The subject of the invention is the use of naftopidil for the therapy of dysuria in the case of benign prostatic hypertrophy.

Naftopidil, chemical designation 1-(2-methoxyphenyl)-4-[3-(naphth-1-yloxy)-2-hydroxypropyl]-piperazine, is the subject of Patent DE-B-24 08 804 and is there described as a compound with outstanding blood pressure lowering and thus antihypertensive properties. Furthermore, it is said to inhibit the anaphylactoid reactions in rats induced by dextran.

In "Drugs of the Future", Vol. 12, No. 1, 1987, naftopidil is described as a selective α-blocker.

In "British Journal of Urology" (1976), Vol. 48, No. 4, pages 255 - 263, it is indicated that "alpha-adrenergic blockers" can be used in the case of the treatment of benign prostate obstructions.

In "Urology", Vol. 32, pages 27 - 31, it is described that terazosin can find use for the treatment of benign prostatic hypertrophy.

In the case of clinical investigations with naftopidil, it has now been found that the compound alleviates complaints in the case of prostatic hypertrophy. The complaints are characterised by a disturbance of micturation, especially the urge to micturate during the night. As a rule, men over 60 years are hereby affected. Hitherto, a specific therapy has not been established. By way of experiment, active materials based on plant extracts or on β-sitosterol (cf. Rote Liste 1989) are used.

The effectiveness of naftopidil for the treatment of dysuria due to prostatic hypertrophy is founded in the clinical study described in detail in the following.

The investigations were carried out on a total of 39 patients. 37 of them suffered from a prostatic

hypertrophy. After a preliminary period of one week in which placebo medication took place, naftopidil was administered in doses between 12.5 and 100 mg daily. The dose administered depended upon the effectiveness; in the case of insufficient action, the dose was increased twofold at intervals of one week, commencing with 12.5 mg.

As criteria, inter alia, there were chosen: frequency of the micturation during the day and the night, period of the micturation, urine flow, abdominal pressure in order to be able to micturate, as well as sensation during micturation.

The evaluation took place on the basis of a scale with the following classification: distinctly improved, improved, slightly improved, unchanged, worsened.

In all, 34 patients could be included in the evaluation. Of these, 8 were distinctly improved, 14 improved, 7 slightly improved, 1 patient had an unchanged behaviour and in the case of 4 further patients no distinct decision could be made.

Naftopidil is preferably administered orally.

The preparation of naftopidil takes place according to the process described in DE-B-24 08 804.

For the preparation of salts, one reacts the compound according to the invention with pharmacologically acceptable organic or inorganic acids, e.g. hydrochloric acid, sulphuric acid, phosphoric acid, lactic acid, citric acid or alkylsulphonic acid.

For the preparation of medicaments, naftopidil is mixed in per se known manner with suitable pharmaceutical carrier substances, aroma, flavouring and colouring materials and formed, for example, into tablets or dragees or, with the addition of appropriate adjuvants, suspended or dissolved in water or oil, such as e.g. olive oil.

Naftopidil is usually administered in amounts between 10 and 100 mg per day. A single or double administration per day in an individual dose of 10 - 50 mg is preferred.

An exemplary formulation for a tablet with 25.0 mg of active material is composed as follows:

naftopidil	25.0 mg
lactose x $1H_2O$	110.0 mg
poly-(1-vinyl-2-pyrrolidone) M.W. 25,000	3.0 mg
microcrystalline cellulose	15.0 mg
highly dispersed SiO_2	1.5 mg
poly-(O-carboxymethyl)-starch, Na salt	4.0 mg
magnesium stearate	1.5 mg
	160.0 mg

Patent Claims

1. Use of 1-(2-methoxyphenyl)-4-[3-(naphth-1-yloxy)-2-hydroxypropyl]-piperazine or of its pharmacologically acceptable salts for the preparation of medicaments for the treatment of dysuria in the case of prostatic hypertrophy.

2. Orally administerable composition containing as active material 1-(2-methoxyphenyl)-4-[3-(naphth-1-yloxy)-2-hydroxypropyl]-piperazine, characterised in that, in a single dose, it contains the active material in an amount of 10 - 50 mg, in addition to usual carrier and adjuvant materials.