

VERONA CAPSULE

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF PREPARATION

Verona

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Active substances:

Tribulus Terrestris	300.0 mg
Withania somnifera	100.0 mg
Argyreia speciosa	60.0 mg
Mucuna pruriens	25.0 mg

For excipients, see 6.1.

3. MEDICINAL FORM

Capsule

Light brown to dark brown color powder with characteristic aromatic odor, filled in red color capsule, size “0”, cap & body printed with “Верона”.

4. CLINICAL CHARACTERISTICS

4.1 Therapeutic indications:

Functional disorders of the sexual sphere in man (decreased libido, weakening of erection, premature ejaculation) formed during the development of chronic asthenizing conditions.

4.2 Dosage and administration:

Adults:

For oral administration. Take 1-2 capsules daily for 4-6 weeks.

Capsules are taken in the morning before meals, in the evening-before going to bed, preferably with milk.

4.3 Contraindications:

- increased individual sensitivity to the components of the drug
- cardiovascular diseases, kidney diseases.
- children and adolescents under 18 years of age

4.4 Side effects:

The frequency of adverse events is determined according to the following criteria: very common ($> 1/10$), common ($> 1/100$ to $< 1/10$), infrequent ($> 1/1000$ to $< 1/100$), rare ($> 1/10000$ to $< 1/1000$), very rare ($< 1/10000$), unknown (cannot be estimated based on available data)

Very rarely

- allergic reactions are possible, in the form of hives, itching of the skin and rashes

If you experience any adverse drug reactions, contact a healthcare professional or pharmacist

4.5 Special instructions and special safety measures

If there is no effect after a single course of treatment, it is necessary to stop taking the drug and consult a specialist doctor.

Important information about excipients.

The composition of the drug includes dyes FD&C yellow No. 6 (E 110) and red acid 14 (E 122), which can cause allergic reactions.

Verona contains methyl parahydroxybenzoate and propyl parahydroxybenzoate, which can cause allergic reactions (even delayed ones).

Features of the influence of drugs on the ability to vehicle management.

Taking the drug has an impact on the ability to drive vehicles or work with precise mechanisms (it may weaken attention).

Application in pediatrics

Contraindicated in children under 18 years of age.

Pregnancy and lactation.

Not applicable

4.6 Over dosage:

Not reported.

4.7 Drug interactions:

To date, the drug interaction of the drug Verona has not been described. It is not taken in combination with drugs that depress the central nervous system, antidepressants, barbiturates, alcohol.

The use of a drug with diuretics may increase the effects of the latter and potentiate the hypotensive effect of antihypertensive drugs.

Concomitant use of the drug with sedatives is not recommended.

If you need to take any other medications at the same time, you should definitely consult your doctor.

5. PHARMACOLOGICAL PROPERTIES

5.1. Pharmacodynamic and Pharmacokinetic Properties

Pharmacokinetics

The drug possesses a combined effect of its components; all the components cannot be traced using biomarkers or bio studies, so it is not possible to conduct pharmacokinetic studies.

Pharmacodynamics

The drug helps to reduce the severity of astheno-neurotic reactions, which leads to increased sexual desire and erection, prolongation of sexual intercourse, has a regulating effect on spermatogenesis (contributes to an increase in sperm volume, increased concentration and motility of spermatozoa, reducing the number of pathological forms)

5.2 Pharmacotherapeutic group:

Drugs for the treatment of urological diseases. Medications for the treatment of erectile dysfunction. Combined medications used for erectile dysfunction.

5.3 Preclinical safety data

- **Single- dose toxicity**

Verona capsules to rat's male and female (220-270g body weight) in doses up to 2300mg/kg did not pose any deaths in animals.

- **Repeated-dose toxicity**

Verona was administered daily in the doses of 27.71mg/kg (normal dose), 55.42 mg/kg (moderate dose) and 83.14 mg/kg (high dose) of body weight for a period of 60 days orally.

- **Genotoxicity (in vitro, in-vivo, toxicokinetic assessment)**

Verona capsules in the studied dose of 100mg/ kg showed no mutagenic activity in a test account of chromosome aberrations in bone marrow cells of mice.

- **Carcinogenicity (long-term studies; short-term or medium-term studies)**

Verona capsules have no influence on humoral reaction of mice-hybrids F1 C57Blx CBA/Lac.

- **Reproductive and ontogenetic toxicity: ability to reproduce offspring and early embryonic development; fetal embryo development; intrauterine and postnatal development; studies where offspring (growing animals) received a certain dose and / or evaluated later.**

Rat's embryonic growth, as measured by yolk sac diameter, crown-rump length and number of somites were not affected by Verona Capsules up to 1000 mg/kg.

6. PHARMACEUTICAL CHARACTERISTICS

6.1. List of excipients:

Talc..... 15mg

Composition of capsule shell in %

Gelatin... 85 – 88

Water.... 12.5 – 15

Titanium dioxide (E-171)..... NMT 0.6 BP

FD&C Allura red # 40 (E-129)..... NMT 0.12

FD&C Brilliant blue # 1 (E-133)..... NMT 0.1

FD&C Yellow # 10 Quinoline (E-104)..... NMT 0.07

Methylparahydroxybenzoate....0.04

Propylparahydroxybenzoate..... 0.01

Sodium lauryl sulphate..... 0.01

6.2. Shelf life:

3 years; not to be used after the expiry date.

6.3. Special safety measures for storage:

Store in a dry place at a temperature not exceeding 25°C.

6.4. Type and volume of primary packing:

20, 60 capsules in a plastic bottle with a screw cap;

1 bottle with instructions for medical use in a cardboard box.

6.5. Sales conditions:

To be sold without doctor's prescription

7. TRADE LICENSE HOLDER

Herbion Pakistan (Pvt.) Ltd.,
30/28, Korangi Industrial Area, Karachi, Pakistan

8. MANUFACTURER

Herbion Pakistan (Pvt.) Ltd.,
30/28, Korangi Industrial Area, Karachi, Pakistan

