Ketotifen Protocol

Intestinal Permeability “Leaky Gut Syndrome” Protocol
Dr. Kurt Woeller, D.O.

Kurt N. Woeller, DO, is an osteopathic physician specializing in natural medicine. Dr. Woeller began his study of natural medicine in 1992 as a 2nd-year medical student. Realizing his training in conventional medicine was severely lacking in the areas of nutrition and natural medicine he began a pursuit of self-education to learn about the many alternative and complementary therapies available to treat and prevent disease.

Dr. Woeller holds advanced training certificates from BioHealth Diagnostics, and is licensed from the Osteopathic Medical Board of California as an Osteopathic Physician and Surgeon. He is also a referral physician for DAN! (Defeat Autism Now!), an organization of physicians dedicated to the biological causes of autism.

Ketotifen & Intestinal Permeability

I have been using the medication Ketotifen (oral suspension or tablet) with good results. Children’s parents, and some adults taking it as well, are reporting more normal bowel movements, less gas and bloating, and decreased food reactions. Most of the time it seems to take about 2 to 3 weeks to notice these differences, but you should expect long term use and immediate results may not be seen. A trial period of 60 days is recommended. Be patient and give it time to do it’s thing, which is to reduce intestinal inflammation and promote healing of a leaky gut.

A few parents have reported some hyperactivity and drowsiness in their kids when the medication is started at full dose; which is one dose 30 minutes before each meal and an optional dose at bedtime. I now recommend that you start slowly with initial dosing. Start by increasing one dose every 2 days. For example, start the initial dose before breakfast; then after two days add another before lunch, etc. This should help offset the hyperactivity and drowsiness. Finally, if you are dosing just three times per day, and finding it difficult to administer the lunchtime dose, then simply dose before breakfast, dinner and bedtime.

Ketotifen is a prescription medication that requires a doctor’s prescription.
1mg Oral Capsules or 1mg/2cc Hypoallergenic Oral Suspension

Sincerely,
Kurt N. Woeller, DO

Please Note: College Pharmacy will dispense prescription drugs only after having received a valid patient specific prescription. Our compounded formulations are the result of prescriber requests, the purpose of any information that you may receive is to illustrate College Pharmacy compounding capabilities. These statements have not been evaluated by the FDA.
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Information About Ketotifen

General Overview:
Ketotifen works by inhibiting certain substances in the body that are known to cause inflammation. It is an antihistamine that reduces the harmful effects of histamine and promotes the healing of the intestinal wall. Ketotifen is not commercially available in the United States and must be compounded by a compounding pharmacy.

When Ketotifen is prescribed for “leaky Gut Syndrome” it is often dosed as follows: 1-2 1mg capsule (or oral suspension), 3 times daily, 30 minutes before meals, for about 6 months or up to 12 months depending on severity. Ketotifen is a prescription medication and requires a doctor’s prescription and supervision.

Commercial Names:
Ketotifen is not commercially available in the United States.
Canadian Brand Names: Apo-Ketotifen, Novo-Ketotifen, Zaditen

Before Using
In deciding to use a medicine, the risks of taking the medicine must be weighed against the good it will do. This is a decision you and your doctor will make. For this medicine, the following should be considered:

Allergies
Tell your doctor if you have ever had any unusual or allergic reaction to this medicine or any other medicines. Also tell your health care professional if you have any other types of allergies, such as to foods, dyes, preservatives, or animals. For non-prescription products, read the label or package ingredients carefully.

Pediatric
This medicine has been tested in children and, in effective doses, has not been shown to cause different side effects or problems than it does in adults.

Older Adults
Many medicines have not been studied specifically in older people. Therefore, it may not be known whether they work exactly the same way they do in younger adults or if they cause different side effects or problems in older people. There is no specific information comparing use of ketotifen in the elderly with use in other age groups.

Pregnancy
Ketotifen has not been studied in pregnant women. However, studies in animals have shown that Ketotifen crosses the placenta and, at high doses, causes problems. Before using this medicine, make sure your doctor knows if you are pregnant or if you may become pregnant.
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Breast-Feeding
It is not known whether ketotifen passes into human breast milk. However, it does pass into the milk of rats. It may be necessary for you to take another medicine or to stop breast-feeding during treatment. Be sure you have discussed the risks and benefits of the medicine with your doctor.

Drug Interactions
Although certain medicines should not be used together at all, in other cases two different medicines may be used together even if an interaction might occur. In these cases, your doctor may want to change the dose, or other precautions may be necessary. Tell your healthcare professional if you are taking any other prescription or nonprescription (over-the-counter [OTC]) medicine. When you are taking Ketotifen, it is especially important that your health care professional knows if you are taking any of the following:

- Antidiabetic Agents, oral: May increase the risk of bruising or bleeding and affect blood sugar concentrations.
- Alcohol or
- Antihistamines or
- Hypnotics or
- Sedatives: May increase the chance of side-effects (i.e., drowsiness).

Other Interactions
Certain medicines should not be used at or around the time of eating food or eating certain types of food since interactions may occur. Using alcohol or tobacco with certain medicines may also cause interactions to occur. Discuss with your healthcare professional the use of your medicine with food, alcohol, or tobacco.

Other Medical Problems
The presence of other medical problems may affect the use of this medicine. Make sure you tell your doctor if you have any other medical problems, especially:

- Diabetes Mellitus (sugar diabetes)—May alter low-sugar diet (syrup contains carbohydrates)
- Epilepsy—May increase risk of convulsions (seizures)

Proper Use
Make certain your health care professional knows if you are on any special diet, such as a low-sugar diet. The syrup contains carbohydrates.

- Ketotifen must be taken continuously in order to be effective.
- Ketotifen may be taken with or without food.
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Dosing
The dose of this medicine will be different for different patients. Follow your doctor’s orders or the directions on the label. The following information includes only the average doses of this medicine. If your dose is different, do not change it unless your doctor tells you to do so.

The amount of medicine that you take depends on the strength of the medicine. Also, the number of doses you take each day, the time allowed between doses, and the length of time you take the medicine depend on the medical problem for which you are using the medicine.

For oral dosage form (capsule and oral suspension):
Adults and children 3 years of age and older: The usual dose is 1 milligram (mg) three times daily, 30 minutes before meals. Infants and children from 6 months to 3 years of age—Dose is based on body weight and must be determined by the doctor.

Missed Dose
If you miss a dose of this medicine, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not double doses.

Storage
• Store the medicine in a closed container at room temperature, away from heat, moisture, and direct light.
• Keep from freezing.
• Keep out of the reach of children.
• Do not keep outdated medicine or medicine no longer needed.

Precautions
It is very important that your doctor check your progress at regular visits. This will allow your doctor to see if the medicine is working properly and to decide if you should continue to take it. If your symptoms worsen, you should check with your doctor.

This medicine may cause some people to become drowsy, dizzy, or less alert than they are normally. Make sure you know how you react to this medicine before you drive, use machines, or do anything else that could be dangerous if you are dizzy or are not alert.

This medicine may cause some people to become excited, irritable, or nervous or to have trouble in sleeping. These are symptoms of central nervous system stimulation and are especially likely to occur in children.
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Side Effects of This Medicine
Along with its needed effects, a medicine may cause some unwanted effects. Although not all of these side effects may occur, if they do occur they may need medical attention. Check with your doctor as soon as possible if any of the following side effects occur:

Less Common: Chills; Cough; Diarrhea; Fever; General feeling of discomfort or illness; Headache; Joint pain; Loss of appetite; Muscle aches and pains; Nausea; Runny nose; Shivering; Sore throat; Sweating; Trouble sleeping; Unusual tiredness or weakness; Vomiting.

Rare: Abdominal or stomach pain; Blistering, itching, peeling, or redness of skin; Bloody or cloudy urine; Clay-colored stools; Convulsions; Dark urine; Difficult, burning, or painful urination; Dizziness; Frequent urge to urinate; Muscle spasm or jerking of all extremities; Rash; Sudden loss of consciousness; Unpleasant breath odor; Vomiting of blood; Yellow eyes or skin.

Symptoms of Overdose
Call your doctor and get emergency help immediately if any of the following symptoms of overdose occur: Blurred vision; Confusion; Convulsions; Disorientation; Dizziness; Drowsiness (severe); Faintness or light-headedness when getting up from a lying or sitting position; Fast, pounding, or irregular heartbeat or pulse; Hyperexcitability; Loss of consciousness; Palpitations; Sweating; Unusual tiredness or weakness.

Additional Side Effects
Some side effects may occur that usually do not need medical attention. These side effects may go away during treatment as your body adjusts to the medicine. Also, your health care professional may be able to tell you about ways to prevent or reduce some of these side effects. Check with your health care professional if any of the following side effects continue or are bothersome or if you have any questions about them:

More Common: Weight Gain.

Less Common or Rare: Bloody nose; Drowsiness; Dryness of mouth; Excitation; Increased appetite; Irritability; Nervousness; Swelling of eyelids; Unexplained nosebleeds.

Other side effects not listed may also occur in some patients. If you notice any other effects, check with your healthcare professional.