

**Product Name: Marvelon 150/30**

**Component: English Package Insert -  
USRN**

**Date Approved: 24 March 2012**

## **SCHEDULING STATUS**

S3

## **PROPRIETARY NAME AND DOSAGE FORM**

MARVELON® 150/30 Tablets

## **COMPOSITION**

21 larger white tablets containing 0,15 mg desogestrel and 0,03 mg ethinylestradiol per tablet.

7 smaller white tablets that do not contain any active ingredients (placebo tablets).

**Inactive ingredients:** Colloidal silicon dioxide, lactose, magnesium stearate, potato starch, povidone, stearic acid and dl-alpha-tocopherol. The daily amount of lactose (< 80 mg) is such that women with intolerance to lactose are highly unlikely to experience a problem.

## **PHARMACOLOGICAL CLASSIFICATION**

A.18.8 Ovulation controlling agents

## **PHARMACOLOGICAL ACTION**

MARVELON 150/30 is an oestrogen/progestogen combination oral contraceptive that inhibits ovulation.

## **PHARMACODYNAMIC PROPERTIES**

The contraceptive effect of MARVELON 150/30 is based on the interaction of various factors, the most important of which are seen as the inhibition of ovulation and the changes

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in the cervical secretion.

## **PHARMACOKINETIC PROPERTIES**

### **Desogestrel**

#### **Absorption**

Orally administered desogestrel is rapidly and completely absorbed and converted to etonogestrel. Peak serum concentrations of approximately 2 ng/ml are reached at about 1,5 hours after single ingestion. Bioavailability is 62 to 81 %.

#### **Distribution**

Etonogestrel is bound to serum albumin and to sex hormone binding globulin (SHBG). Only 2 to 4 % of the total serum drug concentrations are present as free steroid, 40 to 70 % are specifically bound to SHBG. The ethinylestradiol-induced increase in SHBG influences the distribution over the serum proteins, causing an increase of the SHBG-bound fraction and a decrease of the albumin-bound fraction. The apparent volume of distribution of desogestrel is 1,5 litre/kg.

#### **Metabolism**

Etonogestrel is completely metabolised by the known pathways of steroid metabolism. The metabolic clearance rate from serum is about 2 ml/min/kg. No interaction was found with the co-administered ethinylestradiol.

#### **Elimination**

Etonogestrel serum levels decrease in two phases. The terminal disposition phase is characterised by a half-life of approximately 30 hours. Desogestrel and its metabolites are

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excreted at a urinary to biliary ratio of about 6:4.

### **Steady-state conditions**

Etonogestrel pharmacokinetics are influenced by SHBG levels, which are increased threefold by ethinylestradiol. Following daily ingestion, drug serum levels increase about two- to threefold, reaching steady state conditions during the second half of the treatment cycle.

### **Ethinylestradiol**

#### **Absorption**

Orally administered ethinylestradiol is rapidly and completely absorbed. Peak serum concentrations of about 80 pg/ml are reached within 1 to 2 hours. Absolute bioavailability as a result of pre-systemic conjugation and first-pass metabolism is approximately 60 %.

#### **Distribution**

Ethinylestradiol is highly but non-specifically bound to serum albumin (approximately 98,5 %) and induces an increase in the serum concentrations of SHBG. An apparent volume of distribution of about 5 litre/kg was determined.

#### **Metabolism**

Ethinylestradiol is subject to pre-systemic conjugation in both small bowel mucosa and the liver. Ethinylestradiol is primarily metabolised by aromatic hydroxylation but a wide variety of hydroxylated and methylated metabolites are formed, and these are present as free metabolites and as conjugates with glucuronides and sulphate. The metabolic clearance rate is about 5 ml/min/kg.

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### **Elimination**

Ethinylestradiol serum levels decrease in two phases, the terminal disposition phase is characterised by a half-life of approximately 24 hours. Unchanged drug is not excreted, ethinylestradiol metabolites are excreted at a urinary to biliary ratio of 4:6. The half-life of metabolite excretion is about one day.

### **Steady-state conditions**

Steady-state concentrations are reached after 3 to 4 days when serum drug levels are higher by 30 to 40 % as compared to single dose.

### **INDICATIONS**

Oral contraception.

### **CONTRA-INDICATIONS**

Combined oral contraceptives should not be used in the presence of any of the conditions listed below. Should any of the conditions appear for the first time during combined oral contraceptive use, the product should be stopped immediately.

- Thrombosis (venous or arterial) present or in history (e.g. deep venous thrombosis, pulmonary embolism, myocardial infarction, cerebrovascular accident).
- Presence or history of prodromal features of a thrombosis (e.g. transient ischaemic attack, angina pectoris).
- The presence of a serious or multiple risk factors for venous or arterial thrombosis (such as e.g. hypertension, a family history of thromboembolic events, prolonged immobilisation see "**WARNINGS, Circulatory Disorders**").
- Migraine or a history of this condition.

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- Presence or history of hepatic disease as long as liver function values have not returned to normal.
- Presence or history of liver tumours (benign or malignant).
- Known or suspected malignant conditions of the genital organs or the breasts, if sex steroid-influenced.
- Undiagnosed vaginal bleeding.
- Known or suspected pregnancy.
- Diabetes mellitus with vascular involvement.
- Hypersensitivity to any of the active or inactive ingredients of MARVELON 150/30.

## **WARNINGS**

If any of the conditions/risk factors mentioned below is present, the benefits of combined oral contraceptive use should be weighed against the possible risks for each individual woman, and discussed with the woman before she decides to start using it. In case of aggravation, exacerbation or first appearance of any of these conditions or risk factors, the woman should contact her medical practitioner. The medical practitioner should then decide on whether its use should be discontinued.

### **1. Circulatory Disorders**

Epidemiological studies have suggested an association between the use of combined oral contraceptives, and an increased risk of arterial and venous thrombotic and thromboembolic diseases such as myocardial infarction, stroke, deep venous thrombosis and pulmonary embolism.

Venous thromboembolism (VTE), manifesting as deep venous thrombosis and/or pulmonary

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embolism, may occur during the use of combined oral contraceptives. Thrombosis has been reported to occur in other blood vessels e.g. hepatic, mesenteric, renal or retinal veins and arteries, in combined oral contraceptive users. Symptoms of venous or arterial thrombosis can include: Unilateral leg pain and/or swelling; sudden severe pain in the chest, whether or not it radiates to the left arm; sudden breathlessness; sudden onset of coughing; any unusual, severe, prolonged headache; sudden partial or complete loss of vision; diplopia; slurred speech or aphasia; vertigo; collapse with or without focal seizure; weakness or very marked numbness suddenly affecting one side or one part of the body; motor disturbances; “acute” abdomen.

The risk of thromboembolism (venous and/or arterial) increases with:

- Age
- Smoking (with heavier smoking and increasing age the risk further increases, especially in women over 35 years of age)
- A positive family history (i.e. venous or arterial thromboembolism ever in a sibling or parent at a relatively early age). If a hereditary predisposition is suspected, the woman should be referred to a specialist for advice before deciding about any combined oral contraceptive use.
- Obesity (Body mass index over 30 kg/m<sup>2</sup>)
- Dyslipoproteinaemia
- Hypertension
- Valvular heart disease
- Atrial fibrillation
- Prolonged immobilisation, major surgery, any surgery to the legs, or major trauma. In these situations it is advisable to discontinue combined oral contraceptive use (in the

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case of elective surgery at least 4 weeks in advance), and not to resume until 2 weeks after complete remobilisation.

Other medical conditions that have been associated with thrombotic disorders include diabetes mellitus, systemic lupus erythematosus, haemolytic uraemic syndrome, chronic inflammatory bowel disease (Crohn's disease or ulcerative colitis) and sickle cell disease.

The onset of or increase in frequency or severity of migraine during combined oral contraceptive use (which may be prodromal of a cerebrovascular event) is a reason for immediate discontinuation of the combined oral contraceptive.

Biochemical factors that may be indicative of hereditary or acquired predisposition of venous or arterial thrombosis include Activated Protein C (APC) resistance, hyperhomocysteinaemia, antithrombin-III deficiency, protein C deficiency, protein S deficiency, antiphospholipid antibodies (anticardiolipin antibodies, plus anticoagulants).

When considering risk/benefit, the medical practitioner should take into account that adequate treatment of a condition may reduce the associated risk of thrombosis, and that the risk associated with pregnancy is higher than that associated with combined oral contraceptive use.

## **2. Tumours**

An increased risk of cervical cancer in long-term users of combined oral contraceptives has been reported in epidemiological studies.

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A meta-analysis from epidemiological studies reports that there is an increased relative risk of having breast cancer diagnosed in women who are currently using combined oral contraceptives.

Benign liver tumours and more rarely, malignant liver tumours, have been reported in users of combined oral contraceptives. In isolated cases, these tumours have led to life-threatening intra-abdominal haemorrhages. A hepatic tumour should be considered in the differential diagnosis when severe upper abdominal pain, liver enlargement or signs of intra-abdominal haemorrhage occur in women taking combined oral contraceptives.

### **3. Other conditions**

- Women with hypertriglyceridaemia, or a family history thereof, may be at an increased risk of pancreatitis when using combined oral contraceptives.
- Small increases in blood pressure have been reported in many women taking combined oral contraceptives and clinically relevant increases may occur. If a sustained clinically significant hypertension develops during the use of a combined oral contraceptive then, it is prudent for the medical practitioner to withdraw the combined oral contraceptive and treat the hypertension. Where considered appropriate, combined oral contraceptive use may be resumed if normotensive values can be achieved with antihypertensive therapy.
- The following conditions have been reported to occur or deteriorate with combined oral contraceptive use:
  - jaundice and/or pruritus related to cholestasis
  - gallstone formation
  - porphyria
  - systemic lupus erythematosus

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- haemolytic uraemic syndrome
  - Sydenham's chorea
  - herpes gestationis
  - otosclerosis-related hearing loss
  - (hereditary) angioedema.
- Acute or chronic disturbances of liver function may necessitate the discontinuation of combined oral contraceptive use until markers of liver function return to normal. Recurrence of cholestatic jaundice that occurred first during pregnancy or previous use of sex steroids necessitates the discontinuation of combined oral contraceptives.
- Although combined oral contraceptives may have an effect on peripheral insulin resistance and glucose tolerance, there is no evidence for a need to alter the therapeutic regimen in diabetics using combined oral contraceptives. However, diabetic women should be carefully observed while taking combined oral contraceptives.
- Crohn's disease and ulcerative colitis have been associated with combined oral contraceptive use.
- Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst taking combined oral contraceptives.
- Respiratory: Asthma may deteriorate in women using combined oral contraceptives.
- MARVELON 150/30 contains < 80 mg lactose per tablet. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption who are on a lactose-free diet should take this amount into consideration.

## **INTERACTIONS**

Drug interactions that result in an increased clearance of sex hormones can lead to

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breakthrough bleeding and oral contraceptive failure. This has been established with hydantoins, barbiturates, primidone, carbamazepine and rifampicin; oxcarbamazepine, topiramate, felbamate, griseofulvin and products containing St. John's wort. The mechanism of this interaction appears to be based on the hepatic enzyme-inducing properties of these drugs. Maximal enzyme induction is generally not seen for 2 to 3 weeks, but may then be sustained for at least 4 weeks after the cessation of drug therapy.

Contraceptive failures have also been reported with antibiotics, such as ampicillins and tetracyclines. The mechanism of this effect has not been elucidated.

Women on short-term treatment with any of the above-mentioned classes of medicines or individual medicines should use a barrier method temporarily, in addition to the combined oral contraceptive i.e. during the time of concomitant drug administration and for 7 days after their discontinuation. For women on rifampicin, a barrier method should be used in addition to the combined oral contraceptive during the time of rifampicin administration and for 28 days after its discontinuation. If concomitant drug administration runs beyond the end of the tablets in the current oral contraceptive pack, the placebo tablets must be discarded and the next oral contraceptive pack should be started right away, with the active 'Saturday' tablet in the green starting zone.

In women on long-term treatment with hepatic enzyme-inducing drugs, increased contraceptive steroid doses are recommended. If a high contraceptive dosage is not desirable or appears to be unsatisfactory or unreliable e.g. in the case of irregular bleeding, another method of contraception should be advised.

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Oral contraceptives may affect the metabolism of other drugs. Accordingly, plasma and tissue concentrations may be affected (e.g. benzodiazepines).

## **PREGNANCY AND LACTATION**

Extensive epidemiological studies have revealed neither an increased risk of birth defects in children born to women who have used combined oral contraceptives prior to pregnancy, nor a teratogenic effect when combined oral contraceptives were taken inadvertently during early pregnancy. See also “**CONTRA-INDICATIONS**”. Feminisation of the male foetus may occur.

Lactation may be influenced by combined oral contraceptives, as they may reduce the quantity and change the composition of breast milk, therefore the use of combined oral contraceptives should generally not be recommended until the nursing mother has completely weaned her child. Small amounts of the contraceptive steroids and/or their metabolites may be excreted with the milk, but there is no evidence that this adversely affects infant health.

## **DOSAGE AND DIRECTIONS FOR USE**

### **Medical Examination/Consultation**

Prior to the initiation or reinstatement of MARVELON a complete medical history including family history should be taken, and physical examination should be taken prior to the initiation or reinstatement of combined oral contraceptive use, guided by the contra-indications and warnings, and should be repeated at least annually during the use of combined oral contraceptives. Periodic medical assessment is also of importance, because contra-indications (e.g. a transient ischaemic attack etc.) or risk factors (e.g. a family history of

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venous or arterial thrombosis) may appear for the first time during the use of a combined oral contraceptives. The frequency and nature of these assessments should be adapted to the individual woman, but should generally include special reference to blood pressure, breasts, abdomen and pelvic organs, including cervical cytology and relevant laboratory tests.

### **How to take MARVELON 150/30**

Tablets must be taken in the order directed on the package every day at about the same time with some liquid as needed. One tablet is to be taken daily for 28 consecutive days. The first tablet should be taken from the blister in the green section of the calendar pack marked with the appropriate day of the week. Each subsequent pack is started the day after the last tablet of the current pack. During the placebo days a withdrawal bleed usually occurs. This usually starts on day 2 to 3 after the last active tablet and may not have finished before the next pack is started.

### **How to start MARVELON 150/30**

#### **No preceding hormonal contraceptive use [in the past month]**

Tablet-taking has to start on day 1 of the woman's natural cycle (i.e. the first day of her menstrual bleeding). If the woman starts with an inactive tablet on day 1, she should be advised to additionally use a barrier method for the first 14 days of tablet-taking.

### **Changing from another combined oral contraceptive**

The woman should start with MARVELON 150/30 on the day after the last active tablet of her previous combined oral contraceptive.

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### **Changing from a progestogen-only-method (mini pill, injection, implant)**

The woman may switch any day from the mini pill (from an implant on the day of its removal, from an injectable when the next injection would be due), but should in all of these cases be advised to use a barrier method additionally for the first 14 days of tablet-taking.

### **Following first-trimester abortion**

The woman may start immediately. She should be advised to additionally use a barrier method for the first 14 days of tablet-taking.

### **Following delivery or second-trimester abortion**

For breastfeeding women see “**PREGNANCY AND LACTATION**”.

Women should be advised to start at day 21 after delivery or second-trimester abortion.

When starting later, the woman should be advised to use a barrier method additionally for the first 14 days of tablet-taking. However if intercourse has already occurred, pregnancy should be excluded before the actual start of combined oral contraceptive use, or the woman has to wait for her first menstrual period.

### **Management of missed tablets**

Note: The five small tablets immediately before the green starting zone and the first two (small) tablets in the green starting zone of the blister pack contain placebo tablets, and can thus be disregarded if missed. However, they should be discarded to avoid unintentional prolonging of the placebo tablet phase. These rules for the management of missed tablets refer to missed “**active**” tablets i.e. the **21** large tablets starting with 'Saturday' in the green section.

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If the user is **less than 12 hours late** in taking any tablet, contraceptive protection is not reduced. The woman should take the tablet as soon as she remembers and should take further tablets at the usual time.

If she is **more than 12 hours late** in taking any active tablet, contraceptive protection may be reduced. The management of missed tablets can be guided by the following two basic rules:

- “active tablet”-taking must never be discontinued for longer than 7 days.
- 7 days of uninterrupted “active tablet”-taking are required to attain adequate suppression of the hypothalamic-pituitary-ovarian-axis.

Accordingly the following advice can be given in daily practice:

- The user should take the last missed tablet as soon as she remembers, even if this means taking two tablets at the same time. She then continues to take tablets at her usual time. In addition, a barrier method such as a condom should be used for the next 7 days. If these 7 days extend beyond the last 'Friday' -tablet in the pack, the user should take the tablets up to and including that Friday, discard the pack and start a new pack next day with the Saturday tablet in the green starting zone. The user is unlikely to have a withdrawal bleed until the placebo tablet interval of the second pack, but she may experience spotting or breakthrough bleeding on “active tablet”-taking days.
- If the user has missed any of the first seven active tablets (counting from 'Saturday' in the green starting zone onwards) and intercourse took place in the preceding 7 days, the possibility of a pregnancy should be considered. The more tablets missed and the closer they are to the regular placebo tablet interval, the higher the risk of a pregnancy.

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If the woman missed active tablets and subsequently has no withdrawal bleed in the first normal placebo tablet interval, the possibility of a pregnancy should be considered.

### **Advice in case of vomiting**

If vomiting occurs within 3 to 4 hours after tablet-taking, absorption may not be complete. In such an event the advice concerning missed tablets, as given in the previous section, is applicable. If the woman does not want to change her normal tablet-taking schedule she has to take the extra tablet(s) needed from another pack.

### **How to delay a period**

To delay a period, the woman should continue with another pack of MARVELON 150/30 without having a placebo tablet interval (i.e. she should stop the current pack after taking the last large tablet on Friday, and start the next day with the 'Saturday' tablet in the green starting zone of the new pack). The extension can be carried on for as long as wished until the end of the second pack. During the extension the woman may experience breakthrough bleeding or spotting. Regular intake of MARVELON 150/30 is then resumed after the usual 7-day placebo tablet interval.

### **Reduced cycle control**

With all combined oral contraceptives, irregular bleeding (spotting or breakthrough bleeding) may occur, especially during the first months of use. Therefore, the evaluation of any irregular bleeding is only meaningful after an adaptation interval of about three cycles.

If bleeding irregularities persist or occur after previously regular cycles, then non-hormonal

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causes should be considered and adequate diagnostic measures are indicated to exclude malignancy or pregnancy. These may include curettage.

In some women withdrawal bleeding may not occur during the tablet free interval. If the combined oral contraceptive has been taken according to the directions described above, it is unlikely that the woman is pregnant. However, if the combined oral contraceptive has not been taken according to these directions prior to the first missed withdrawal bleed, or if two withdrawal bleeds are missed, pregnancy must be ruled out before combined oral contraceptive use is continued.

## **SIDE EFFECTS AND SPECIAL PRECAUTIONS**

### **Side Effects**

Possibly related adverse effects that have been reported in users of MARVELON 150/30 or combined oral contraceptives users in general are listed in the table below<sup>1</sup>

<b>System Organ Class</b>	<b>Common (≥ 1/100 and &lt; 1/10)</b>	<b>Uncommon (≥ 1/1 000 and &lt; 1/100)</b>	<b>Rare (≥ 1/10 000 and &lt; 1/1 000)</b>
<b>Immune system disorders</b>			Hypersensitivity
<b>Metabolism and nutrition disorders</b>		Fluid retention	
<b>Psychiatric disorders</b>	Depressed mood, mood altered	Libido decreased	Libido increased
<b>Nervous system</b>	Headache	Migraine	

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<b>disorders</b>			
<b>Eye disorders</b>			Contact lens intolerance
<b>Gastrointestinal disorders</b>	Nausea, abdominal pain	Vomiting, diarrhoea	
<b>Skin and subcutaneous tissue disorders</b>		Rash, urticaria	Erythema nodosum, erythema multiforme
<b>Reproductive system and breast disorders</b>	Breast pain, breast tenderness	Breast enlargement	Vaginal discharge, breast discharge
<b>Investigations</b>	Weight increased		Weight decreased

<sup>1</sup> The most appropriate MEDRA term (version 11.0) to describe a certain adverse reaction is listed. Synonyms or related conditions are not listed, but should be taken into account as well.

### Special Precautions

Women should be advised that oral contraceptives do not protect against HIV infections (AIDS) and other sexually transmissible diseases.

**Reduced efficacy:** The efficacy of combined oral contraceptives may be reduced in the event of missed tablets, vomiting or concomitant medication.

### Laboratory Tests

The use of contraceptive steroids may influence the results of certain laboratory tests,

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including biochemical parameters of liver, thyroid, adrenal and renal function, plasma levels of (carrier) proteins e.g. corticosteroid binding globulin and lipid/lipoprotein fractions, parameters of carbohydrate metabolites and parameters of coagulation and fibrinolysis. Changes generally remain within the normal laboratory range.

### **Effects on Ability to Drive and Use Machines**

No observed effects.

### **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT**

There have been no reports of serious deleterious effects from overdose. Symptoms that may occur in this case are: Nausea, vomiting and possible slight vaginal bleeding in young girls. There are no antidotes and further treatment should be symptomatic.

### **IDENTIFICATION**

MARVELON 150/30 consists of two types of tablets distinguished by mark and size. The 21 larger white tablets contain the active ingredients and are round and biconvex. They have bevelled edges, coded ORGANON and a star on one side and the tablet code TR above 5 on the reverse side. The 7 smaller white tablets are round and flat with bevelled edges coded KH above 2 on one side and a square on the reverse side.

### **PRESENTATION**

Push-through strips contain 21 active white tablets and 7 smaller white placebo tablets, the latter being circled in red on the strip foil.

### **STORAGE INSTRUCTIONS**

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Store at or below 30 °C. Protect from light and moisture.

Keep out of reach of children.

**REGISTRATION NUMBER**

Q/18.8/324

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF  
REGISTRATION**

MSD (Pty) Ltd

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Halfway House

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South Africa

**DATE OF PUBLICATION**

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