SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Procomil 5 mg, sugar-coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One sugar-coated tablet contains 5 mg of yohimbine hydrochloride.

Excipient(s) with known effect:
Procomil 5 mg contains lactose, sucrose and glucose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Sugar-coated tablets for oral administration.
Procomil 5 mg is a silver coloured, round, sugar-coated tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Procomil 5 mg is indicated in male adults from 18 years of age.

Procomil 5 mg is a tonic for male sexual debility.

Sexual dysfunction, libido disorders, reduced reflex excitability of the lumbosacral spinal cord and general and sex-related symptoms of the male menopause (climacterium virile) e. g. fatigue, lack of concentration, depression and loss of activity.

4.2 Posology and method of administration

Posology

The recommended dose for adults is 1 – 2 tablets up to 3 times daily, which corresponds to a maximum daily dose of 6 tablets (equating to 30 mg yohimbine hydrochloride). It is recommended to start treatment with 2 x 1 tablets per day and then to gradually increase the dose to 3 x 2 tablets when needed.

Renal and hepatic insufficiency
Caution should be taken in patients with mild to moderate impaired renal and/or hepatic function (see section 4.4). The usage of yohimbine hydrochloride is contraindicated in patients with severe impaired renal and/or hepatic function (see section 4.3).

Elderly patients
The safety and efficacy of Procomil 5 mg in elderly patients have not been established.

Children and adolescents
Procomil 5 mg should not be used in children aged below 18 years because of safety concern(s*)*.

Women
Procomil 5 mg should not be used in women because of safety and efficacy concern(s*)*.

Method of administration

Procomil 5 mg should be taken after meals with a glass of water. The duration of treatment depends on the severity of symptoms. It usually lasts for a period of about 8 weeks. In general, a latency period of 2 – 3 weeks from the start of treatment until onset of effect is to be expected.
If side effects occur the dosage needs to be reduced or the usage of Procomil 5 mg should be discontinued.

4.3 Contraindications

Procomil 5 mg must not be used in the following cases:
- in case of hypersensitivity to yohimbine hydrochloride or any of the excipients listed in section 6.1.
- heart disease (especially coronary artery disease, tachycardia arrhythmia)
- hypertension, hypotension
- severe renal or hepatic impairment
- stomach or intestinal ulcers
- increased internal eye pressure (glaucoma)
- psychiatric disorders, particularly mood disorders and anxiety.
- in case the patient takesmedicines that act on the central nervous system (e. g. medicines for psychiatric or neurological diseases, certain remedies for high blood pressure, alcohol).

4.4 Special warnings and precautions for use

Treatment with yohimbine hydrochloride is not indicated in the case of severe organically or psychologically caused erectile dysfunction or in the case of organic genesis with possible causal therapy.

Taking Procomil 5 mg may aggravate existing kidney disease.

Impaired liver function can affect the biotransformation of yohimbine hydrochloride and hence, elevate its effect and side effects.

Glucose
Patients with rare glucose-galactose malabsorption should not take this medicine.

Lactose
Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucosegalactose malabsorption should not take this medicine.

Sucrose
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

The effect of the following drugs or groups of drugs can be influenced by Procomil 5 mg when used concomitantly:

- Procomil 5 mg should not be taken with clonidine preparations, since the effects of yohimbine hydrochloride and clonidine cancel each other out.
- Procomil 5 mg may reduce the effect of other blood pressure lowering drugs.
- During the concomitant intake of Procomil 5 mg and antidepressants or antipsychotics, their effects or side effects may be increased.
- Due to possible increased effects, the simultaneous use of amphetamines (stimulants) with Procomil 5 mg is not recommended.
- Clomipramine increases the plasma level of yohimbine hydrochloride and can thus lead to its increased effectiveness.
- Yohimbine HCl can increase the effectiveness of opiates.
- Interactions with phenothiazine are possible.
- Patients with cardiovascular risk factors should avoid the concomitant intake of drugs with the active substance sibutramine, as this may lead to tachycardia and an increase in blood pressure.

When taking Procomil 5 mg alcohol should not be drunken.

4.6 Fertility, pregnancy and lactation

Procomil 5 mg is not indicated for treating women.

4.7 Effects on ability to drive and use machines

Even when used as intended, this medication can alter responsiveness to such an extent that, for example, the ability to actively participate in driving or operate machinery is impaired. This applies even more when combined with alcohol.

4.8 Undesirable effects

The assessment of side effects is based on the following frequencies:

Very common: (≥1/10),
Common: (≥1/100, <1/10),
Uncommon: (≥1/1000 <1/100),
Rare: (≥1/10 000 <1/1000),
Very rare: (<1/10 000),
Not known: (frequency cannot be estimated from the available data)

<u>General disorders:</u>
Uncommon: sweating, shivers

<u>Immune system disorders</u>:
Uncommon: allergic reactions

<u>Respiratory and thoracic disorders:</u>
Very rare: spasms of the bronchial musculature (bronchospasm)

<u>Skin disorders:</u>
Uncommon: erythema
Very rare: exanthem

Nervous system disorders:
Common: headache
Uncommon: dizziness
Very rare: tremor

Psychiatric disorders:
Common: insomnia, anxiety, restlessness, irritability
Uncommon: nervousness

Cardiovascular disorders:
Uncommon: increased blood pressure and heart rate, palpitations
Very rare: hypotension

Digestive tract disorders:
Common: nausea
Uncommon: vomiting, loss of appetite, stomach upset, diarrhoea

Kidneys and urinary tract:
Common: increased urination
Very rare: pain when urinating (dysuria), decreased urination, genital pain

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to WALTER RITTER GmbH + Co. KG:

WALTER RITTER GmbH + Co. KG
Spaldingstr. 110 B
20097 Hamburg
GERMANY
E-Mail: drugsafety@walterritter.com

4.9 Overdose

Symptoms
The following symptoms occurred after a single oral intake of 200 mg yohimbine HC: Organically caused psychological syndrome with symptoms of anxiety, confusion, coordination disorders, epileptic-like cramps, unconsciousness, hypertension, tachycardia, vegetative disorders, retrosternal pain, cyanosis, urinary retention, systemic lupus erythematosus.

Emergency measures
In case of oral overdoses, during the early stage it is recommended to remove the toxin by gastric lavage in connection with the administration of medicinal charcoal, as well as possibly supporting medicinal measures depending on the clinical course. Diazepam, phenobarbital and phenytoin have an anticonvulsant effect; Clonidine antagonises the psycho-vegetative effects; in the case of strong arousal, give benzodiazepines. If necessary, support breathing with intubation and ventilation, bladder catheterization.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: α2-receptor antagonist
ATC code: G04BE04

5.2 Pharmacokinetic properties

Absorption

Yohimbine hydrochloride is completely absorbed within about an hour. Maximum blood levels are reached after 45 - 75 minutes. The bioavailability is subject to very strong inter- and intra-individual fluctuations, which is mainly due to a hepatic first-pass effect.

Distribution

Yohimbine hydrochloride has a high level of tissue binding. In plasma approx. 82% of yohimbine is bound to protein. Only a small proportion of yohimbine hydrochloride and the active metabolite 11-hydroxyyohimbine can be detected in the liquor.

Elimination

Elimination takes place via both hepatic and extrahepatic metabolic pathways. Two hydroxylated metabolites could be detected, 11-hydroxyyohimbine and 10-hydroxyyohimbine.

The elimination half-life after a single dose varies between 0.25 and 2.5 hours. The active metabolite 11-hydroxyyohimbine is eliminated with a longer half-life of approx. 6 hours.

5.3 Preclinical safety data

The symptoms of acute yohimbine poisoning are described in section 4.9. Very limited preclinical data on chronic toxicity do not reveal any specific organ damage in the rat, but a dose-dependent disturbance in weight gain was found. In-vitro and in-vivo studies on the genotoxic potential with yohimbine yielded negative results. In a fertility study, yohimbine did not affect fertility or reproductive behavior in male rats. At doses above 6 mg / kg body weight, however, decreased testicular and epididymal weights were observed.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

lactose monohydrate
maize starch
microcrystalline cellulose
povidone K 25
colloidal anhydrous silica
talc
sodium starch glycollate type A
magnesium stearate
sucrose
heavy kaolin
calcium carbonate

titanium dioxide E 171
acacia
macrogol 6000
liquid glucose
aluminium powder
gelatin powder

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a dry place at a temperature of max. 30°C.
Protect from sunlight.

6.5 Nature and contents of container

Blister contains 10 sugar-coated tablets.
Original packaging contains 30 sugar-coated tablets.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

WALTER RITTER GmbH + Co. KG
Spaldingstr. 110 B
20097 Hamburg
GERMANY
Tel.: (0049) 40 236996-0
Fax: (0049) 40 236996-33

8. MARKETING AUTHORISATION NUMBER(S)

FDA/SD.203-01007

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of latest renewal: 1st February 2020

10. DATE OF REVISION OF THE TEXT

March 2021

PRESCRIPTION AND PHARMACY-ONLY
Prescription and pharmacy-only