

INFORMATION REGARDING ACCLYDINE

&

The 14-Week Protocol

Prepared By:

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Introduction

This information is meant for those persons who are starting (or going to start) the use of Acclodyne. Physicians and therapists can use this information for their patients. This information is the result of the experiences of physicians and patients who have used Acclodyne. Because Acclodyne is a new therapy showing great promise among patients with Chronic Fatigue Syndrome (CFS) and Fibromyalgia, all comments are important and welcome, both from physicians and patients. See section 12 for where to send comments. The Table of Contents is as follows:

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1. How does Acclodyne Work?

Many CFS and Fibromyalgia patients have poor hypothalamic function. As a result, not enough GH (growth hormone) is released, which leads to many of the typical symptoms and complaints of CFS patients. Acclodyne is harvested from a special species of potato and artichokes. It stimulates the production and release of GH in the body and also imitates the working of GH. Acclodyne stimulates the growth processes in the body just as GH does.

GH works by stimulating the production of growth factor IGF-1 (Insulin Growth Factor-1). The liver uses GH and insulin to produce IGF-1. The majority of IGF-1 is then transported by an albumin called IGF-BP-3 (Insulin Growth Factor Binding Protein-3). The IGF-1, which is not transported by IGF-BP-3 is called free IGF-1. The free IGF-1 can bind on cells, which enables cells to more readily absorb nutrients. This causes cells to grow and significantly increases their energy production. IGF-1 also stimulates cellular-defense.

Acclodyne shows to have a positive effect in two ways:

1. It stimulates the production of GH-RH in the hypothalamus. GH-RH stimulates the pituitary gland to produce GH, which is then put into circulation. The increase in GH stimulates the production of IGF-1 as described in the last paragraph. The more GH released into circulation, the more IGF-1 is produced, which is a positive for the cells.
2. Acclodyne also mimics the free IGF-1. Just as IGF-1 stimulates cellular defense and enables cells to more readily absorb and process nutrients, Acclodyne acts in a similar way.

2. Conditions to Consider Accllydine

Before considering Accllydine, one has to be sure that other diseases aren't the cause of the fatigue, such as anemia, dysfunction of the thyroid, infections, and polycystic ovarian syndrome (PCO). The liver and pancreas have to be functioning well. Common infections need to be treated before starting Accllydine. Accllydine can be used by patients with chronic infections and mycoplasma infections. Consult your physician before beginning any treatment, which includes Accllydine.

In the Accllydine Study conducted by P De Becker, PhD, J Nijs, PT; E Van Hoof, Clin Psych; N McGregor, PhD, MSc and K De Meirleir, MD, PhD, the researchers tested levels of Growth Hormone, IGF-1 and IGF-BP-3 in the patient's blood before Accllydine was taken. Table 1 summarizes the researchers findings when a simple ratio is calculated; IGF-BP-3/IGF-1.

TABLE 1

Value of IGF-BP-3/IGF-1 General Response to Accllydine

4.5 or greater	Greatest Probability of Response
3.5 to 4.5	Some patients responded, some did not
Less than 3.5	Most patients did not respond

The researchers concluded that Accllydine is best suited for patients with a ratio of IGF-BP-3/IGF-1 greater than 3.5. Patients with a ratio greater than 3.5 have a IGF-1 deficiency. In the case the ratio is less than 3.5, but the concentration of IGF-1 is higher than normal, it might be useful to begin with a low dose of Accllydine, 1-2 capsules per day.

In relation to IGF-1 and IGF-BP-3, the researches also found that patients with low growth hormone levels responded very positively to Accllydine. Besides a ratio of greater than 4.5, low or no growth hormone production is also an indication for the use of Accllydine.

3. Composition of the Use of Accllydine

The body can make the best use of Accllydine when used with the following supplements:

- ♣ Amino acids (All-Amino S) to build muscular tissue. Accllydine stimulates the formation of muscle tissue in combination with exercise and the intake of the right nutrition.
- ♣ Glutamine, fuel for the brain.
- ♣ Anti-oxidants, to activate the circulation in small blood vessels and the binding of free radicals (elements that damage the cells).

One can also take Co-enzyme Q-10 and a multi-vitamin complex, but nothing else is required by the body to efficiently utilize Acclidyne.

How to take:

♣ Take the Acclidyne, Amino Acids, Glutamine, and the Anti-Oxidants 1-hour before eating or 2-hours after eating.

♣ Examples:

– **When 4 Acclidyne are taken per day**

In the morning, 1-hour before eating, around 8:00 a.m.: 2-Acclidyne, 7-All Amino-S, 1,000 mg Glutamine, 1-Anti-Oxidant, and then rest.

In the evening, 2-hours after eating, around 8:00 p.m.: 2-Acclidyne, 7-All Amino-S, 1,000 mg Glutamine, 0-Anti-Oxidant, and then rest.

– **When you take 3 Acclidyne a day**

In the morning, 1-hour before eating, around 8:00 a.m.: 2-Acclidyne, 7-All Amino-S, 1,000 mg Glutamine, 1-Anti-Oxidant, and then rest.

In the evening, 2-hours after eating, around 8:00 p.m.: 1-Acclidyne, 4-All Amino-S, 1,000 mg Glutamine, 0-Anti-Oxidant, and then rest.

– **When you take 2 Acclidyne a day**

In the morning, 1-hour before eating, around 8:00 a.m.: 1-Acclidyne, 4-All Amino-S, 1,000 mg Glutamine, 1-Anti-Oxidant, and then rest.

In the evening, 2-hours after eating, around 8:00 p.m.: 1-Acclidyne, 4-All Amino-S, 1,000 mg Glutamine, 0-Anti-Oxidant, and then rest.

– **When you take 1 Acclidyne a day**

In the morning, 1-hour before eating, around 8:00 a.m.: 1-Acclidyne, 4-All Amino-S, 1,000 mg Glutamine, 1-Anti-Oxidant, and then rest.

In the evening, 2-hours after eating, around 8:00 p.m.: 0-Acclidyne, 2-All Amino-S, 500 mg Glutamine, 0-Anti-Oxidant, and then rest.

♣ If taking Acclidyne 1-hour before eating causes an upset stomach, then take 2-hours after eating.

4. Length of Use of Acclidyne

How long one takes Acclidyne depends on the concentrations of IGF-1 and IGF-BP-3 in the blood. The researchers found about 50% of the CFS patients have enough IGF-1 and IGF-BP-3 by taking Acclidyne for the 14-week protocol. Every CFS patient is different, some may require less than 14 weeks and some may require more. As an example, when one gets an infection while taking Acclidyne, then Acclidyne should be stopped while the infection is being treated. Once the infection is taken care of and is gone, then Acclidyne can be started again.

Researchers have found it useful to do a blood test approximately every 8-weeks to get an impression if the body is making more GH. If so, the ratio between IGF-BP-3, and IGF-1 will decrease. If the ratio is the same, but the patient has more energy, it may mean the patient does not yet have enough reserves in the body and the patient

should continue with the same amount of Aclydine for at least two additional weeks. The patient's doctor should decide when to lower the dose. The Aclydine produced by Optipharma contains 250 mg of Aclydine per capsule. Optipharma makes a product called Aclysomadine, which only contains 25 mg of Aclydine per capsule. Aclysomadine has been used by patients after the 14-week protocol as a maintenance dose, taken three times per day, morning, noon, and night.

5. Effects and Contraindications

Researchers have found that some patients taking Aclydine have experienced the following findings and side effects. Researchers found each patient to be different. They found some patients experienced many and others none at all. Here are some findings and how the researchers dealt with each:

♣ **More energy** – Don't use your energy all at once; be sure you have some reserves (more in Section 9 when activity is discussed).

♣ **Hunger** – Presented mainly early in the 14-week protocol. Eat smaller amounts of food 4 to 6 times a day. (In between eat small amounts.)

♣ **Increase of weight** – Usually not more than 1 or 2 kilo's a month. (More in Section 9 – Activity).

♣ **Emotions** – Both positive and negative may show while taking Aclydine, (See Section 10 – Psychological Factors).

♣ **Changes in the brain, for example, pressure in the head** – This may be the result of the stimulation of the brain by Aclydine. (Look at Section 10 Psychological Factors). The researchers found that this normally disappeared spontaneously after a few weeks.

♣ **Headache** – Researchers found that some headaches disappeared spontaneously after 1-3 days. The patients who did not experience remission of their headaches were given an extra 1000 mg of Glutamine per day and the Aclydine capsules were distributed throughout the day. If the headaches still persisted then the patients took 1 less Aclydine each day.

♣ **Nausea when Aclydine is taken before eating (in the morning)** – Take Aclydine 2-hours after eating if it causes nausea.

♣ **Infections (bladder, respiratory track, ears, etc.) especially when a patient first starts taking Aclydine** – Stop taking Aclydine until the infection is over. This can take 5 to 10 days, sometimes longer.

♣ **Normalization of the women's hormones** – More regular menstruation cycle.

♣ **Increase in libido** – More sexual desire.

6. Support During the Use of Acclidyne

Your physician or therapist should provide support during the use of Acclidyne. If you have questions you should contact your physician or therapist to obtain medical advice. The researchers found no major side-effects in their study and the patient questions were very minimal. Most patients in the study tolerated Acclidyne very well.

7. Combination With Other Treatments

Patients who participated in the research study of Acclidyne in Belgium, used Acclidyne as their major treatment for the duration of the study. When a patient begins taking Acclidyne, the medical advice of a physician should be sought to determine which additional therapies would be compatible with Acclidyne and which ones might not be. It is very important that your physician knows of all the therapies you are taking for your symptoms so a thorough evaluation can be made before starting Acclidyne.

8. Nutrition While Taking Acclidyne

Acclidyne increases the uptake of nutrients by the cell and consequently stimulates the energy production in the cells. Therefore, it is important that you eat sufficiently. Three nutrient groups that are essential are amino acids, fats, and carbohydrates.

A. Amino Acids

To have optimal results with Acclidyne it is important to have a constant supply of amino acids. The product All Amino S, manufactured by OptiPharma, provides the body with the necessary amino acids. These ensure a constant and balanced supply of amino acids to the cells in the body.

B. Fats

Fat is an important source of energy. If there is a deficiency of growth hormone, body cells will not be able to absorb fats. Acclidyne stimulates the absorption of fats. This is the reason why it is important to consume enough fat while taking Acclidyne. Each meal should contain fat and different sources of fat are optimal. Saturated as well as unsaturated fats are essential. The more unsaturated the fat is, the healthier it is. Here are some guidelines:

ω Use saturated fat (butter) or mono-unsaturated fat (olive oil) to bake your meat

ω Eat seeds and their oils (e.g. wheat-germ oil, sesame oil, linseed oil), which contain poly-unsaturated fat. You can eat seeds or use the oils in salads.

ω Eat at least 2 to 3 sandwiches with butter per day,

ω Use different kinds of oils in your diet, for example olive oil, salad oil, etc.

ω Fry 1 to 3 times per week in butter.

ω An alternative is to take capsules containing wheat-germ oil, evening primrose oil, or fish oil.

ω Don't use fat-blockers or diet products.

C. Carbohydrates

Carbohydrates should be a **main constituent** of each meal. Preferentially, non-refined carbohydrates, such as, unpolished rice, corn, wheat, oat, rye, barley, legumes, potatoes and products made of these carbohydrates. It is the intention that one eats more of the above mentioned carbohydrates than usual. In the gastric-intestinal tract these carbohydrates are broken down slowly into glucose, which will then be used by the cells.

Refined carbohydrates, such as white flour, sugar, white bread, cookies, pastries, candy, sodas, are all broken down very quickly and are therefore less suitable for providing a constant supply of glucose to the cells. These should be avoided during meals, but can be consumed in between meals.

As general guidelines:

ω Use mainly "good" carbohydrates: whole wheat bread, brown rice, etc. Limit the consumption of bad carbohydrates, such as sugar or flour.

ω Use potatoes at least 3 to 4 times per week

ω Limit the consumption of flour products, white rice, and regular pasta to 1- 2 times per week.

ω Limit the consumption of sweet products, such as pastries, cookies, etc.

ω Limit the consumption of soft drinks.

ω You can use chocolate, energy bars, bananas, prunes, etc., if you have a "hypo-feeling" (when you are "light headed," because of a low blood sugar). Body cells can absorb sugar from these products very quickly.

D. Proteins

ω Proteins are made up of amino acids. Amino acids are part of the Acclidine protocol. Amino acids are also necessary to build muscular tissue, which occurs with increasing activity.

ω Eating protein is fine unless the blood test shows that the IgF-BP3 level is greatly increased. A diet rich in protein could cause the increase. In this case you should consult your physician.

E. Vegetables and Fruits

ω It is fine to eat fruit and vegetables while taking Acclidine. They are healthy for you.

If the fruit is ripe, you should moderate the consumption. Ripe fruits contain a lot of sugar.

F. General

ω Try to vary your eating pattern as much as possible. If your eating pattern is one-sided, change it gradually.

ω While taking Acclidine your appetite may increase. It is best to eat 4 to 6 meals per day in smaller amounts.

ω Eat many carbohydrates and do not go on a diet while taking Acclidine.

ω Take Acclidine and the All Amino S together.

ω If you are using a special diet due to food allergies or candidiasis, keep those food habits, but try to take into account these recommendations as it fits with your diet or special needs.

ω If you are currently using food supplements and vitamins which are not part of the 14-week protocol schedule, you can keep taking them if your physician approves.

ω It may be necessary to prolong taking Acclidine depending on your results after the 14 weeks.

9. Activities

Acclidine stimulates the absorption of amino acids, lipids, and carbohydrates by the body's cells. This is why it is possible to increase the energy production. Increased energy production will allow for you to increase your activity. Exercising stimulates the hypothalamus. The hypothalamus is responsible for the production of certain hormones including Growth Hormone. In this way, the IGF-1 production is also stimulated. In time the IGF-1 level will be high enough to normalize the intake of lipids and carbohydrates. For this reason, the 14-week protocol starts with a high dose of Acclidine. During the protocol the Acclidine is decreased and activity must be increased. There is no schedule available as to how to increase your activity. The level of exercise strongly depends on the patient's level of activity at the start of the protocol. However, there are some guidelines.

It is important to develop a routine. Rise at approximately 8 o'clock and exercise 3 times per day (controlled). Always listen to your body. Every one is unique. It is advised to set a schedule together with your therapist.

For people who stay in bed most of the day, it is necessary to start with caution. Try to exercise the same way every day if this is the case. It might be better to start your exercise in bed. Please start only a few minutes per day. After this period you can start using a home-trainer cycle. However, only if the resistance and/or the speed are controllable. Also walking stairs is a possibility. It is preferred to start exercising in your home so the patient can control the environment. Outside weather, wind, and temperature are always different. If you already exercise, it is advisable to increase your exercise in a controlled manner. Don't force the activity level, especially in the beginning of the protocol. The beginning is important to build up your reserves.

If your body mass increases by more than 4 pounds per month, you should increase the level of exercise. The gaining of too much weight is a signal that the body has reserves but they are not being fully utilized.

Guidelines for home trainer cycle use for those who have little energy from CFS:

1. A daily exercise in the morning of 60 to 80 rotations per minute (RPM), lowest resistance for 2 or 3 minutes.
2. Increase the rotation to 100 RPM if you feel comfortable with this.
3. Also exercise during the evening. Start with only a few minutes.
4. Gradually increase the duration of the exercise to 15 minutes in the morning and in the evening.
5. Start exercising in the afternoon for a few minutes. Increase the exercise to 3 times 15 minutes per day.
6. Increase the duration of the exercise to 30 to 45 minutes per day.
7. If you are comfortable with it, increase the resistance level during step 1 to 6.

If you were exercising at the start of the protocol, you can determine your own starting level. However, it is recommended not to exercise too much. It is important to build up a reserve of energy. The technique of exercise is more important than the level. If you feel a set back, take 1 or 2 steps back in your level of exercise. It won't be necessary to start all over again. This is because that a certain level of conditioning has already been achieved.

10. Psychological Factors to Consider

With CFS patients, the brain doesn't function optimally. Most patients are sensitive to stress, especially unexpected events. When one is stressed, the production of several hormones, such as growth hormones and endorphins are decreased as the activity of the hypothalamus decreases. Try to prevent stress during the protocol. Endorphins are responsible for emotions. Endorphins in CFS patients can be both over produced and under produced. Acclidine stimulates the activity of the hypothalamus to produce more growth hormones and endorphins. An increasing level of endorphins could lead to more emotion. Emotions you already got over, but those which your body didn't get over. It's important to realize that these emotions can be a part of the recovery. Express your emotions and don't avoid the confrontation. The confrontation with your emotions can be heavy. In this case, it may be useful to ask for help from a trained professional to process your feelings. The psychological effects are different with every patient.

A setback during the protocol is possible. This could effect your motivation to continue the protocol. If a setback occurs, please consult your doctor so blood testing can be performed to check your IGF-1 and IGF-BP-3 levels. Having your blood checked approximately every 8-weeks can help to document your progress to determine objectively if Acclidine is working for you. Also, tracking your activity level and exercise will help build your confidence and mark your improvement. Positive thinking is important for recovery. Sometimes it is hard because most patients have tried many treatments to get well. Keep working on a positive state of mind. Periodically,

celebrate the improvement you see.

Your sleep may be shorter while you progress through the protocol. It is true that if you have more energy, the time you sleep can be shorter. Also, it is logical that when you sleep better, you don't need to sleep as long.

11. After the 14-Week Aclydine Protocol

It is important to maintain exercise 3 to 5 times per week for 30 minutes, or more if you have the strength. Also, keep paying attention to your food intake; sufficient carbohydrates and fats are important. If you experience a setback for several days, it is recommended to take 1 Aclydine, 2 All-Amino S and 1-1000 mg of Glutamine for 3 days.

Aclydine is expensive, a much cheaper alternative is Aclysomadine. Aclysomadine contains 25 mg Aclydine per capsule in addition to some vitamins and amino acids, versus the 250 mg of Aclydine in one Aclydine capsule. After the 14-week protocol, if you see a decline in your energy and/or activity level you can take 3 Aclysomadine per day. This would be 75 mg of Aclydine per day, which should be enough to maintain your strength. During and after the 14-week protocol you should keep your physician abreast of your progress and your condition. All medical questions and needed advice should come from your physician.

12. Comments and Ordering Information

A. Pricing as of April 15, 2003

14-Week Protocol – \$1,343 (which includes: 2 bottles Aclydine, 8 Bottles All Amino S, 2 bottles L-Glutamine, and 1 bottle Anti-Oxidants)

Items Sold Separately

Aclydine 100 capsules per bottle – \$500

All Amino S 100 capsules per bottle – \$35

Aclysomadine 90 capsules bottle – \$150

B. Ordering Information

Payment is accepted via check or money order made payable to: **Creative Strategies, LLC.**, and mailed to:

Creative Strategies, LLC

4807 Elkcreek Trail

Reno, NV 89509

C. Questions and Comments

Questions and comments can be e-mailed to or directed to Creative Strategies, LLC at (775) 828-6011. Creative Strategies, LLC is acting solely as a consultant to OptiPharma bv.

13. Calculation Example

As an example, let's use the following values for the lab test results:

IGF-BP3 is 6.5 mg/l and IGF-1 is 221 ng/ml

Please take special notice, as the units are different for the two tests. This is the way laboratories usually report the test values. The units on the IGF-BP3 are milligrams per liter and the units on the IGF-1 are nanograms per milliliter. So you have to convert one of the values so the units are the same, then a ratio can be calculated.

The conversion of the IGF-1 units to mg/l is as follows:

$$221 \text{ ng/ml} \times 1000 \text{ ml/l} \times 1 \text{ mg}/1,000,000 \text{ ng} = .221 \text{ mg/l}$$

The simple conversion calculation is $221/1000 = .221 \text{ mg/l}$

The ratio of IGF-BP3/IGF-1 can now be calculated:

$$6.5/.221 = 29.41$$

Dr. De Meirleir sees a high response in patients with a ratio greater than 4.5 on the 14-week Aclydine Protocol.

14. The OptiPharma's Compassionate Care Program

OptiPharma will establish a Compassionate Care Program for patients who are under financial duress because of their Chronic Fatigue Syndrome. OptiPharma will provide 5% of the Aclydine sold in the United States at no cost to patients who meet the appropriate criteria.

OptiPharma will begin providing Aclydine through the Compassionate Care Program once 200 patients in the United States are on the 14-week protocol. Once 200 patients are on the protocol, applications will be taken by submitting the following:

1. A description of your financial situation;
2. A copy of your lab tests showing the values of your
 - i. Growth Hormone Level
 - ii. IGF-BP-3
 - iii. IGF-1; and
3. A signed letter of recommendation from your physician stating your condition and that he/she recommends Aclydine for you.

All information should be submitted in one package to:

Creative Strategies, LLC

OptiPharma Compassionate Care Program

4807 Elk Creek Trail

Reno, NV 89509 Questions or comments can be e-mailed to: aclydine@yahoo.com