Q. DOES EFALEX® HAVE ANY SIDE EFFECTS?

A. Side effects are **very** rare and may include headache, nausea, soft stool, diarrhoea or other gastrointestinal disturbances and skin rashes. The digestive upsets can usually be eliminated by taking the product with food and/or reducing the dose to one capsule per day and then slowly increasing the dose up to the recommended amount over the course of a week. People who take the product on an empty stomach tend to have more digestive side effects. If a skin rash develops, discontinue use.

Q. CAN I TAKE EFALEX® WITH OTHER MEDICATIONS OR SUPPLEMENTS?

A. There are no known interactions of Efalex® with other natural health products. You should consult a qualified health care provider if you are taking anticoagulants, epileptogenic drugs, ASA, or phenothiazines. Anyone under medical supervision or taking medication should consult their health care provider before taking any supplement including Efalex®.

Fatty acid supplementation can take 3-4 months to have an effect therefore we strongly advise to continuing taking any prescribed stimulant medication when Efalex® treatment is started. Always remember this should be done **in conjunction with your specialist**, as a treated child will need to be closely monitored for changes in the effectiveness of the stimulant medication. There is usually a certain time during the day that the stimulant medication has 'worn off'. At this time, monitor the child; if they appear more in control, more focussed and calmer, then we suggest you discuss with your doctor the possibility of reducing the level of stimulant medication. Alternatively, about an hour after the stimulant medication is administered, the child should be monitored to see if the child is more restless or 'uncontrolled'. This may mean that the child's fatty acid balance has been corrected by Efalex® and so the response to the stimulate medication has also been normalized (the stimulant medication has begun to act as a stimulant). Again, you should talk to your doctor about reducing stimulate medication when this occurs. We strongly urge you to seek your doctors advice when combining Efalex® with other learning disorder medications.

Q. DO I TAKE EFALEX® UNTIL I GET BETTER AND THEN STOP TAKING IT?

A. Efalex® is considered a daily supplement and should be taken as long as you want to maintain a satisfactory condition. Fatty acid supplementation does not "fix" a problem in the body. Instead, it provides nutrients that your body needs to by-pass the problem. Therefore, if you stop taking the supplement, the symptoms will recur.

Q. WHO SHOULD NOT TAKE EFALEX®?

A. Due to the thyme oil in the formula, Efalex® is not recommended during pregnancy, unless under medical advice.

Q. DO YOU RECOMMEND ANY OTHER PRECAUTIONS WHEN TAKING EFALEX®?

A. Efalex® capsules are not recommended for children under 2 years of age for fear of choking on the capsules.

High DHA tuna oil contains the same fatty acids that are normally found in tuna. Evening Primrose oil is not a normal food item but has been extensively tested in a whole range of toxicity trials. These included measurements of acute toxicity, chronic toxicity, carcinogenicity and reproductive toxicity. Results of all these studies showed a lack of toxicity. This is not surprising since evening primrose oil is composed of fatty acids that are normal components of your body.

Q. HOW LONG WILL IT TAKE BEFORE I SEE RESULTS?

A. It normally takes about twelve weeks before you will notice an improvement in your health. Fatty acid supplementation provides nutrients that have been depleted from the body and correcting this takes time to achieve maximum benefit. Therefore, allow at least three months before evaluating whether the treatment is effective.

Q. EFALEX® WAS WORKING FOR MY CHILD FOR SOMETIME, BUT NOW IT DOESN'T SEEM TO BE WORKING. WHAT'S WRONG?

A. There may be times that you notice that Efalex® doesn't seem to be as effective as in the past, this usually coincides with viral infections, growth spurts or hormonal changes. That's because all these factors put increased requirements on the body for fatty acids. If this does happen it may be necessary to increase the dose of Efalex® back to the initial start dose during these times.

Q. WHAT IS MORE IMPORTANT FOR BRAIN FUNCTION - DOCOSAHEXAENOIC ACID (DHA) OR EICOSAPENTAENOIC ACID (EPA)? WHAT'S THE BEST BALANCE OF THESE OMEGA 3 FATTY ACIDS?

A.

- The most important structural omega 3 fatty acid in the brain is DHA
- The most important structural omega-6 fatty acids in the brain are arachidonic acid (AA) and adrenic acid, which is made from AA.
- There is hardly any EPA in the brain and in nerve cells.
- Studies on infants show the supply of DHA and AA in early life is critical for good brain and visual development. No studies on EPA in infancy have shown similar results yet.
- Plasma fatty acids of ADHD boys with high scores for signs of fatty acid deficiency were compared with those with low fatty acid deficiency signs. There was no significant difference between EPA values in the two groups, but the high fatty acid

deficiency group did have lower DHA levels. (Stevens L et al. Omega-3 fatty acids in boys with behaviour, learning and health problems. Physiol Behav 1996;59(4-5):915-920.)

- EPA is converted in the body to DHA. It is not know yet whether this conversion process is impaired in dyslexia, ADHD or dyspraxia. Until the specific biochemical differences between people with and without specific learning disorders are known, supplements that provide the fatty acids that are deficient in their tissues should be supplied (i.e. DHA and AA).
- Studies of more than 100 children with dyslexia, 35 children with features of ADHD, and 15 children with dyspraxia, have shown that Efalex® improves reading performance, reduces symptoms of ADHD and improves movement skills.
- All fish oils provide DHA and EPA, as well as AA; it is just the proportions that vary.

In conclusion, the high-DHA fish oil based supplement Efalex® has been shown to be effective for dyslexia, ADHD and dyspraxia in 7 clinical studies. There is very little evidence of EPA deficiency in these conditions, whereas there is evidence for DHA deficiency.

All successful trials have used a combination of DHA and EPA in varying proportions (plus some GLA from Evening Primrose Oil) . It is not possible to claim one or the other individual fatty acids is the 'effective' one . It is possible both are required and certainly this is the case for optimal health in general.

Q. WHY ARE EFALEX® CHEWIES RECOMMENDED FOR 3 YRS AND OLDER WHILE THE EFALEX® CAPSULES ARE RECOMMENDED FOR 2 YEARS AND OLDER?

A. Efalex® Chewies are recommended for three years and older to ensure that younger children do not choke on the capsules while they are trying to chew them. The non chewable Efalex® capsules are designed to be swallowed and may be difficult for a child younger than age 2 to swallow whole.

In Canada, the Efalex® non-chewable capsule is sold in association with the following health claim: '*May help to relieve some symptoms of Learning/Behavior Disorders including dyslexia, dyspraxia, and attention deficit hyperactivity disorder. Maintains and supports brain and eye functions including learning ability, concentration, coordination and nerve transmission'.* In that country, the product can only be recommended for children age 5 years and up because there were no children younger than age 5 years included in the clinical studies that were submitted in support of the product license.

REFERENCE	# OF CAPSULES/DAY	AGE OF PATIENT	DURATION OF USE
Stevens et al. 2003	8 (divided dose)	6-13 years	4 months
Richardson and Puri 2002	8 (divided dose)	8-12 years	12 weeks
Noréns and Fors 2002	8 (divided dose)	Not Reported	6 months
Richardson et al. 2002	8 (divided dose)	8-12 years	12 months
Stordy 2000	8 (divided dose)	5-12 years	4 months

Q. WHY IS EFALEX® NOT RECOMMENDED FOR PREGNANT AND BREAST FEEDING WOMEN?

A. Efalex® is not recommended for pregnant and breast feeding women because of the thyme oil ingredient. That is why we created Efanatal® specifically for women to take during pregnancy and while breast feeding. **Although an approved food ingredient**, to date, there have not been any studies done **specifically** to confirm that thyme oil is safe to take during pregnancy and while breast feeding.

Q. WHY DO THE EFALEX® CAPSULES, LIQUID AND CHEWIES PROVIDE SLIGHTLY DIFFERENT QUANTITIES OF THE ACTIVE INGREDIENTS PER DOSE?

A. The Efalex® Liquid formulation does differ slightly from the Capsule formulation because it contains a carrier oil to improve palatability. However, that difference is in favor of maintaining an effective dose because it is actually higher than the capsule dose. In addition, it is worth recognizing that there is a very large therapeutic range for fatty acid supplements due to individual variations in patient's needs such that an effective dose in one patient may not be an effective dose in another. Things that may impact on individual patient requirements include size, physical activity, age, intake of particular fatty acids as part of their normal diet and growth rate. Consequently, the small differences between the capsule and liquid dose are actually insignificant compared to individual patient variations in dosage requirements.

The Efalex® Chewies are positioned as a nutritional product, not as a therapeutic product as is the case for Efalex® Capsules and Liquid. According to the International Society for the Study of Fatty Acids and Lipids (ISSFAL), the adult intake of EPA+DHA should be 500 mg per day. If a child should consume ½ an adult dose, that would equal 250 mg per day. Population studies show that the average westerner consumes much less than the recommended amount. Efalex® Chewies provide 175 mg per day which added on top of the small amount that a child would consume as part of their diet should be roughly enough to bring their intake up to near 250 mg per day.