COMPOSITION

The 28-day pack (Every-Day pack) contains 21 hormonal tablets each with drospirenone (6β,7β,15β,16β-dimethylene-3-oxo-17α-pregn-4-ene-21,17-carbolactone) 3 mg and ethinylestradiol (17α-ethinyl-1,3,5(10)-estratriene-3,17β-diol) 0,03 mg, plus 7 inactive tablets.

PHARMACOLOGICAL ACTION

Pharmacodynamic properties

The contraceptive effect of Yasmin is based on the interaction of various factors, the most important of which are seen as the inhibition of ovulation and the changes in the endometrium.

Yasmin is a combined oral contraceptive with ethinylestradiol and the progestogen drospirenone. In a therapeutic dosage, drospirenone also possesses antiandrogenic and mild antimineralocorticoid properties. It has no estrogenic, glucocorticoid and antiglucocorticoid activity.

There are indications from clinical studies that the mild antimineralocorticoid properties of Yasmin result in a mild antimineralocorticoid effect.

With the use of the higher dosed combined oral contraceptives (50 µg ethinylestradiol) the risk of endometrial and ovarian cancer is reduced. Whether this also applies to lower dosed combined oral contraceptives remains to be confirmed.

Pharmacokinetic properties

- Drospirenone (3 mg)

Absorption

The absolute bioavailability of drospirenone is between 76 and 85%. Concomitant ingestion of food has no influence on bioavailability.

Distribution

After oral administration, serum drospirenone levels decrease in two phases which are characterised by half-lives of 1,6 ± 0,7 hours and 27,0 ± 7,5 hours, respectively. Drospirenone is bound to serum proteins.
albumin and does not bind to sex hormone binding globulin (SHBG) or corticoid binding globulin (CBG). Only 3 to 5% of the total serum drug concentrations are present as free steroid. The ethinylestradiol-induced increase in SHBG does not influence the serum protein binding of drospirenone. The mean apparent volume of distribution of drospirenone is 3.7 ± 1.2 l/kg.

**Metabolism**

Drospirenone is extensively metabolised after oral administration. The major metabolites in the plasma are the acid form of drospirenone, generated by opening of the lactone ring, and the 4,5-dihydro-drospirenone-3-sulfate, both of which are formed without involvement of the P450 system. Drospirenone is metabolised to a minor extent by cytochrome P450 3A4 based on *in vitro* data.

**Elimination**

The metabolic clearance rate of drospirenone in serum is 1.5 ± 0.2 ml/min/kg. Drospirenone is excreted only in trace amounts in unchanged form. The metabolites of drospirenone are excreted with the faeces and urine at an excretion ratio of about 1.2 to 1.4. The half-life of metabolite excretion with the urine and faeces is about 40 hours.

**Steady-state conditions**

During a treatment cycle, maximum steady-state concentrations of drospirenone in serum of about 60 ng/ml are reached between day 7 and day 14 of treatment. Serum drospirenone levels accumulated by a factor of about 2 to 3 as a consequence of the ratio of terminal half-life and dosing interval. Further accumulation of drospirenone levels beyond treatment cycles was observed between cycles 1 and 6 but thereafter, no further accumulation was observed.

- Ethinylestradiol (30 µg)

**Absorption**

Ethinylestradiol is rapidly and completely absorbed after ingestion. After administration of 30 µg, peak plasma concentrations of 100 pg/ml are reached 1 to 2 hours after ingestion. Ethinylestradiol undergoes an extensive first-pass effect, which displays great interindividual variation. The absolute bioavailability is approximately 45%.

**Distribution**

Ethinylestradiol has an apparent volume of distribution of 5 l/kg and binding to plasma proteins is approximately 98%. Ethinylestradiol induces the hepatic synthesis of SHBG and CBG. During treatment with 30 µg ethinylestradiol the plasma concentration of SHBG increases from 70 to about 350 nmol/l. Ethinylestradiol passes in small amounts into breast milk (0.02% of the dose).

**Metabolism**

Ethinylestradiol is metabolised completely (metabolic plasma clearance 5 ml/min/kg).

**Elimination**

Ethinylestradiol is not excreted in unchanged form to any significant extent. The metabolites of ethinylestradiol are excreted at a urinary to biliary ratio of 4:6. The half-life of metabolite excretion is about 1 day. The elimination half-life is 20 hours.

**Steady-state conditions**

Steady-state conditions are reached during the second half of a treatment cycle and serum levels of ethinylestradiol accumulate by a factor of about 1.4 to 2.1.
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.

- Venous thrombosis present or in history (deep venous thrombosis, pulmonary embolism).
- Arterial thrombosis present or in history (eg cerebrovascular accident, myocardial infarction) or prodromal conditions (eg angina pectoris and transient ischaemic attack).
- The presence of a severe or multiple risk factor(s) for arterial thrombosis:
  - diabetes mellitus with vascular symptoms;
  - uncontrolled hypertension;
  - severe dyslipoproteinaemia.
- Hereditary or acquired predisposition for venous or arterial thrombosis, such as activated protein C resistance, antithrombin III deficiency, protein C deficiency, protein S deficiency, hyperhomocysteinemia and antiphospholipid antibodies (anticardiolipin antibodies, lupus anticoagulant).
- Presence or history of severe hepatic disease as long as liver function values have not returned to normal.
- Severe renal insufficiency or acute renal failure. Potassium excretory capacity may be limited in patients with renal insufficiency. Drospirenone intake did not show a significant effect on the serum potassium concentration in patients with mild or moderate renal impairment. However, if additionally concomitant potassium sparing drugs are taken, these patients should be monitored for hyperkalaemia.
- 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.
- History of migraine.
- Hypersensitivity to the active substances or to any of the excipients of Yasmin film-coated tablets.
- Known or suspected pregnancy.

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 the event of aggravation, exacerbation or first appearance of any of these conditions or risk factors, the woman should contact her physician. The physician should then decide on whether its use should be discontinued.

Vascular disorders

Epidemiological studies have associated the use of combined oral contraceptives with an increased risk for venous (deep venous thrombosis, pulmonary embolism) and arterial (myocardial infarction, transient ischaemic attack) thromboembolism.

These studies have shown that the risk of venous thromboembolic disorders is increased by the use of oral contraceptives. The approximate occurrence of venous thromboembolism in users of oral contraceptives with low estrogen content (< 50 µg ethinylestradiol) is up to 10 to 15 cases per 100 000 women-years compared to 4 cases per 100 000 woman-years for non-users.

Nevertheless, the risk is lower than that associated with pregnancy (ie 60 cases per 100 000 woman-years).
Extremely rarely, thrombosis has been reported to occur in other blood vessels, eg hepatic, mesenteric, renal or retinal veins and arteries, in contraceptive pill users. There is no consensus as to whether the occurrence of these events is associated with the use of hormonal contraceptives.

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 for venous thromboembolic complications in combined oral contraceptives users increases with:

- Increasing age.
- A positive family history (venous 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.
- Prolonged immobilisation, major surgery, any surgery to the legs, or major trauma. In these situations it is advisable to discontinue the pill (in the case of elective surgery at least four weeks in advance) and not resume until two weeks after complete remobilisation. Antithrombotic treatment should be considered if the pills have not been discontinued in advance.
- Obesity (body mass index over 30 kg/m²).
- There is no consensus about the possible role of varicose veins and superficial thrombophlebitis in the onset or progression of venous thrombosis.

The risk of arterial thromboembolic complications in combined oral contraceptive users increases with:

- increasing age;
- smoking (women over 35 years should be strongly advised not to smoke if they wish to use a combined oral contraceptive);
- dyslipoproteinemia;
- hypertension;
- valvular heart disease;
- atrial fibrillation.

The presence of one serious risk factor or multiple risk factors for venous or arterial disease, respectively, can also constitute a contra-indication. The possibility of anticoagulant therapy should also be taken into account. Combined oral contraceptive users should be specifically pointed out to contact their physician in case of possible symptoms of thrombosis. In case of suspected or confirmed thrombosis, combined oral contraceptive use should be discontinued. Adequate alternative contraception should be initiated because of the teratogenicity of anticoagulant therapy (coumarins).

The increased risk of thromboembolism in the puerperium must be considered (for information on pregnancy and lactation see “Side-effects and special precautions”).
Other medical conditions which have been associated with adverse vascular events include diabetes mellitus, systemic lupus erythematosus, haemolytic uremic syndrome and chronic inflammatory bowel disease (Crohn's disease or ulcerative colitis).

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

Tumours

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

A meta-analysis from 54 epidemiological studies reported that there is a slightly increased relative risk (RR = 1.24) of having breast cancer diagnosed in women who are currently using combined oral contraceptives. The excess risk gradually disappears during the course of the 10 years after cessation of combined oral contraceptive use. Because breast cancer is rare in women under 40 years of age, the excess number of breast cancer diagnoses in current and recent combined oral contraceptive users is small in relation to the overall risk of breast cancer.

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

Other conditions

- Women using Yasmin and concomitant medications with the potential to increase serum potassium such as ACE-inhibitors, angiotensin II receptor antagonists, aldosterone antagonists, potassium-sparing diuretics or NSAIDs used for longterm treatment should be tested for serum potassium during the first treatment cycle.
- 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, 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 physician 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; haemolytic uraemic syndrome; Sydenham's chorea; herpes gestationis; otosclerosis-related hearing loss.
- 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 which 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.
DOSAGE AND DIRECTIONS FOR USE

A complete medical history and physical examination should be taken prior to the initiation or re-institution 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 venous or arterial thrombosis) may appear for the first time during the use of a combined oral contraceptive. 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 Yasmin

The first course of Yasmin is started on the first day of the menstrual period (day 1 of the cycle) from the silver section of the pack by selecting the appropriate tablet for that day of the week (e.g. “MO” for Monday). The tablet is swallowed whole with some liquid. Thereafter one tablet must be taken daily for 28 days following the direction shown by the arrows. It does not matter at what time of the day the tablet is taken, but once the patient has selected a particular time, the tablet should be taken as near as possible at the same time each day. Withdrawal bleeding usually starts on day 2 to 3 after starting the inactive tablets and may not have finished before the next pack is started. Each subsequent pack is started the day after the last tablet of the current pack. If a patient starts Yasmin during the latter part of the week, the very first cycle may be slightly shortened.

How to start Yasmin

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). During the first cycle an additional barrier method is recommended for the first 7 days of tablet-taking.

Changing from another combined oral contraceptive

The woman should start with Yasmin preferably on the day after the last active tablet of her previous combined oral contraceptive, but at the latest on the day following the usual tablet-free or inactive tablet interval of her previous combined oral contraceptive.

Changing from a progestogen-only method (minipill, injection, implant)

The woman may switch any day from the minipill, from an implant on the day of its removal and from an injectable when the next injection would be due, but should in all these cases be advised to use an additional barrier method for the first 7 days of tablet-taking.

Following first-trimester abortion

The woman may start immediately. When doing so, she need not take additional contraceptive measures.

Following delivery or second-trimester abortion.

For breastfeeding women see “Special precautions”.

Women should be advised to start at day 21 to 28 after delivery or second-trimester abortion. When starting later, the woman should be advised to additionally use a barrier method for the first 7 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
The management of missed tablets can be guided by the following two basic rules:

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

Accordingly the following advice can be given:

If you are less than 12 hours late in taking your Yasmin tablet, you are still protected against pregnancy. Take the tablet as soon as you remember and take the next one at your usual time. This may mean that you are taking 2 tablets in one day.

If you are more than 12 hours late in taking your Yasmin tablet you will not be protected. Take the tablet as soon as you remember and take the next one at your normal time. This may mean taking 2 tablets in one day. You must take extra contraceptive precautions and you must follow the 7 day rule. Read the sections on “Extra contraceptive precautions” and “The 7 day rule” carefully.

If you have forgotten to take your Yasmin tablets for a few days, consult your doctor to be sure you are not pregnant, then discard the missed tablets and follow the 7 day rule.

Extra contraceptive precautions
When you need extra contraceptive precautions, either:
- don’t have sex; or
- use a cap plus spermicide, or a condom.
Don’t use the rhythm or temperature methods as extra contraceptive precautions. This is because oral contraceptives disrupt the usual menstrual cycle changes such as changes in temperature and cervical mucus.

The 7 day rule
If:
you are more than 12 hours late in taking a tablet; or
you have vomiting; or
your doctor advises you to follow the 7 day rule because you are taking certain medicines;
continue to take your tablets as usual.
However, take extra contraceptive precautions during the next 7 days, BUT - if these days run beyond the end of the light yellow active tablets in your pack - the 7 white inactive tablets must NOT be taken (ie discard the current pack after taking the last light yellow tablet on “FR”). Start a new pack on the next day with the first “SA” tablet from the silver section. You can continue pill taking as before. Read the section “Extra contraceptive precautions” carefully. Don’t leave a gap between packs. Your menstrual period will occur after you have completed the second pack. If the period does not occur, consult your doctor before resuming the next pack.

Errors in taking the inactive white tablets can be ignored.

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 above 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 Yasmin without taking the inactive tablets from her current 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 Yasmin is then resumed after the inactive tablet phase.

Reduced cycle control
With all combined oral contraceptives, irregular bleeding (spotting and 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 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 inactive tablet phase. 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 Yasmin use is continued.

**SIDE-EFFECTS AND SPECIAL PRECAUTIONS**

**Side-effects**

**Serious undesirable effects**

See “Warnings”.

**Other possible undesirable effects**

The following adverse drug reactions have been reported during use of Yasmin:

<table>
<thead>
<tr>
<th>Body System</th>
<th>Frequency of adverse reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Common &gt; 1/100</td>
</tr>
<tr>
<td>Immune system</td>
<td></td>
</tr>
<tr>
<td>Endocrine system</td>
<td>Menstrual disorders</td>
</tr>
<tr>
<td>Nervous system</td>
<td>Headache</td>
</tr>
<tr>
<td>Ear and labyrinth</td>
<td></td>
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<tr>
<td>Vascular system</td>
<td>Migraine</td>
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<tr>
<td>Gastrointestinal system</td>
<td>Nausea</td>
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<tr>
<td>Skin and subcutaneous system</td>
<td></td>
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<tr>
<td>Reproductive system and breast</td>
<td>Leukorrhrea</td>
</tr>
<tr>
<td>General</td>
<td>Vaginitis</td>
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<tr>
<td></td>
<td>Fluid retention</td>
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<td></td>
<td>Body weight changes</td>
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</tbody>
</table>

The following serious adverse events have been reported in women using combined oral contraceptives, which are discussed in the section “Warnings”:

- venous thromboembolic disorders;
- arterial thromboembolic disorders;
- hypertension;
- liver tumours;
- occurrence or deterioration of conditions for which association with combined oral contraceptive use is not conclusive: Crohn’s disease, ulcerative colitis, epilepsy, migraine, endometriosis,
uterine myoma, porphyria, systemic lupus erythematosus, herpes gestationis, Sydenham's chorea, haemolytic uremic syndrome, cholestatic jaundice;
• chloasma.

The frequency of diagnosis of breast cancer is very slightly increased among oral contraceptive users. As breast cancer is rare in women under 40 years of age the excess number is small in relation to the overall risk of breast cancer. Causation with combined oral contraceptive use is unknown. For further information, see "Contra-indications" and "Warnings".

Special precautions

Medical examination/consultation

Prior to the initiation or reinstitution of Yasmin a complete medical history (including family history) should be taken and pregnancy must be ruled out. Blood pressure should be measured and a physical examination should be performed, guided by the "Contra-indications" and "Warnings". The woman should also be instructed to carefully read the package insert and to adhere to the advice given. The frequency and nature of examinations should be based on established practice guidelines and be adapted to the individual woman.

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 severe diarrhoea (see “Dosage and directions for use”), or concomitant medication (see “Side-effects and special precautions”).

Interaction with other medicinal products and other forms of interaction

Influence of other medication on Yasmin

Drug interactions which result in an increased clearance of sex hormones can lead to breakthrough bleeding and oral contraceptive failure. This has been established with hydantoins, barbiturates, primidone, carbamazepine and rifampicin; oxcarbazepine, topiramate, felbamate, ritonavir, griseofulvin and the herbal remedy St John's Wort (hypericum perforatum) are also suspected. 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 ampicillin and tetracyclines. The mechanism of this effect has not been elucidated.

Women on short-term treatment (up to one week) with any of the abovementioned classes of drugs or individual drugs should temporarily use a barrier method in addition to the combined oral contraceptive, ie 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 combined oral contraceptive blister pack, the next combined oral contraceptive pack should be started without the usual inactive tablet interval.

In women on chronic treatment with hepatic enzyme-inducing drugs, experts have recommended to increase the contraceptive steroid dose. If a high contraceptive dosage is not desirable or appears to be unsatisfactory or unreliable, eg in the case of irregular bleeding, another, nonhormonal, method of contraception should be advised.
The main metabolites of drospirenone in human plasma are generated without involvement of the
cytochrome P450 system. Inhibitors of this enzyme system are therefore unlikely to influence the
metabolism of drospirenone.

*Influence of Yasmin on other medication*

Based on *in vitro* inhibition studies and an *in vivo* interaction study in female volunteers using
omeprazole as marker substrate, drospirenone shows little propensity to interact with the metabolism
of other drugs.

*Other interactions*

Women using Yasmin and concomitant medications with the potential to increase serum potassium
such as ACE-inhibitors, angiotensin-II-receptor-antagonists, aldosterone antagonists, potassium-
sparing diuretics or NSAIDs used for long-term treatment should be tested for serum potassium during
the first treatment cycle. See also "Warnings".

*Laboratory tests*

The use of contraceptive steroids may influence the results of certain laboratory tests, including
biochemical parameters of liver, thyroid, adrenal and renal function, plasma levels of (carrier) proteins,
eg corticosteroid-binding globulin and lipid/lipoprotein fractions, parameters of carbohydrate
metabolism and parameters of coagulation and fibrinolysis. Changes generally remain within the
normal laboratory range. Drospirenone causes an increase in plasma renin activity and plasma
aldosterone induced by its mild antimineralocorticoid activity.

*Pregnancy and lactation*

Yasmin is not indicated during pregnancy.

If pregnancy occurs during medication with Yasmin, the preparation should be withdrawn immediately.
However, extensive epidemiological studies have revealed neither an increased risk of birth defects in
children born to women who used combined oral contraceptives prior to pregnancy, nor a teratogenic
effect when combined oral contraceptives were taken inadvertently during pregnancy. No such
studies have been carried out with Yasmin.

Animal studies have shown adverse effects during pregnancy and lactation. Based on these animal
data, an adverse effect due to hormonal action of the active compounds cannot be excluded.
However, general experience with combined oral contraceptives during pregnancy did not provide
evidence for an actual adverse effect in humans.

The available data regarding the use of Yasmin during pregnancy are too limited to permit conclusions
concerning negative effects of Yasmin on pregnancy, health of the foetus or neonate. Until now, no
relevant epidemiological data are available.

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 during
combined oral contraceptive use. These amounts may affect the child.

**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, in young girls, slight vaginal bleeding. There are no antidotes
and further treatment should be symptomatic.
21 light yellow film-coated hormonal tablets plus 7 white film coated inactive tablets.

PRESENTATION
Cartons with one or three blister strips each containing 28 tablets.

STORAGE INSTRUCTIONS
Store below 25°C. Keep out of reach of children.

REGISTRATION NUMBER
34/18.8/0494

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
Bayer (Pty) Ltd
Trading as Bayer Schering Pharma
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