Assessment of the activity of a cosmetic formula on patients showing a light to moderate couperose..

Clinical Trials

This study was conducted by 152 dermatologists. At the beginning of treatment and at the end of observation period, a pattern typical of the symptomatology of Rosacea was evaluated. By the end of the treatment took place an evaluation of results of the treatment and tolerability, by both physicians and patients.

Etude multicentrique. Étude réalisé en Allemagne avec 152 dermatologues. Sur 441 patients.
En complément d'une étude clinique – réalisée au Méxique. Mexico Military Hospital – Service de Dermatology.
Étude demandée par les Laboratoires ISISPHARMA.

PATIENTS:

441 patients (316 females and 125 males)

54 patients = grade 0 rosacea

387 patients = grade 1 rosacea

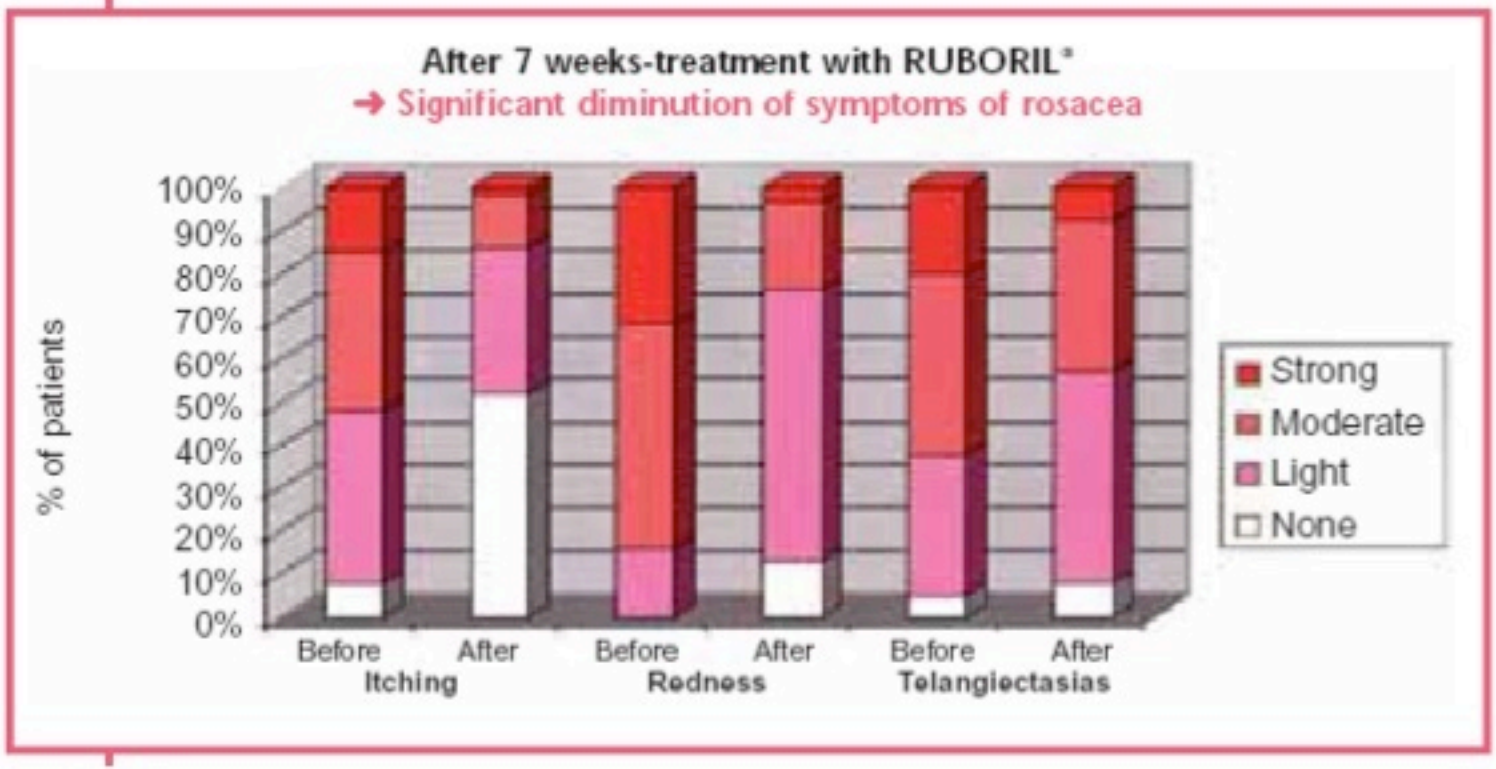
DURATION:

Apply RUBORIL twice a day

Treatment during 12 weeks – Evalutation at 7W and 12W

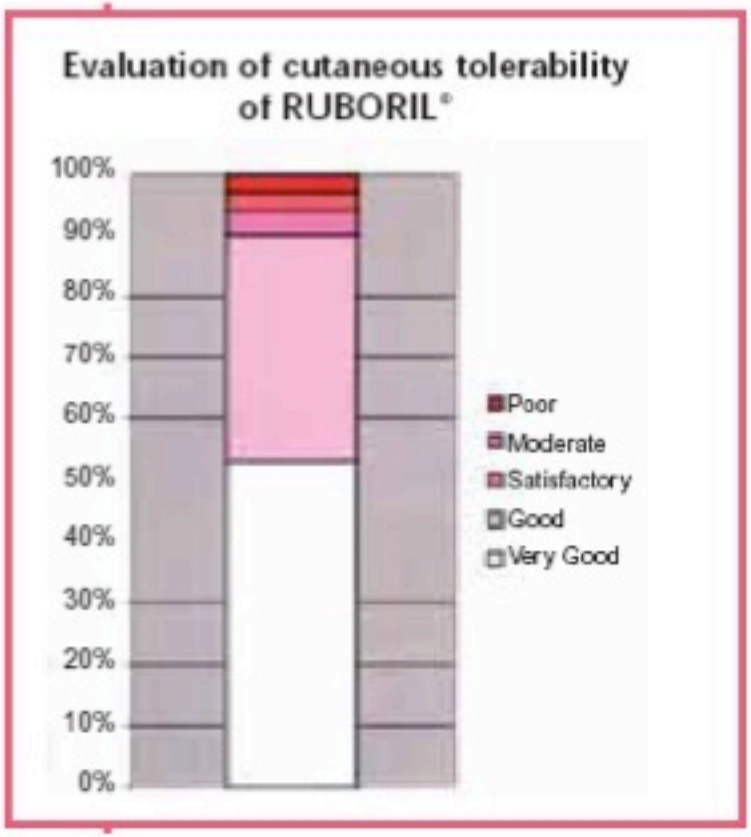
328 patients received exclusively RUBORIL as treatment

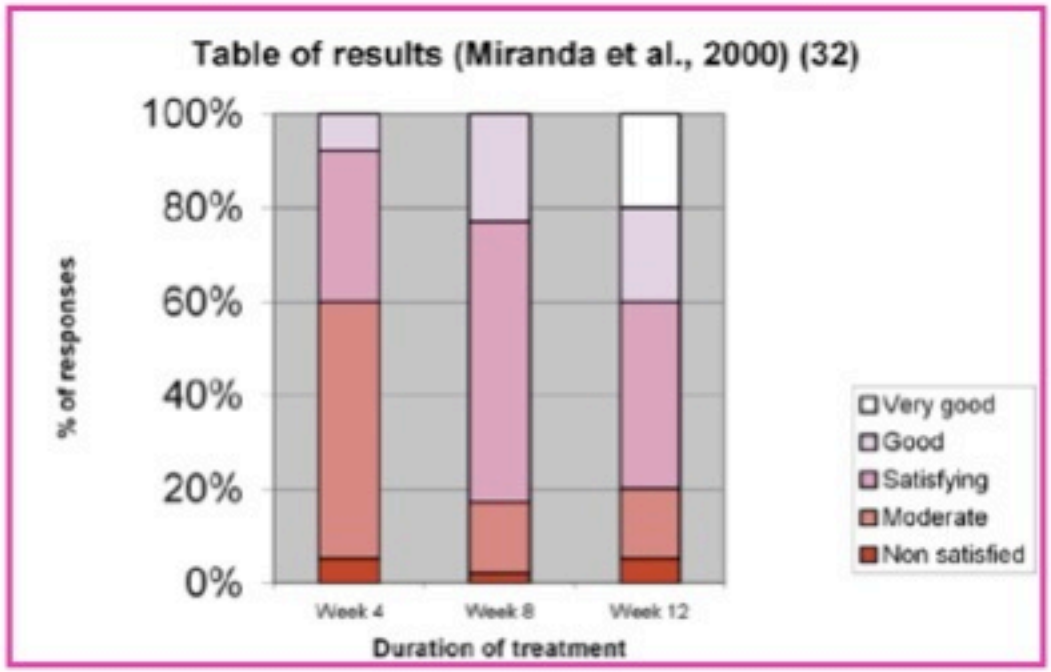
EVALUATION OF RUBORIL



Results: As soon as 7 weeks-treatment with RUBORIL®, the comparison before/after showed a significant improvement of symptoms.

EVALUATION OF THE TOLERANCE





Ruboril® shows a good cutaneous tolerability

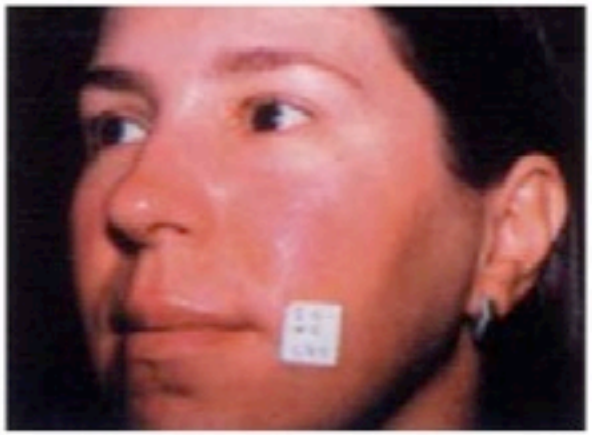
Symptom (Number of patients)	% of patients showing a significant reduction of their symptoms
Itching (229)	92%
Redness (356)	88%
Telangiectasias (186)	69%

Results of auto-evaluation realised on the patients after 12 weeks of treatment.

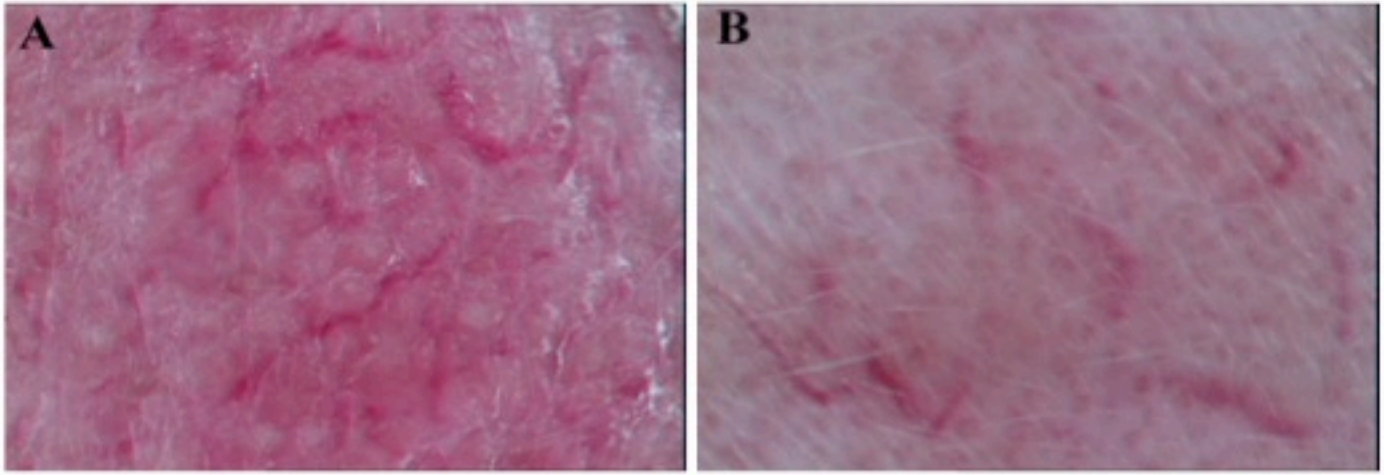
The amelioration based on the 3 symptoms is significative.

VISUAL EVALUATION

Avant traitement avec **RUBORIL®**
Before treatment with **RUBORIL®**
Antes del tratamiento con **RUBORIL®**



Après 12 semaines de traitement avec **RUBORIL®**
After 12 weeks of treatment with **RUBORIL®**
Luego de 12 semanas de tratamiento con **RUBORIL®**



CONCLUSION

- ✔ RUBORIL® improves deficient cutaneous blood circulation.
- ✔ Redness has been reduced by 88% of patients, and telangiectasias by 69% of them.
- ✔ RUBORIL® calms and heals epidermis. Itching, burning sensations disappeared by 92% of patients.
- ✔ RUBORIL® provides an excellent cutaneous tolerability and is easy for use.
- ✔ RUBORIL® is the ideal solution for cosmetic treatment of Rosacea.

RuboriL - MetroRuboriL

- **Trial:** - double blind versus placebo;
  - 2 centers (in the dermatological departments of the university research hospitals: **Bucharest and Iasi**)
  - total 30 patients (15 patients/center),
  - trial period: 3 months (12weeks), monthly control examination (total of 3 exams + first day examination D0)
  - Application twice per day

- Patients caracteristics:

  - 8 had mild redness (degree of severity 1-2);
  - 10 had moderate redness (degree of severity 3-4);
  - 12 had rosacea (degree of severity 5-6)

  22 females / 8 males - All caucasian peoples

Scale of severity:
0 : without redness
1-2 : light - moderate redness
3-4 : moderate - severe redness (rosacea erythema-telengietasic)
5-6 : grave rosacea (rosacea papulo pustular)

Products	Patients G1	Patients G2
Ruboril	5	5
MetroRuboriL	5	6
Placebo	5	4
TOTAL	**15**	**15**

- From these 30 patients - 6 ended the trial prematurely, being lost from the trial:
  - 3 after the first examination
  - 3 after the second one.

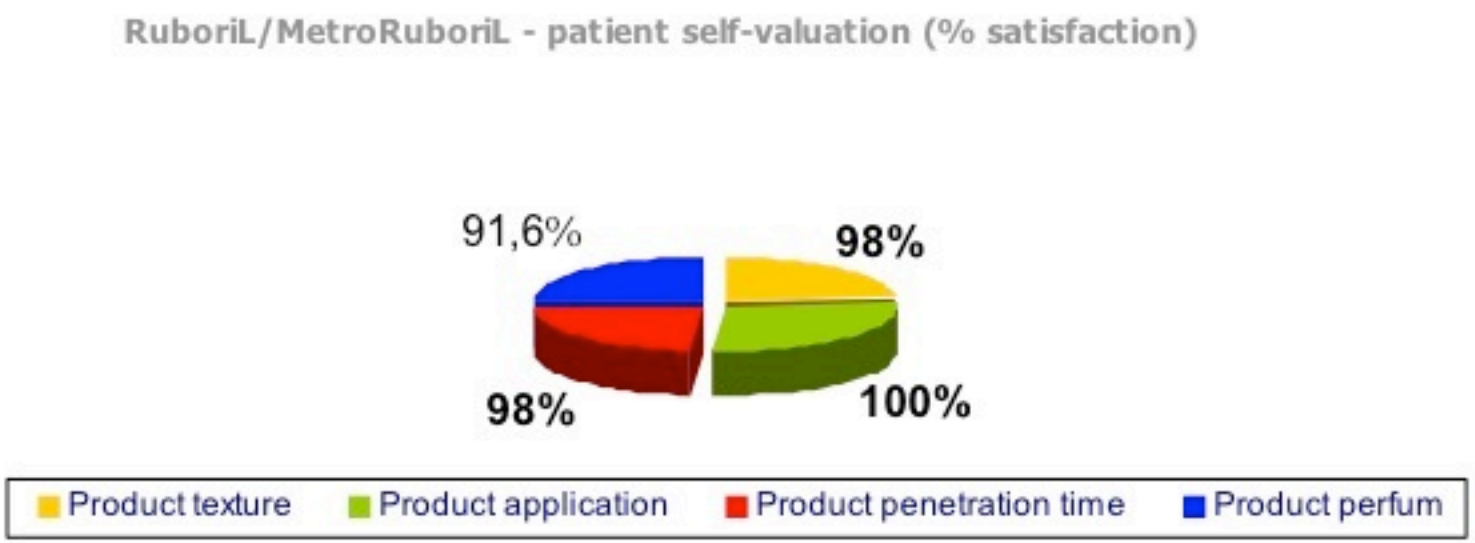
  Conclusion: 80% of them have completed the trial (24 patients)

The patients witch have completed the trial

Products	Patients G1	Patients G2
Ruboril	5	3
MetroRuboriL	5	5
Placebo	2	4
TOTAL	**12**	**12**

Patient Self-Evaluation

- By the end of the trial, every patient had done a self-valuation regarding the:
  - texture;
  - facility of use (application);
  - penetration time;
  - perfume.



✓ 96,8% of patients appreciated the characteristics - good and very good;

Scale of efficacy

1 – to aggravate
2 – unchanged
3 - mild improve
4 – moderate improve
5 – important improve
6 – without symptoms

Scale of tolerability

0 - without side eff.
1 - mild side eff.
2 - moderate side eff.
3 – moder.to severe
4 - severe side eff.

Total of patients	Pat./ Scale of severity	Efficacy	Tolerability
8 with Ruboril	5p. / 1-2 legere red. 3p. / 3-4 couperosis	**5** imp.impr. **4/5**mod/imp.	0 0
10 with MetroRuboriL	7p. / 3-4 couperosis 3p. / 5-6 rosacee	**5-6** without **5** imp.impr.	1p./ 1-2 0
6 with Placebo	4p. / 1-2 legere red. 2p. / 3-4 moder.red.	**2–3** mild imp **2** unchang.	0 0

Clinical Evaluation

Total of patients with Placebo = 6	Month1 Eryth/Couper.	Month2 Erythr/Couper.	Month3 Eryth/Couper.
Efficacy Scale	2=unchanged	2=unchanged	2-3=mild impr.
Tolerability	Perfect	Perfect	Perfect
Total	+ 3%	- 4%	**- 12%**

Total of patients with Ruboril = 8	Month 1 Erith./Couper.	Month 2 Erithr./Couper.	Month 3 Red./Erithr.
Efficacy	3-mild improve	3-4mild/mod. improve	4-5 mod./imp. improve
Tolerability	Perfect	Perfect	Perfect
Total	- 22%	- 36%	**- 54% High Improve**

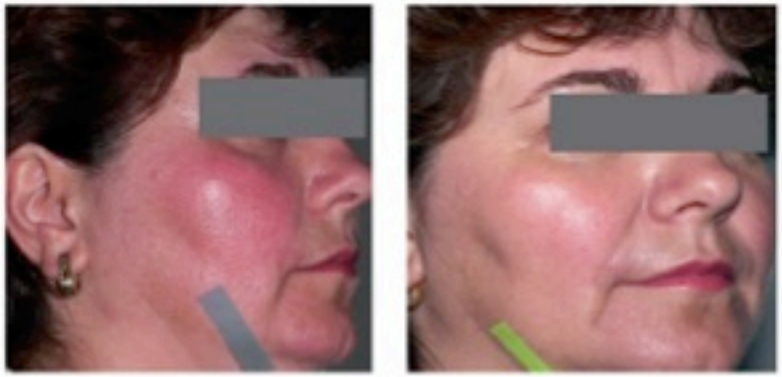
Total of patients with MR = 10	Month 1 Coup./Rosac.	Month 2 Coup./Rosac.	Month 3 Red./Coup.
Efficacy	3-4 (mild/mod. improve)	4-5 (mod/imp. improve)	5-6 (imp.improv, without simpt.)
Tolerability	Moderate (1pat.with red.)	Perfect	Perfect
Total	- 42%	- 56%	**- 82% High improve**

- ✓ Dermatologists point of view, the products had an **increased efficacy** scaled as good or very good in **78,3%** of the cases and also a **good and very good tolerability** in **94,5%** cases.

- ✓ On the next photos you can observe the patients before and after 3 months treatment.

RUBORIL

68% reduction of redness



METRORUBORIL

82% reduction of erythema