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## **ParActin® For Cold & Flu**

Colds and flu can reach epidemic proportions during the winter months. There are more than 95 million flu cases in the U.S. annually, according to the Centers for Disease Control, and more than 62 million cases of the common cold!

### **What is the Flu?**

The flu is a contagious respiratory illness caused by influenza viruses. It can cause mild to severe illness, and at times can lead to death. Some people are at high risk for serious flu complications, such as older people, young children, and people with certain health conditions where their immune response has been compromised. Symptoms of flu include: fever (usually high), headache, extreme tiredness, dry cough, sore throat, runny or stuffy nose, and muscle aches. Some of the complications caused by flu include bacterial pneumonia, dehydration, and worsening of existing chronic medical conditions, such as congestive heart failure, asthma, or diabetes.

Interferon gamma plays an important role in the first line of defense against viral infections. They are part of the non-specific immune system and are induced at an early stage in viral infection such as in influenza— before the specific immune system has had time to respond. Interferon-gamma is produced by certain activated T-cells and NK cells and is made in response to viral antigen or when stimulated by lymphocytes. Interferons are responsible for reactions as cold, fever, shivers, migraine, and gastrointestinal disorders. Interferon gamma



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interacts with other interleukin molecules such as interleukin-2 and others to form a complex, lymphokine regulatory network.

Interleukin-2 (IL-2) is a protein made by the body. T-helper cells, a kind of white blood cell, produce IL-2 when they are stimulated by an infection such as in influenza. IL-2 is essential in antibody production and activation of killer T cells, and helps maximize the ability of the immune system. IL-2 makes infection-fighting cells multiply and mature and increases killer T-cell (CD4+ cell) counts. However, overload of IL-2 may cause fever and muscle aches.

## **CELLULAR IMMUNE RESPONSE**

Cell-mediated immunity (CMI) is mediated by a variety of T cells, macrophages, and natural killer (NK) cells. Virus-infected cells activate strong cell-mediated immune responses, which in some cases may be more important than antibody in preventing the spreading of the infection and shortening the illness.

**T cells** play a central role in regulation of the immune response to antigens. T cells can recognize and destroy virus-infected cells, and this recognition is virus specific and is important in preventing viral multiplication. T lymphocytes prevent virus multiplication by destroying infected cells before the virus mature and split. CD4+ T cells control the functions of other lymphocyte and CD8+ T cells regulate immune by fighting against viruses, fungi, and bacteria. T cells are vital in recovery from viral infections.

**T Helper (Th) Cells** regulate T cell and B cell mediated immune response and is required for generation of T cells and optimal antibody production. Th1 cells produce IFN- $\gamma$  and IL-2 and promotes cellular immunity; Th2 cells produce IL-4 and IL-5, which induces humoral immunity (help antibody production)

Macrophages retard virus multiplication in neighboring cells by destroying virus-infected cells or by producing Interferons that destroy the infected cells. Natural Killer (NK) cells destroy virus infected cells by increasing the production of Interleukin-2 and Interferon gamma.



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## **WHAT IS PARACTIN® (14-NEO-ANDRO)?**

ParActin<sup>®</sup> (14-Neo-Andro) is the result of over 15 years of research by scientists from the Universidad Austral de Chile, who pioneered the research and development of immuno-modulating therapies. The scientists owned 2 worldwide technical patents and 1 US utility patent pending on ParActin<sup>®</sup>: (a) (WO/2005/074953) COMPOSITION OF LABDANE DITERPENES EXTRACTED FROM ANDROGRAPHIS PANICULATA, USEFUL FOR THE TREATMENT OF AUTOIMMUNE DISEASES, AND ALZHEIMER DISEASE BY ACTIVATION OF PPR-GAMMA RECEPTORS (b) (WO/2006/008115) DITERPENIC LABDANS AS IMMUNOSTIMULANTS FOR TREATING INFECTIOUS DISEASES. (c) US Patent Pending Serial No: 10/516,500.

ParActin<sup>®</sup> (14-Neo-Andro) is a patented blend of bioactive compounds from Andrographis Paniculata, consist of Andrographolide, 14-Deoxyandrographolides, and Neoandrographolides. Preliminary research has shown ParActin<sup>®</sup> to stimulate immune response at low doses and promote healthy inflammatory response at high doses. In addition, ParActin<sup>®</sup> (14-Neo-Andro) also exhibits anti-viral properties and is useful as a cold weather companion.

## **HOW DOES PARACTIN® WORK?**

At low dosage (20mg to 40mg), ParActin<sup>®</sup> (14-Neo-Andro) stimulate natural defense mechanisms by activating NFkappaB, thereby increases the production of cytokines such as interferon gamma and interleukin 2 to help boost the immune response for prevention of common cold and flu.

Once contracting a flu or common cold, 150mg to 250mg of ParActin<sup>®</sup> (14-Neo-Andro) will inhibits NFkappaB, thereby reducing the production of pro-



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inflammatory cytokines such as Interferon gamma and Interleukin 2 to help reduce flu symptoms. The anti-viral property of ParActin<sup>®</sup> (14-Neo-Andro) will assist the body to help fight the viral antigen while reducing the overload of cytokines.

By supplementing the body's ability to fight viral infection, ParActin<sup>®</sup> helps to promote healthy immune response to prevent occurrence of common cold. Once contracting the flu, ParActin<sup>®</sup> (14-Neo-Andro) will help reduce the overload of cytokines.

## **MECHANISM OF ACTION FOR INCREASING CELLULAR IMMUNE RESPONSE**

- Increase Interleukin 2 production
- Increase Interferon gamma production
- Increase Natural Killer cell Tumor Necrosis Factor alpha (TNF  $\alpha$ ) production
- Stimulate Th-1 immune response without causing undesirable side effects
- Increase RNA messenger for Interferon gamma

### **ParActin<sup>®</sup> (14-Neo-Andro) Prevention of Common Cold Occurrence**

<b>Location</b>	Universidad Austral de Chile, Valdivia
<b>Study Design</b>	Randomized, Double Blind Placebo Controlled Study
<b>Patients</b>	109 healthy students during cold and flu season: 54 on ParActin <sup>®</sup> , 53 on placebo
<b>Dosage</b>	25mg of ParActin <sup>®</sup> /day
<b>Duration</b>	3 months
<b>Evaluation</b>	Evaluated by clinician for presence or absence of common colds
<b>Result</b>	No significant change between ParActin <sup>®</sup> and placebo group during the 1st month. During month 2 and 3, there is significantly decrease the incidence



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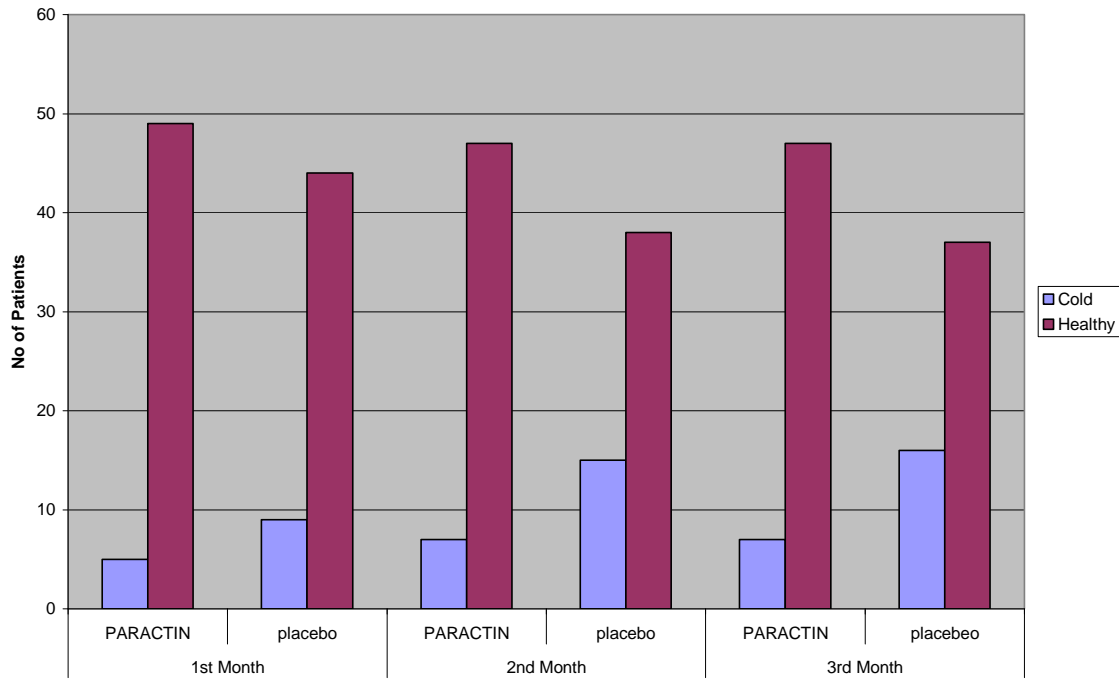
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	of common cold in ParActin® group (30%) compared to placebo group (62%)
<b>Adverse Report</b>	No adverse effects were reported
<b>Conclusion</b>	ParActin® is effective for prevention of common cold occurrence during winter months

Occurrence of Common Cold During Winter Month





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## ParActin® (14-Neo-Andro) Reduce the Intensity of Symptoms and signs of common cold.

<b>Location</b>	Universidad Austral de Chile, Valdivia
<b>Study Design</b>	Randomized, Double Blind Placebo Controlled Study
<b>Patients</b>	158 adult patients already contracting common cold of both sex: 79 on PARACTIN®, 79 on placebo
<b>Dosage</b>	200mg of ParActin® /day
<b>Duration</b>	5 days
<b>Evaluation</b>	Self Evaluation for: frequency & intensity of cough, expectoration, nasal Headaches, tiredness, ear ache, sleeplessness, sore throat on Day 0, 2, and 4.
<b>Result</b>	ParActin® significantly decrease in the intensity of all symptoms for compared with placebo group
<b>Adverse Report</b>	No adverse effects were reported
<b>Conclusion</b>	ParActin® is highly effective in reducing the occurrence and intensity of the symptoms in uncomplicated common cold beginning at day two of treatment.

### Levels of significance symptoms

Symptoms	Treatment	Day 0	Day 2	Day 4
Intensity of Cough	ParActin®	3.87	3.2	1.67
	Placebo	3.22	2.9	2.48
Frequency of Cough	ParActin®	3.25	2.58	1.35
	Placebo	2.95	2.75	2.37
Expectoration	ParActin®	2.17	1.88	1.28



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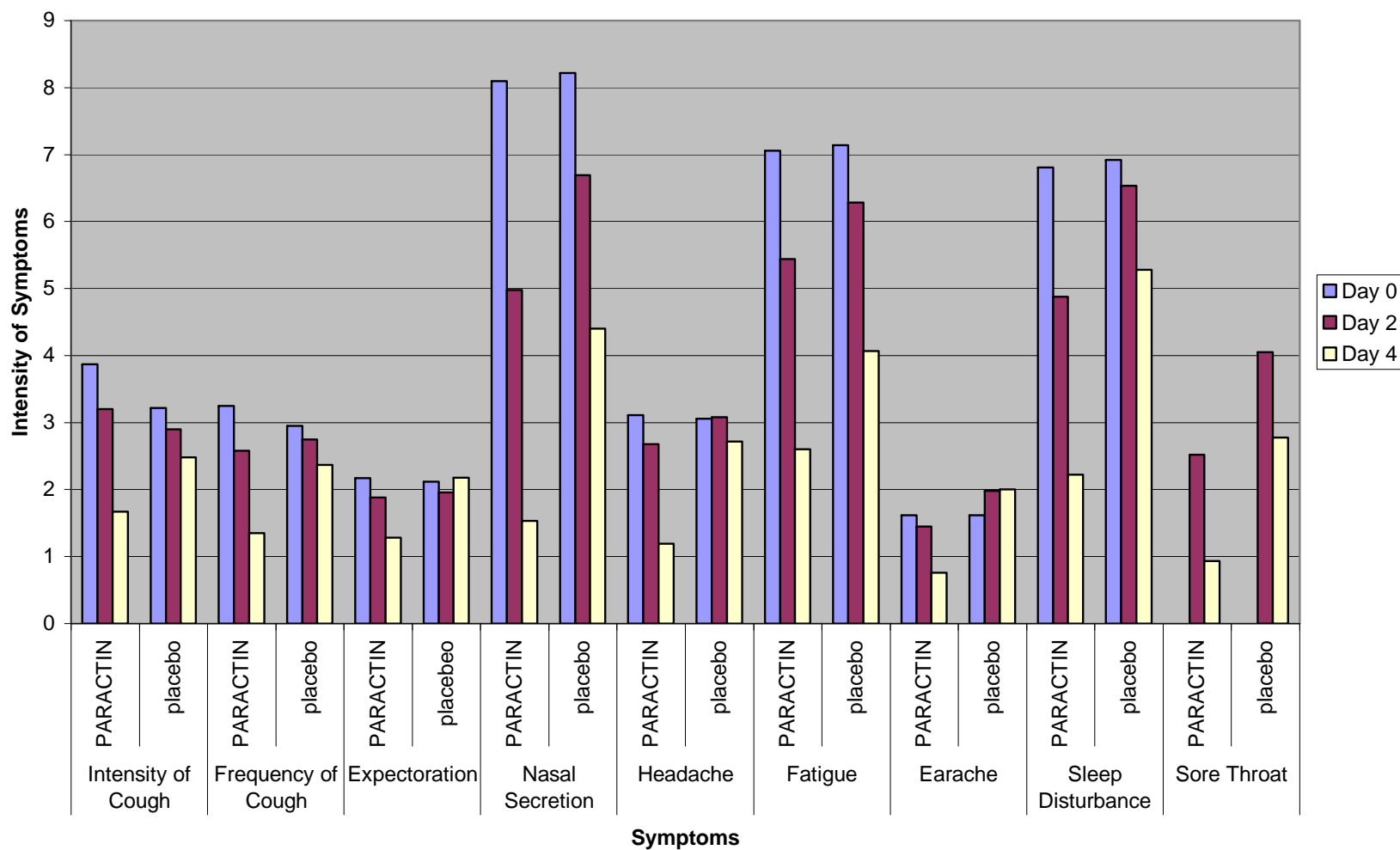
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	Placebo	2.12	1.96	2.18
<b>Nasal Secretion</b>	ParActin®	8.10	4.98	1.53
	Placebo	8.22	6.69	4.40
<b>Headache</b>	ParActin®	3.11	2.68	1.19
	Placebo	3.06	3.08	2.72
<b>Fatigue</b>	ParActin®	7.06	5.44	2.60
	Placebo	7.14	6.28	4.07
<b>Earache</b>	ParActin®	1.62	1.45	0.76
	Placebo	1.62	1.98	2.00
<b>Sleep Disturbance</b>	ParActin®	6.81	4.88	2.22
	Placebo	6.92	6.53	5.28
<b>Sore Throat</b>	ParActin®	ND	2.52	0.93
	Placebo	ND	4.05	2.78



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### Statistical Analysis of Symptoms







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## ParActin® Exhibits Immuno Stimulant Effect By Increasing Cellular Immune Response

<b>Study Design</b>	In Vivo & In Vitro
<b>Objective</b>	ParActin® in low concentrations (0.3mg/kg BW) is able to increase the cellular immunity, inducing IFN-gamma and IL-2 production specifically increasing the Th-1 response.
<b>Animal</b>	50 Rockefeller male mice (25 immunized, 25 non-immunized)
<b>Dosage</b>	6.138 or 61.68 µg/kg of ParActin® in PBS (treated intraperitoneally)
<b>Duration</b>	6 days
<b>Method</b>	T cell isolated from lymph nodes, treated with concanavaline-A (CON-A) (3.3 or 10 µg/ml), B. abortus protein (0, 1, 5 y 10 µg/ml) and/or ParActin® (0.165, 1.65 or 16.5 nM) for 24 hours. <ul style="list-style-type: none"> <li>• IFN-gamma, IL-2 and IL-4 production was measured using ELISA</li> <li>• Total RNA of T-cells were measured</li> </ul>
<b>In Vitro Result</b>	0165 nM and 16.5 nM of ParActin® <ul style="list-style-type: none"> <li>• significantly increase T-cell proliferation, IFN-γ (2.77 fold compared to control) and IL-2 production, no changes in IL-4 were observed</li> <li>• 0.165 and 16.5 nM of PARACTIN® increase the IFN-γ mRNA</li> </ul>
<b>In Vivo Result</b>	6.14 and 61.38 µg/Kg of ParActin® <ul style="list-style-type: none"> <li>• significantly increase the Th1 production in immunized mice, increase the IFN-γ and IL-2 production, without modifying IL-4 (Th2).</li> </ul>
<b>Conclusion</b>	The immunostimulatory effect of ParActin® is both antigen specific and nonspecific. <ul style="list-style-type: none"> <li>• Th1 cells produce IFN-γ and IL-2 and promotes cellular immunity; Th2 cells produce IL-4 and IL-5, which induces humoral immunity</li> </ul> <p>The increase of cellular proliferation of only IFN-γ and IL-2, and not IL-4, suggest that ParActin® stimulate the cellular immune system, specifically through Th1 response.</p> <ul style="list-style-type: none"> <li>• ParActin® can be used for the prevention of common colds (a</li> </ul>



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	minimum of 15-25 mg of ParActin® , corresponding to a dose of 0.3mg/Kg/day of ParActin®) in healthy individuals
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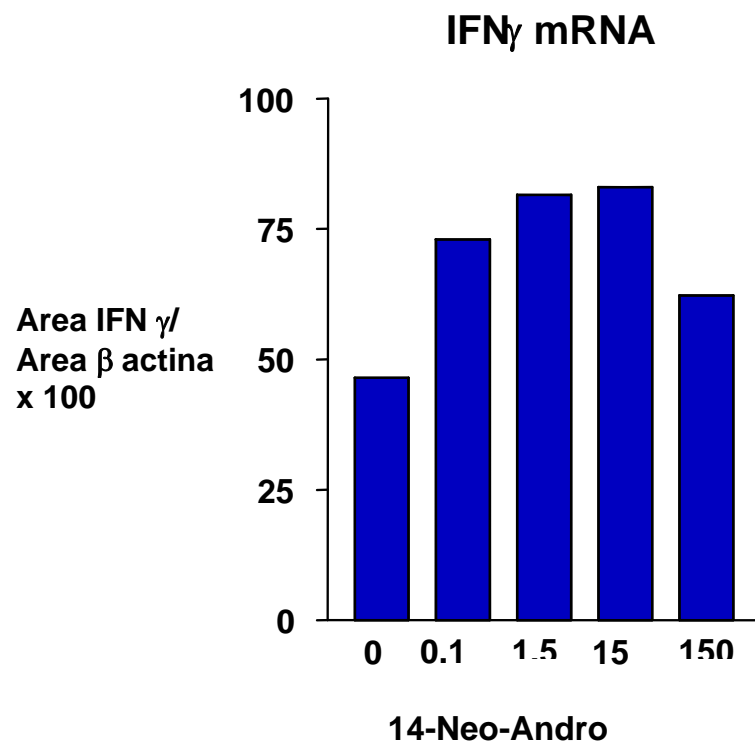
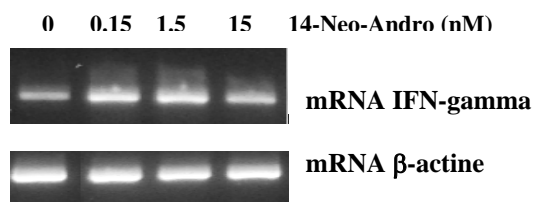
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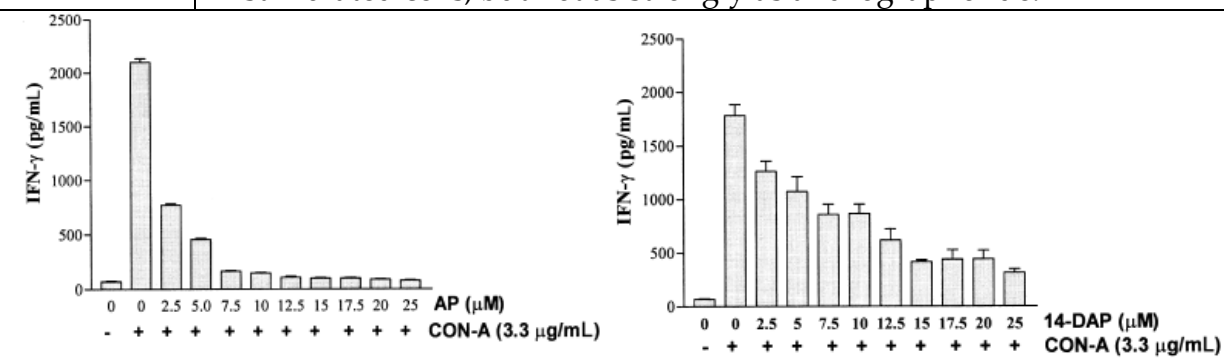
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## IFN-gamma in T-cells RT-PCR



## ParActin® (14-NEO-ANDRO) inhibits IFN $\gamma$ and IL-2 production

<b>Study Design</b>	In Vitro
<b>Objective</b>	ParActin® in high concentrations (3mg/kg BW) is able to reduce IFN-gamma and IL-2 production
<b>Animal</b>	6-8 weeks old Rockefeller mice
<b>Dosage</b>	6.138 or 61.68 $\mu\text{g}/\text{kg}$ of ParActin® in PBS (treated intraperitoneally)
<b>Duration</b>	6 days
<b>Method</b>	<ul style="list-style-type: none"> <li>T cell isolated from lymph nodes, treated with concanavaline-A (3.3 <math>\mu\text{g}/\text{ml}</math> CON-A) and Andrographolides or 14-Deoxyandrographolides for 24 hours.</li> <li>IFN-gamma, IL-2 and IL-4 production was measured using ELISA</li> </ul>
<b>IFN-<math>\gamma</math> Result</b>	<ul style="list-style-type: none"> <li>All doses of andrographolide inhibited dramatically the CON-A rise of IFN-<math>\gamma</math> with maximum inhibitory response at doses of 7.5<math>\mu\text{M}</math> and <math>\text{IC}_{50}</math> 1.7<math>\pm</math>0.07<math>\mu\text{M}</math>.</li> <li>14-DAP was also able to inhibit the IFN- <math>\gamma</math> production in CON-A stimulated cells, but not as strongly as andrographolide.</li> </ul>
	
<b>IL-2 &amp; IL-4 Result</b>	<p>ANDRO but not 14-DAP inhibited the IL-2 production induced by CON-A.</p> <p>The IL-4 production was not modified either by ANDRO or 14-DAP in T-cells.</p>



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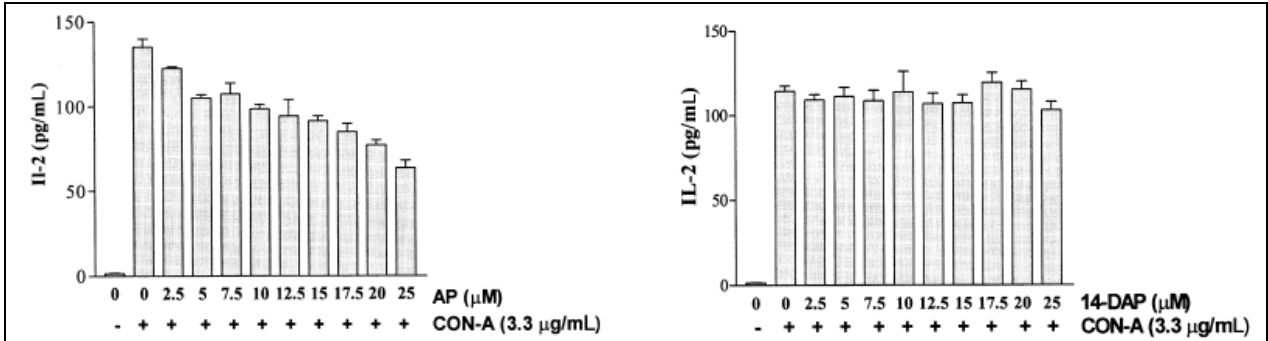
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**Conclusion**

The active compounds in ParActin® (14-NEO-ANDRO) inhibit significantly the production of IFN $\gamma$  in T-cells, and reduce IL-2 without modifying IL-4.

- ParActin® can be used to reduce common colds symptoms such as fever, nasal congestion, and muscle pain associated overload of Interferon gamma and Interleukin 2 (150-250 mg of PARACTIN®, corresponding to a dose of 3mg/Kg/day of PARACTIN®) in individuals already contracted cold and flu.