SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Pro-viron®

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 25mg mesterolone

3 PHARMACEUTICAL FORM

Tablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Androgen deficiency or male infertility when associated with primary or secondary male hypogonadism.

4.2 Posology and method of administration

The following dosages are recommended:
Adults:
Initially: 3 or 4 tablets daily for several months, followed by maintenance therapy of 2-3 tablets (50-75mg) daily.

Children:
Not recommended in children.

4.3 Contraindications

Pro-viron is contraindicated in the presence of prostatic carcinoma since androgens can stimulate the growth of an existing carcinoma. Previous or existing liver tumours. Hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

Androgens are not suitable for enhancing muscular development in healthy individuals or for increasing physical ability. Regular examination of the prostate during treatment is advised, in order to exclude prostatic carcinoma.

In rare cases benign, and in even rarer cases, malignant liver tumours leading in isolated cases to life-threatening intra-abdominal haemorrhage have been observed after the use of hormonal substances such as the one contained in Pro-viron. If severe upper abdominal complaints, liver enlargement or signs of intra-abdominal haemorrhage occur, the possibility of a liver tumour should be included in the differential diagnosis.

Frequent or persistent erections of the penis may occur (see section 4.8 “Undesirable effects”).

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Not applicable.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

If, in individual cases, frequent or persistent erections occur, the dose should be discontinued in order to avoid injury to the penis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisations 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 via the Yellow Card scheme at www.mhra.gov.uk/yellowcard

4.9 Overdose

There have been no reports of ill-effects from overdosage and treatment is generally unncessary. If overdosage is discovered within two to three hours and is so large that treatment seems desirable, gastric lavage can safely be used.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pro-viron is an orally active androgen.The presence of a methyl group at C-1 confers special properties on this steroid which, unlike testosterone and all its derivatives that are used for androgen therapy, is not metabolised to oestrogen.
This difference almost certainly accounts for the observation that, in its usual therapeutic dosage in normal men, Pro-viron does not significantly depress the release of gonadotrophins from the pituitary. Hence (1) spermatogenesis is unimpaired (2) unlike other androgens, which suppress and therefore replace endogenous androgens, Pro-viron supplements endogenous androgens.
In contrast to other orally active androgens, liver tolerance is excellent (a fact probably related to the absence of 17-alkyl substitution of the steroid nucleus).

5.2 Pharmacokinetic properties

Following oral ingestion mesterolone is rapidly and almost completely absorbed in a wide dose range of 25 - 100 mg. The intake of Pro-viron generates maximum serum drug levels of 3.1 ± 1.1 ng/ml after 1.6 ± 0.6 hours. Thereafter, drug levels in serum decrease with a terminal half-life of 12 - 13 hours. Mesterolone is 98% bound to serum proteins., 40% to albumin and 58% to SHBG (sex hormone binding globulin). Mesterolone is rapidly inactivated by metabolism. The metabolic clearance rate from serum accounts for 4.4 ± 1.6 $ml \cdot min^{-1} \cdot kg^{-1}$. There is no renal excretion of unchanged drug. The main metabolite has been identified as 1α-methyl-androsterone, which - in conjugated form - accounts for 55 - 70 % of renally excreted metabolites. The ratio of the main metabolite glucuronide to sulphate is about 12:1. A further metabolite 1α-methyl-5α-androstane-3α,17β-diol has been recognized, which accounted for about 3 % of renally eliminated metabolites. No metabolic conversion into oestrogens or corticoids has been observed. 77% of the mesterolone metabolites are excreted via the urine and 13% with the faeces. 50% of the dose is excreted in the urine within 24 hours and 90% within 7 days via the faeces and urine.
The absolute bioavailability of mesterolone is about 3 % of the oral dose.

5.3 Preclinical safety data

There are no preclinical data which could be of relevance to the prescriber and which are not already included in other relevant sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose
maize starch
povidone 25 000 (E1201)
methyl parahydroxybenzoate (E218)
propyl parahydroxybenzoate (E216)
magnesium stearate (E572)

6.2 Incompatibilities

None known.

6.3 Shelf life

5 years.

6.4 Special precautions for storage

None

6.5 Nature and contents of container

3 blister packs of 10 tablets contained in a cardboard outer pack.

6.6 Special precautions for disposal

Store all drugs properly and keep them out of reach of children.

7 MARKETING AUTHORISATION HOLDER

Bayer plc
400 South Oak Way
Reading
RG2 6AD

8 MARKETING AUTHORISATION NUMBER(S)

PL 00010/0562

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

01/05/2008

10 DATE OF REVISION OF THE TEXT

13/12/2017