paste, a new treatment for recurrent minor aphthous ulcers: I. Clinical demonstration of acceleration of healing and resolution of pain. *Oral Surg Oral Med Oral Pathol Oral Radiol Endod*. 1997. February;83(2):222-30. DOI: 10.1016/s1079-2104(97)90009-3 10.1016/S1079-2104(97)90009-3
- <sup>3</sup> Mucke HAM. Drug Repurposing Patent Applications April-June 2020. *Assay Drug Dev Technol*. 2020;18(8):385-390. DOI: 10.1089/adt.2020.1019
- <sup>4</sup> Amlexanox - A Repurposed Anti-Inflammatory. <https://rumble.com/v3orj0g-amlexanox-a-repurposed-anti-inflammatory.html>
- <sup>5</sup> Makino H, Saijo T, Ashida Y, Kuriki H, Maki Y. Mechanism of action of an antiallergic agent, amlexanox (AA-673), in inhibiting histamine release from mast cells. Acceleration of cAMP generation and inhibition of phosphodiesterase. *Int Arch Allergy Appl Immunol*. 1987;82(1):66-71. DOI: 10.1159/000234292
- <sup>6</sup> Shishibori T, Oyama Y, Matsushita O, et al. Three distinct anti-allergic drugs, amlexanox, cromolyn and tranilast, bind to S100A12 and S100A13 of the S100 protein family. *Biochem J*. 1999;338 ( Pt 3)(Pt 3):583-589.