

CHRIS PAYNE:- WRITTEN SUBMISSION

My Condition and History

I have had Chronic Renal Failure secondary to adult polycystic kidney disease since 1983 supported by Haemodialysis and a transplant. The transplant was successful from February 1989 to December 2001, when I returned to Haemodialysis.

One of the many side effects of haemodialysis is hyperphosphataemia. Elevated levels of phosphate cause bone disease and may well be linked to cardiovascular disease. On a personal basis they also create intolerable itching. Another of the many problems with kidney disease is secondary hyperparathyroidism. This is a rise in the parathyroid hormone PTH to levels that affect calcium and phosphate balance and allow them to get out of control.

During my earlier dialysis, five years of which was "home dialysis" I had no trouble with high phosphates. I believe this was due to the phosphate binders in common use at the time ALUMINIUM HYDROXIDE GEL (ALU-CAP) CAPSULES. At this time I was taking 3 alucaps before meals. I also had no problems with high levels of parathyroid hormone, although this may have been due to ignorance of the condition.

ALUCAPS are a very good phosphate binder. For nearly six years they had kept my phosphate levels within acceptable limits. Unfortunately they have been found to be toxic with very serious side effects to the brain. For this reason they are not generally prescribed to Kidney patients.

When I returned to dialysis I was prescribed calcium based phosphate binders PHOSEX. These were partially successful but I started to increase the dose before meals to keep my phosphate levels down to acceptable levels. After some time I had increased the calcium to such an extent that I became hypercalcemic and had to reduce the calcium. At this time there was a new drug SEVELAMER (RENAGEL) and this was prescribed for me. I took this with PHOSEX until early 2005. By then my PTH was rising and I had readings of well over a hundred. I was experiencing unusual symptoms of burning skin and found that I was allergic to the RENAGEL I was taking and had to stop them. This led to me taking only calcium based phosphate binders PHOSEX. As previously explained I had to be careful of the amount of calcium based phosphate binders I took for fear of becoming hypercalcemic. At this time I was taking two 100mg tablets with my main meal of the day and one 100mg tablet with lighter meals, breakfast, lunch etc. My phosphates went up and up to a high of 2.7 the itching became unbearable and I did not know what to do next. I was referred to a surgeon to counsel me about surgery on the parathyroid glands in my neck but by the time I got an appointment my PTH was down to acceptable levels and surgery was not required. The surgeon went ahead with the counselling just in case I needed surgery in the future.

This led to me researching non-calcium based phosphate binders I came across LANTHANUM CARBONATE. I have been trying, without success, to get my consultant and my G.P. to agree to me having this drug on a named patient basis. However if CINACALCIT is the success I hope it to be, then I will not need to look for non-calcium based phosphate binders.

Finally in desperation I asked if I could be prescribed ALUCAPS, my consultant agreed to me starting on a three-month trial. Dose is now only two before meals. I am two months into the ALUCAPS. I have now started on CINACALCET. I have been taking 30 mg for four weeks

My hopes for CINACALCET

If CINACALCET is the success I hope it to be it will lower my parathyroid hormone and help to control my calcium and phosphate. My figures have been very encouraging during the past four weeks

There is another way of lowering my parathyroid hormone. This involves surgery and the removal of some or all of the parathyroid glands. This is not a permanent cure and in the future may require more surgery.

It would be a very good thing if CINACALCET were to keep my PTH under control thus allowing me to avoid surgery and all the associated risks of infection including M.R.S.A. Judging by my figures after two weeks of taking CINACALCET it has already had a beneficial effect on my PTH and on my phosphate

Before being prescribed CINACALCET my phosphate and calcium figures were all over the place in particular my phosphate had risen to 2.7 with all the worries that it may be shortening my life expectancy. High phosphates are known to cause calcification of the veins and arteries and it is believed to be detrimental to the heart. It also causes bone disease My PTH was steadily rising and looked as though I may have to be referred to a surgeon again for the removal of all or some of my parathoid glands.

Once prescribed CINACALCET my life took a turn for the better my phosphate figures returned to acceptable levels after two weeks. My phosphate should be between 0.8 and 1.4 my phosphate level was 1.2 almost in the middle of the range. In a desperate attempt to lower my phosphate level I had started using ALUCAPS as a phosphate binder together with PHOSEX, a limited dose because of fear of hypercalcemia, some six or seven weeks prior to beginning the CINACALCET. This did have a beneficial effect and dropped my phosphate to 1.8 better than before but I was still suffering the effects of high phosphates. I can only take ALUCAPS for three months because of their toxicity so I will start to decrease the

daily dose and hope that the CINACALCET will do all that I hope it will, enabling me to come off the dangerous ALUCAPS. I intend to lower the dose gradually for the next month and then not need to take them any more.

The Difference CINACALCET could make to my life

If CINACALCET is as successful as it appears to be from the first four weeks of using it then it will have a life changing effect for me and will also be beneficial to my family.

1. It will allow me to come off ALUMINIUM HYDROXIDE (ALU CAPS)
2. It will make sure I never have to take high levels of calcium based phosphate binders. Thus avoiding hypercalcemia and the dreadful symptoms associated with it. It will also relieve me of the need to research non-calcium phosphate binders.
3. My phosphate level will be within acceptable limits thus stopping the intolerable itching associated with the high levels I have been experiencing
4. I will be able to go back onto a normal renal diet. I have been trying to control my phosphate levels by a diet of foods with low phosphorous. I might add, without success, although I do not know how high my phosphates would have gone had I not done so
5. Once I am free of the itching I will be able to sleep better Perhaps for longer periods or who knows maybe all night.
6. Most importantly, a reduction of my high phosphate levels would stop decalcification of my bones (bone disease). I have also been told that high phosphates cause calcification of my veins and arteries and can lead to cardiac problems thus shortening my life expectancy.
7. If my parathyroid hormone (PTH) remains under control then this will relieve me of the worry of surgery and the chance of infection.

Using CINACALCET

The medicine is in the form of a small pill. It is very convenient, packed in a tinfoil bubble pack and very easy to take. I take mine one a day after my evening meal.