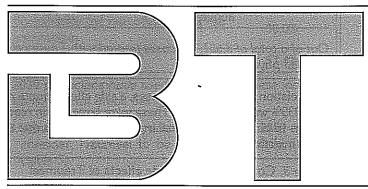
## BIOLOGICAL THERAPY

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**Investigation by Questionnaire into the Therapeutic Effectiveness and Compatibility of Traumeel**  In one action, 3300 physicians (up to the deadline of August 4, 1981) were questioned in detail in writing in the form of a questionnaire concerning their experiences using Traumeel. They were queried with regard to the number of cases treated by them, the treatment periods and with regard to the experience period in relation to observed side effects or generally regarding compatibility in the cases of more lengthy treatment. Out of the 3300 questionnaires received, 270 = 8.2% could not be evaluated while 3030 = 91.8% were subjected to statistic evaluation.

According to specializations, the 3030 physicians were divided into the following categories: (Table 1)

Table 1: Classification of the specializations participating in the Traumeel study corresponding to percentages of all practitioners in the Federal Republic of Germany related to the specialization.

public of Germany related to the specialization		
prakt. Arzte	= general practitioners	57.2%
Internisten	= internists	8.8%
Orthopaden	= orthopedists	8.1%
Padiater	= pediatricians	6.1%
sonstige Arzte	= other physicians	19.8%
comprised of: HNO Chirurgie Gynakologie Dermatologie Zahnmedizin Sonstige	= ENT = surgery = gynaecology = dermatology = dentistry = other	

## Results of this study:

 All 3030 physicians had extensive experience with Traumeel.

A total of 3,651,710 cases were treated in which: 91.0% ointments (see also under 6.)

67.9% ampules 65.8% tablets

and

57.6% drops

were prescribed.

- Traumeel was prescribed by all these physicians with experience ranging between 1 year and 40 years. The individual physican's average experience with Traumeel was 12.2 years.
- 3. A large number of these physicians had experience using Traumeel in long range therapy. Of the 3,651,710 cases, 30.7% were treated for longer than three months as follows: 18.4% from 3-6 months and 12.3% longer than six months, with some individual cases lasting years. (table 2).

Table 2: Treatment period in the Traumeel therapy

up to 3 months	69.3%
3-6 months	18.4%
above 6 months	12.3%

Out of a total of 3,651,710 cases treated with Traumeel by 3030 physicians

4. In relation to the 3,651,710 cases, a side effects quota of 0.0035% was determined. These were largely skin reactions to ointments and local irritation conditions due to the injection (table 3).

Table 3: Compatibility and side effects of Traumeel	
99.9965% without side effects =3,651,580 cases	
0.0035%	with side effects = 130 cases
The side effects of the 130 cases can be classified as allergic reactions	

- 5. The following relationships are revealed by the items 1 to 4:
  - the representative number of prescribing physicans (3030)
  - the correspondingly long experience of these physicians with Traumeel (on average more than 12.2 years)
  - the significant number of cases treated with Traumeel (3,651,710 patients)
  - the correspondingly long therapy and observation periods

## stand in relation to

- the low side effects quota (0.0035%)
- the thoroughly positive experience with regard to compatibility, whereby no carcinoma cases were observed in connection with the administration of Traumeel.
- 6. The connection between the most frequently used form of application of ointment and the low side effects quota with regard to allergic skin compaints permits the conclusion to be drawn without doubt that carcinogenesis is not present. With the prescription width, application period and number of cases treated with Traumeel ointment, a carcinoma would have had to manifest itself on the skin in a certain percentage of cases because of constant skin irritation.
- 7. The fields of application of Traumeel were summarized in the investigation into inflammations, soft tissue swellings, injuries, arthrosis and for increasing non-specific defensive action, whereby the statement of several indications was possible. The result can be seen in table 4.

njuries	75.5%
nflammations	78.3%
Soft tissue swellings	75.7%
To increase the non-specific defense mechanism	50.0%
Arthroses	57.4%

8. Among the 3030 physicians questioned, 2859 = 94.3% consider Traumeel to be necessary in daily practice (table 5).

Table 5: Is Traumeel a necessary preparation?	
Yes	94.3%
Na	2.6%
No statement	3.1%
Out of the 3030 physicians questione Traumeel to be necessary in their pr	<del>-</del>

9. The same positive experiences were also reported by veterinary surgeons in the course of this enquiry. Out of 186 veterinary surgeons questioned and included into the evaluation (194 total questionnaires received of which eight, 4.1%, could not be evaluated) 124,272 large and small animals were treated. The following survey provides information on details:

a) Questionnaires received Questionnaires which could	194
not be evaluated Questionnaires evaluated	8 = 4.1% 186 = 95.9%
b) Treated cases	124,272 large and small animals

c) Traumeel prescribed:	1-29 years, 5.8 years on average	
d) Application forms used:	165 = 88.7%: ointment 160 = 86.0%: ampules 123 = 66.1%: tablets 112 = 60.2%: drops	
e) Treatment periods involved:		
below 3 months:	111,435 cases = 89.7%	
3-6 months:	9,066 cases = 7.3%	
above· 6 months:	3,771  cases = .3.0%	
f) Used in the following indication	ns:	
inflammations	162 = 87.1%	
injuries	161 = 86.6%	
soft tissue swellings	139 = 74.7%	
arthroses	110 = 59.1%	
to increase the non-specific		
defense mechanism	62 = 33.3%	
g) Side effects in connection		
with Traumeel	10  cases = 0.008%	
	(fatigue)	
h) Do you consider Traumeel to		
be a necessary preparation?	182 = 97.9% yes	
	0 = 0.0% no	
	4 = 2.1% no statement	

The indication areas in which Traumeel was used in veterinary medicine were also largely identical with the Traumeel indication areas in human medicine in their percentage distribution, as can be seen from table 4. The largest percentage difference occurred concerning Traumeel for increasing the non-specific defense mechanism (human medicine: 50.0%, veterinary medicine: 33.3%). The lowest percentage difference occurred in the use of Traumeel in arthrosis therapy (human medicine: 57.4%, veterinary medicine: 59.1%). Here it should be noted that all large animals were covered by the meat inspection and were also statistically recorded in the meat inspection. According to information from the slaughter house, no carcinoma cases have become known in the corresponding statistics.

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