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Company:
CPS Pharma

Product:
Seredyl 8 Hours
A4 Info for Alexander Pharma

Current Artwork Status
Initial Draft

Artwork Control
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CMYK
A4 double sided

SEREDYL® 8 HOURS

Suffering from tension and sleepless nights?

SEREDYL® 8 HOURS The first functional food supplement whose efficacy is comparable to that of drugs to tackle sleep disorders and everyday anxiety.

Indications

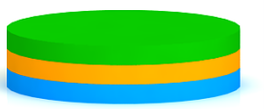
- **Sleep disorders** of various origin*
- **Neurovegetatlve disorders:** sensation of oppression, visceral sornatisation

Formulation

Dianxial Complex™	200 mg / tablet
Dianoctem Complex™	150 mg / tablet

Two active principles are perfectly distributed within the 3 layers of the tablet, optimizing bioavailabilty and kinetics.

An exclusive galenic form to guarantee prolonged efficacy



TRANQUILIZING and HYPNOTIC action
Dissolves completely within 5 minutes: immediate plasma peaks for a fast effect and better *quality of sleep*.

SEDATIVE and VISCERAL SPASMOLYTIC action
Dissolves completely within 8 hours: for a continual, prolonged effect - effective *visceral spasmolytic action.*

SEDATIVE and CARDIAC MYORELAXANT action
Dissolves completely within 45 minutes: progressive plasma peaks for an *effective sedative action.*

Effective: in 100% of subjects

Results of a 5-week multicentric clinical trial on **60 subjects suffering from sleep disorders** complicated by neurovegetative problems and visceral somatizations.
After approximately 5 weeks, the efficacy of this treatment was **comparable to that of pharmacological treatment** in all subjects:

- Sleep was **easily Induced** and maintained
- **Disappearance of:** anxiety, sensations of tightness in throat/thorax, tachycardia and palpitations, abdominal cramps and muscular pains on waking.

No rebound effect when pharmacological drugs are replaced with **morning drowsiness**, which always seems to be present in subjects treated with pharmacological drugs, is completely absent.

Usage

- **Anti insomnia:** 1 tablet (or possibly 2 for the first few days, if necessary) 30 minutes before bedtime.

- **Anti stress:** 1 tablet in the morning. If necessary, the product can be taken daily on an ongoing basis. Non-addictive. Optimal results are obtained after 4-5 weeks. Effective from the first administration.

Safety

The product has a high safety profile, with no significant side effects recorded in the clinical trial.

Clinical Results

Polycentric study: 60 subjects of both sexes
The 40 subjects treated with drugs at T_0 were already undergoing constant treatment with the same drugs.

Treatment outline:

Patients (t=0)		N°	Therapy (0 to 14 days)	Therapy (15 to 35 days)
20 no therapy	A	20	Seredial 8 hours (2 tab/day)	Seredial 8 hours (1 tab/day)
20 Synthetic product 1	B	10	Seredial 8 hours (2 tab/day)	Seredial 8 hours (1 tab/day)
	C	10	Synthetic product 1	Synthetic product 1
20 Synthetic product 2	B	10	Seredial 8 hours (2 tab/day)	Seredial 8 hours (1 tab/day)
	C	10	Synthetic product 2	Synthetic product 2

Synthetic product 1: Bromazepan.
Synthetic product 2: Bromazepan + Propantheline.

20 Subjects with SEREDYL® 8 HOURS as a monotherapy without previous pharmacological therapy

20 Subjects: SEREDYL® 8 HOURS	(A)	Score	
Parameter	t=0	t=2weeks	t=5weeks
Sleep induction*	2 ± 0	0.5 ± 0.5	0.12 ± 0.5
Sleep maintenance*	2 ± 0	0.5 ± 0.5	0
Tachycardia/palpitations	2 ± 0	0	0
Anxiety	2 ± 0	0.5 ± 0.5	0
Sensation of throat/thoracic oppression	2 ± 0	0	0
Abdominal pain	2 ± 0	0.5 ± 0.5	0.25 ± 0.5
Muscular pain on waking	2 ± 0	0.5 ± 0.5	0

Score 0=absent, 1=slight, 2=significant (*identified as a problem)

In subjects treated with **SEREDYL® 8 HOURS** a **progressive reduction** in the clinical score was recorded for almost all parameters, culminating in the **complete disappearance** of symptoms. Tachycarrdia and sensation of oppression were already absent after 2 weeks, all other parameters had disappeared after 5 weeks.

20 Subjects with SEREDYL® 8 HOURS after pharmacological therapy (B)

Parameter		t=0	t=2weeks	t=5weeks
Sleep induction*	2 ± 0	0	0	0
Sleep maintenance*	2 ± 0	0	0	0
Tachycardia/palpitations	2 ± 0	0	0	0
Anxiety	2 ± 0	0	0	0
Sensation of throat/ thoracic oppression	2 ± 0	0	0	0
Abdominal pain	2 ± 0	0.25±0.5	0.25±0.5	0.12±0.5
Muscular pain on waking	2 ± 0	0.25 ± 0.5	0.25 ± 0.5	0

Subjects undergoing pharmacological therapy took **SEREDYL® 8 HOURS** together with their existing drug for one day at T_0, and then continued the treatment with the food suppleement only.
Not only was no rebound effect reported, but in addition the symptomatology, previously treated with the drug, **maintained the same clinical score in relation to disappearance of symptoms**, thereby demonstrating a substantial similarity in terms of clinical effectiveness.

20 Subjects with only pharmacological therapy (C)

Parameter		t=0	t=2weeks	t=5weeks
Sleep induction*	2 ± 0	0	0	0
Sleep maintenance*	2 ± 0	0	0	0
Tachycardia/palpitations	2 ± 0	0	0	0
Anxiety	2 ± 0	0	0	0
Sensation of throat/thoracic oppression	2 ± 0	0	0	0
Abdominal pain	2 ± 0	0.12 ± 0.5	0.12 ± 0.5	0.12 ± 0.5
Muscular pain on waking	2 ± 0	0.12 ± 0.5	0	0

Score 0=absent, 1=slight, 2=significant (*identified as a problem)

As expected, the two synthetic products, already taken for some time prior to T0, prove to have a prolonged effect.

Summary

In all 60 subjects, **morning drowsiness** was reported as a side effect. No drowsiness was reported in the 40 subjects treated with **SEREDYL® 8 HOURS** , whilst significant drowsiness was recorded in the subjects treated with Bromazepam or Bromazepam + Propantheline.

Morning drowsiness Score

Parameter	N°	t=2weeks	t=5weeks
Synthetic product 1	10	2 ± 0	2 ± 0
Synthetic product 2	10	2 ± 0	2 ± 0
SEREDYL® 8 HOURS	**40**	**0**	**0**

Score 0=absent, 1=slight, 2=significant (*identified as a problem)

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