

April 2002 – August 2002

**Clinical Studies of
Blue Cap® Spray
in China (2002)**

Blue Cap® Spray in the treatment of Psoriasis.

Number of patients under treatment: 144.

Institution responsible for the tests

Dermatology Department of the *Hua Xi Hospital* at the Chengdu University, Sichuan.

Collaborating Institutions

Chongqing Hospital number 1 at the Chongqing University of Medicine.

Tong Ji Hospital at the *Hua Zhong* University of Medicine, Tong Ji, Wuhan.

Professors in charge of the studies

Prof. Guo Zai Zhang / Prof. Zhang Yi Zhi.

Objective

To demonstrate the efficiency and harmlessness of Blue Cap® Spray in the treatment of psoriasis using a comparative clinical study with 144 patients (Blue Cap® Spray / Camptothecine Ointment).

Psoriasis: Brief introduction

Psoriasis is a frequent dermatological illness which can become chronic. The ratio of people affected by it varies in each country. The dermatological studies of Epstein and Christophers mention a ratio of the population affected naturally by psoriasis of between 2.84% and 2.3% (1). In 1984 the studies carried out in China talk about a ratio of population affected by psoriasis of 0.123% (2.3). Psoriasis extends very easily and, because it is a recurrent illness, it can ultimately affect patients both physically and psychologically; for this reason it occupies an important place in the field of dermatology. Due to the fact that the causes of psoriasis have still not been determined, treatment of this illness continues to be difficult today. Up until now, numerous clinical studies which have been done with other products in the treatment of psoriasis have either given barely satisfactory results or have, in some cases, produced severe side effects.

Blue Cap® Spray

Clinical Studies in China with 144 Patients.

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Choosing the Patients

The patients were selected in accordance with the following criteria:

- a.- Patients suffering from common psoriasis.
- b.- Aged between 18 and 65 years (men and women).
- c.- Areas affected by the illness > 20%.
- d.- For one month prior to the treatment, the patients must not have received any type of general treatment. For one week prior to the treatment they must not have received any type of treatment (including preventive treatment) in the affected areas.
- e.- All the patients have undergone the treatment voluntarily and have signed a written declaration to this effect.

General Report of the Study elaborated by Prof. Guo Zai Zhang.
Dermatology Department, Hua Xi Hospital, Chengdu, Sichuan

General Results

The efficacy of the product was obvious after only a few days of treatment. The general results of the study confirm that the ratio of efficacy of Blue Cap® is 87.0% as against 67.6% of the comparative product.

The ratio of patients treated with Blue Cap® Spray who suffered from side effects is 4.2% as against 29.2% in the comparative product. The side effects which appeared were unimportant (slight itching, skin-dryness...). The product is easy to use and a small amount of Blue Cap® is sufficient to bring about a notable improvement over a large area affected. Given the composition of the product, its regular use does not affect other organs.

Conclusion

The general cases given in the final report demonstrate the considerable efficacy of Blue Cap® in the treatment of psoriasis, as well as the harmlessness of the product and its rapid action.

Report elaborated by the Hua Xi Hospital, Sichuan

General Results

Blue Cap® Spray is a product manufactured by **Catalysis, S.L.**

Its main component is Zinc Pyrithione. The tests have demonstrated that the product delays the accelerated growth of the skin cells, and it is also capable of eliminating the rest of the signs which occur in the cases of common psoriasis. After various years of using the product in clinical tests, it is obvious that it acts quickly and efficiently; the initial results appear during the first days of use. The result of our tests can be appreciated in the cases which we attach, where the greater efficacy and speed of **Blue Cap® Spray** is evident as against the comparative product.

The general results of the study confirm that the ratio of efficiency of **Blue Cap®** is **87.0%** as against **63.7%** in the comparative product.

The ratio of patients treated with **Blue Cap®** who suffered side effects is insignificant, as against the 41.6% shown for the comparative product. The side effects in both can be observed in the statistical study ($p = 0.000$). It should be noted that **Blue Cap® Spray** did not provoke any change in the skin colour in any of the patients; it is therefore suitable for use on the face or on visible parts of the body. Its easy use has meant that it has been very well accepted by patients.

Conclusion

The results manifest the obvious efficacy of **Blue Cap® Spray** in the treatment of psoriasis, as well as the harmlessness of the product.

Report of the Study elaborated by the Chongqing Hospital

General Results

Psoriasis is a widely-spread illness; it is recurrent and takes a very long time to cure. The product **Blue Cap® Spray** manufactured in the laboratories of **Catalysis, S. L.** has been used in the treatment of psoriasis for more than 10 years, with excellent results. Our studies show that **Blue Cap®** can delay the abnormal growth of skin cells without affecting the state of the skin, and can also combat other irregularities typical of psoriasis. In a few days only, the positive results of **Blue Cap®** can be appreciated.

The general results of the study confirm that the ratio of efficiency of **Blue Cap®** is **86.4%** as against **68.2%** of the comparative product.

During the treatment with **Blue Cap®** only one case with side effects was observed, and these effects were minimal – dryness of the skin; for this reason it was not necessary to apply special treatment or to interrupt the treatment. There were no other cases with side effects. As the product does not contain cortisone, the effects typical of this component were not observed (shrivelling of the skin, change in the colour of the skin...). A small dose of **Blue Cap®** will cover a large area affected and, because of this, all the patients took to the product extremely well.

Conclusion

The results show that **Blue Cap® Spray** is effective, innocuous, easy to use and suitable for the treatment of psoriasis.

General Results

Psoriasis is a very common recurrent illness and, as a long time passes before it can be cured, it can affect patients both physically and psychologically. Up until now, the treatment of it has been extremely difficult because the causes provoking this illness were unknown. The different treatments available for psoriasis known to date have not had good results and some of them have produced serious side effects.

The product **Blue Cap® Spray** manufactured by **Catalysis, S.L.** has been used in the treatment of psoriasis for over 10 years with excellent results. Our studies show that **Blue Cap®** can combat the abnormalities on the skin which psoriasis provokes.

The general results of the study confirm that the efficiency rate of **Blue Cap®** is **87.5%**, and that it will eliminate erythema, papules, flaking of the skin..., in the patients treated.

During the treatment with **Blue Cap®** the rate of patients who suffered from side effects was 8.3% and in all cases these were of little importance, such as skin dryness or slight itching; therefore, it was not necessary in any of the cases to give special treatment or to interrupt the treatment. At the same time, we observed that there were not even cases where the skin changed colour (whilst this did occur in patients using the comparative product). As this product does not contain cortisone, no side effects typical of this component, or its derivatives, were found (shrivelling of the skin, anomalies in the veins, change in the skin colour...). **Blue Cap®** is therefore ideal for use on areas such as the face or visible parts of the body. Because it is in spray form, it may be used on the parts of the body covered with hair as it is not greasy (like other similar products) and it can be applied easily. Thanks to these characteristics, **Blue Cap®** was very well accepted by all the patients.

Conclusion

The results show that **Blue Cap® Spray** is effective and harmless for the treatment of psoriasis.

Representative Patients

Patient number 1

Woman, 54 years old, number 024.

Condition: Extremities, back. Erythema, 2 years.

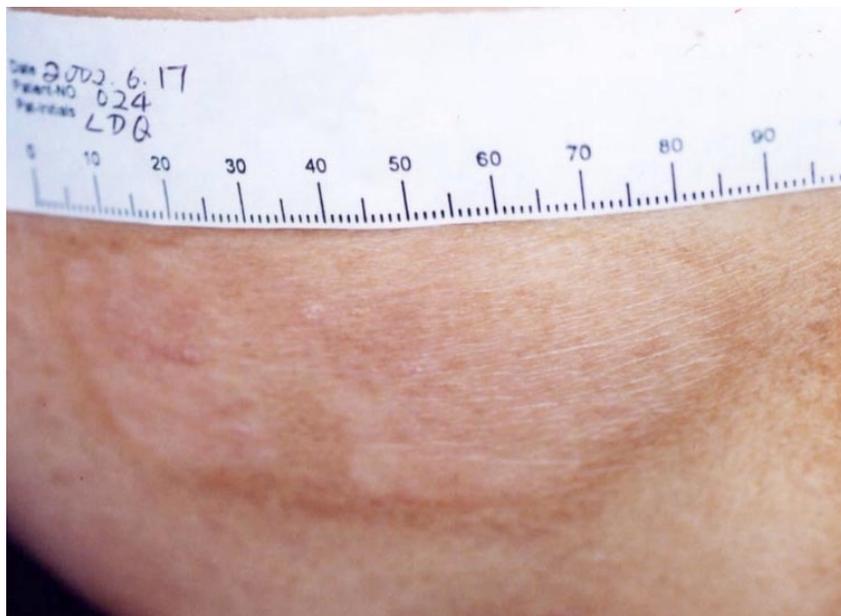
Case History: For two years she has had red papules which have continued to develop until they have shown a whitish colour on the top with flaking of the skin. Itching. She began treatment with different products without any positive effect. The upper part of the area affected continued to show flaking. Two months ago she gave up the treatment. She came to the emergency ward of our hospital on 20 May 2002.

Areas affected: Back, extremities. The area affected presented very obvious erythema of an irregular shape. The spectrum of the size of these erythema was between that of a pea and a coin. *Auspitz* positive. The surface of the area affected measured 8 x 3 cm (see photograph 1).



Blue Cap® Spray

Photograph 1
Before treatment.



Blue Cap® Spray

Photograph 2
4 weeks after treatment.

Case: Common psoriasis.

The patient voluntarily accepted to undergo treatment with **Blue Cap® Spray** signing a written declaration to this effect.

Treatment: 3 daily applications of **Blue Cap® Spray** on the area affected. After the first week of treatment, improvement was evident. The itching diminished. During the fourth week, the erythema disappeared considerably (see photograph 2). During the treatment, no side effect appeared in the area affected, or in any other part of the body. The remaining functions/organs (blood, urine, hepatic function...) were normal.

Patient number 2

Woman, 46 years old, number 051.

Condition: Extremities and head. Erythema. 5 years.

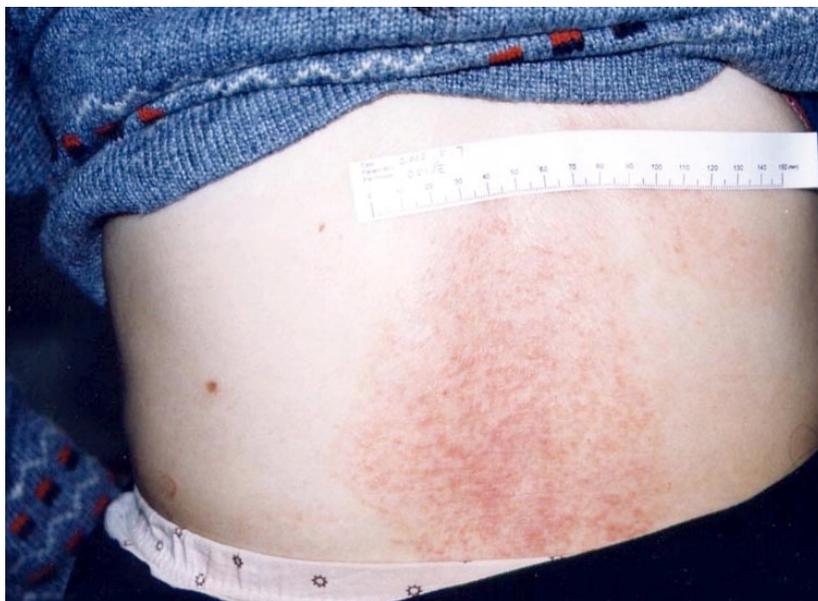
Case History: 5 years ago erythema began to appear on the four extremities and continued to develop over the entire body, slight itching, papules developed provoking flaking of the skin. The illness extended over the whole body when the patient scratched the area affected. After different treatment with a variety of products (Western medicine and traditional Chinese medicine), the disease came back again. In the year 2002 the condition appeared again (back) and the patient came to our hospital where she began treatment on 6 April 2002.

Re-examination: Condition on all extremities and head, erythema of different sizes – from the size of a drop of water to that of a coin. On her back she has papules of a larger size. She presents flaking of the skin. *Auspitz* positive. The area affected measures 18 x 12 cm (see photograph 3).



Blue Cap® Spray

Photograph 3
Before treatment.



Blue Cap® Spray

Photograph 4
4 weeks after treatment.

Case: Common psoriasis.

The patient voluntarily accepted to undergo treatment with **Blue Cap® Spray** and signed a written declaration to this effect.

Treatment: Application of **Blue Cap® Spray** 3 times a day. At the end of one week of treatment, the area affected showed an evident improvement, the red patches and the flaking of the skin disappearing. After 4 weeks of treatment the effect of the product was obvious (see photograph 4), with most of the illness disappearing. During treatment there were no side effects. The remaining functions/organs (blood, urine, liver...) were normal.

Patient number 3

Woman, 32 years old, number 17.

Area affected: Extremities and back. Flaking, 5 years.

Case History: 5 years ago erythema and papules appeared extending over the whole body and increasing in size. On the upper part they were a silvery colour with flaking skin. After using various products (oral and external use) in the treatment of this disease, she did not notice any improvement. After interrupting the treatment a month ago, she came to our hospital. On 10 May 2002 she agreed to start treatment with Blue Cap®.

Condition: Back, extremities. Erythema and papules of different sizes (from the size of a pea to that of a coin), irregular in shape and obvious, with flaking of the skin. *Auspitz* positive. The surface of the area affected measured 10 x 10 cm (see photograph number 1).



Blue Cap® Spray

Photograph 1

Before treatment.



Blue Cap® Spray

Photograph 2

2 weeks after treatment.



Blue Cap® Spray

Photograph 3

4 weeks after treatment.

The patient voluntarily accepted to undergo treatment with [Blue Cap® Spray](#) and signed a written declaration to this effect.

Treatment: Application of [Blue Cap® Spray](#) 3 times a day. After two weeks' treatment, the flaking disappeared and all that could be seen were small, well-defined papules (photograph 2). At the end of 4 weeks of treatment, the effect of the product was obvious (photograph 3), the condition having disappeared. During the treatment no side effects appeared. The remaining functions/organs (blood, urine, hepatic function...) were normal.

Patient number 4

Woman, 36 years, number 035.

Condition: Extremities and head. Erythema and papules. 1 year.

Case History: 1 year ago erythemas began to appear on the four extremities spreading all over the body, slight itching, and flaking of the skin. After different treatment with a variety of products (Western medicine and traditional Chinese medicine) the disease came back again after two months of not having treatment. One month ago the illness seemed to develop even more strongly than before. The patient came to our hospital where she began treatment on 20 May 2002.

Re-examination: Condition all over the extremities and head, erythema of different sizes and flaking of the skin. *Auspitz* positive. The area affected measured 4 x 3 cm (see photograph 1).



Blue Cap® Spray

Photograph 1
Before treatment.



Blue Cap® Spray

Photograph 2
4 weeks after treatment.

Case: Common psoriasis.

The patient voluntarily accepted to undergo treatment with [Blue Cap Spray](#) and signed a written declaration to this effect.

Treatment: Application of [Blue Cap Spray](#) 3 times a day. After one week of treatment, the area affected showed obvious improvement, the red patches and flaking of the skin having disappeared. After 4 weeks of treatment, the improvement was obvious (see photograph 2), the condition mostly subsiding. During the treatment there were no side effects. The remaining functions/organs (blood, urine, liver...) were normal.

Patient number 5

Man, 54 years old, number 041.

Condition: Extremities and back. Erythema and papules. The condition lasted 26 years.

Case History: For the last 26 years this patient has had erythema on the 4 extremities which developed over his whole body, slight itching, and flaking of the skin. After a variety of treatment with different products, there was no obvious improvement. During 6 years he underwent treatment with PUVA, including other different treatments which only afforded him slight improvement. 4 months ago he gave up this treatment. On 6 April 2002 the patient came to our hospital.

Re-examination: On the front of both legs there are erythema and irregularly shaped papules with flaking of the skin. *Auspitz* positive. The surface of the part affected measures 20 x 12 cm (see photograph 1).



Blue Cap® Spray

Photograph 1

Before treatment.



Blue Cap® Spray

Photograph 2

4 weeks after treatment.

Case: Common psoriasis.

Treatment: Application with **Blue Cap® Spray** 3 times a day. After one week's treatment, the area affected showed an obvious improvement with the red patches and the flaking of the skin disappearing. At the end of 4 weeks of treatment the condition almost completely disappeared (see photograph 2). The treatment produced no side effects. The remaining functions/organs (blood, urine, hepatic function...) were normal.