PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

MIRELLE® 0,015 mg/0,06 mg film-coated tablets
Ethinylestradiol/Gestodene
Contains sugar (lactose)

Read all of this leaflet carefully before you taking MIRELLE

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- MIRELLE has been prescribed for you personally and you should not share you r medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What MIRELLE is and what it is used for
2. What you need to know before you take MIRELLE
3. How to take MIRELLE
4. Possible side effects
5. How to store MIRELLE
6. Contents of the pack and other information

1. What MIRELLE is and what it is used for

MIRELLE is a contraceptive pill and is used to prevent pregnancy.

Each pale yellow film-coated tablet contains a small amount of the female hormones ethinylestradiol and gestodene.

Contraceptive pills that contain two hormones are called ‘combined pills’ or ‘combined oral contraceptives’.

2. What you need to know before you take MIRELLE

General notes
Before you can begin taking MIRELLE, your doctor will ask you some questions about your personal health history and that of your close relatives. The doctor will also measure your blood pressure and, depending upon your personal situation, may also carry out some other tests.

In this leaflet, several situations are described where you should stop using MIRELLE, or where the reliability of MIRELLE may be decreased. In such situations you should either not have sex or you should take extra non-hormonal contraceptive precautions, e.g. use a condom or another barrier method. Do not use rhythm or temperature methods. These methods can be unreliable because MIRELLE alters the monthly changes of body temperature and cervical mucus.

MIRELLE, like other hormonal contraceptives, does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Do not take MIRELLE

Do not use the combined pill if you have any of the conditions listed below. If any of these apply to you, tell your doctor before starting to use MIRELLE. Your doctor may advise you to use a different type of pill or an entirely different (including non-hormonal) method of birth control.

- if you are hypersensitive (**allergic)** to ethinylestradiol, gestodene or any of the other ingredients in MIRELLE. This may cause, for example, itching, rash or swelling
- if you have (or have ever had) a **blood clot** in a blood vessel of the leg (thrombosis), of the lung (pulmonary embolism) or other parts of the body
- if you have (or have ever had) a **heart attack** or **stroke** (caused by a blood clot or a rupture of a blood vessel in the brain)
- if you have (or have ever had) a **disease that can be an indicator (i) of a future heart attack** (for example, angina pectoris which causes severe chest pain which may spread to the left arm) **or (ii) of a stroke** (for example, a minor stroke with no residual effects, a so-called transient ischaemic attack)
- if you have a high risk of venous or arterial blood clots (see 'MIRELLE and blood clots' and consult your doctor who will decide whether you may use the Pill)
- if you have (or have ever had) a certain kind of **migraine** (with so-called focal neurological symptoms such as visual symptoms, speech disability, or weakness or numbness in any part of your body)
- if you have diabetes mellitus with damaged blood vessels.
- if you have (or have ever had) **liver disease** (symptoms of which may be yellowing of the skin or itching over the whole body) and your liver is still not working normally
- if you are taking any antiviral medicines which contain ombitasvir, paritaprevir, ritonavir, or dasabuvir, and combinations of these. These antiviral medicines are used to treat chronic (long-term) hepatitis C (an infectious disease that affects the liver, caused by the hepatitis C virus).
- if you have (or have ever had) a **cancer** that may grow under the influence of sex hormones (e.g. **of the breast or the genital organs**)
- if you have (or have ever had) a benign or malignant **tumour of the liver**
- if you have any **unexplained bleeding from the vagina**
- if you are pregnant or think you might be pregnant

If any of these conditions appear for the first time while using MIRELLE, stop taking it at once and consult your doctor. In the meantime, use non-hormonal contraceptive measures. See also 'General notes'.

Warnings and precautions

In some situations you need to take special care while taking MIRELLE, and your doctor may need to examine you regularly. Consult your doctor before starting to use MIRELLE if any of the following conditions apply to you or if any of them develop or worsen while you are taking MIRELLE:

- if you smoke
- if you have diabetes
- if you are overweight
- if you have high blood pressure
- if you have a heart valve disorder or a certain heart rhythm disorder
- if you have an inflammation of your veins (superficial phlebitis)
- if you have varicose veins
- if anyone in your immediate family has ever had a blood clot (thrombosis in the leg, lung 'pulmonary embolism', or elsewhere), a heart attack or a stroke at a young age
- if you suffer from migraine
- if you have epilepsy (see 'Other medicines and MIRELLE')

- if you or someone in your immediate family has ever had high blood levels of cholesterol or triglycerides (fatty substances)
- if a close relative has or has ever had breast cancer
- if you have a disease of the liver or gall bladder
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease)
- if you have systemic lupus erythematosus (or SLE, a disease of the immune system)
- if you have haemolytic uraemia syndrome (or 'HUS', a disorder of blood coagulation causing failure of the kidneys)
- if you have sickle cell disease
- if you have a condition that occurred for the first time or worsened during pregnancy or previous use of sex hormones (e.g. hearing loss, a metabolic disease called porphyria, a skin disease called herpes gestationis, or a neurological disease called Sydenham's chorea)
- if you have (or have ever had) golden brown pigment patches so-called 'pregnancy patches' especially on the face (chloasma). If this is the case, avoid direct exposure to sunlight or ultraviolet light
- if you have hereditary angioedema. Consult your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue or throat, and/or difficulty swallowing, or hives, together with difficulty breathing. Products containing estrogens may induce or worsen symptoms of angioedema

If any of the above conditions appear for the first time, recur or worsen while using the Pill, contact your doctor.

MIRELLE and blood clots

A thrombosis is the formation of a blood clot which may block a blood vessel.

A thrombosis sometimes occurs in the deep veins of the legs (deep venous thrombosis). Venous thromboembolism (VTE) can develop whether or not you are taking the pill. It can also happen if you become pregnant. If a blood clot breaks away from the vein where it has formed, it may reach and block the arteries of the lungs, causing a so-called 'pulmonary embolism'. Blood clots can also occur in the blood vessels of the heart (causing a heart attack). Blood clots or a ruptured blood vessel in the brain may cause a stroke.

Long-term studies have suggested that there may be a link between the use of the pill (also called 'combined oral contraceptive' or 'combined pill', because it combines two different female hormones, so-called estrogens and progestogens) and an increased risk of venous and arterial blood clots, embolism, heart attack or stroke. The occurrence of these events is rare.

The risk of venous thromboembolism is highest during the first year of use. This increased risk is present after initially starting the combined pill or restarting (following a 4 week or greater pill free interval) the same or a different combined pill. Data from a large study suggest that this increased risk is mainly present during the first 3 months.

Overall, the risk for venous thromboembolism in users of low estrogen dose (< 50 µg ethinylestradiol) pills is two to threefold higher than for non-users of combined oral contraceptives who are not pregnant and remains lower than the risk associated with pregnancy and delivery.

Very occasionally venous or arterial thromboembolic events may cause serious permanent disabilities, may be life-threatening, or may even be fatal.

Venous thromboembolism, manifesting as deep venous thrombosis and/or pulmonary embolism, may occur during the use of all combined pills.

Extremely rarely blood clots can occur in other parts of the body including the liver, gut, kidney, brain or eye.

Stop taking the pill and contact a doctor immediately if you notice signs of:
deep venous thrombosis, such as: swelling of one leg or along a vein in the leg; pain or tenderness in the leg which may be felt only when standing or walking, increased warmth in the affected leg; red or discoloured skin on the leg.
pulmonary embolism, such as: sudden onset of unexplained shortness of breath or rapid breathing; sudden coughing which may bring up blood; sharp chest pain which may increase with deep breathing; sense of anxiety; severe lightheadedness or dizziness; rapid or irregular heartbeat. Some of these symptoms (e.g. "shortness of breath", "coughing") are non-specific and might be misinterpreted as more common or less severe events (e.g. respiratory tract infection).
arterial thromboembolism (arterial blood vessels blocked by blood clots and such blood clots which have broken away)
stroke such as: sudden numbness or weakness of the face, arm or leg, especially on one side of the body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, dizziness, loss of balance or coordination; sudden, severe or prolonged headache with no known cause; loss of consciousness or fainting with or without seizure.
blood clots blocking other arterial blood vessels, such as: sudden pain, swelling and slight blue discolouration of an extremity; "acute" abdomen.
heart attack such as: pain, discomfort, pressure, heaviness, sensation of squeezing or fullness in the chest, arm, or below the breastbone; discomfort radiating to the back, jaw, throat, arm, stomach; fullness, indigestion or choking feeling; sweating, nausea, vomiting or dizziness; extreme weakness, anxiety, or shortness of breath; rapid or irregular heartbeats.

Your doctor will check, e.g. whether you have a higher risk of getting a thrombosis due to a combination of risk factors or perhaps one very strong risk factor. In the case of a combination of factors the risk may be higher than simply adding two individual risks. If the risk is too high, your doctor will not prescribe the Pill. (see also 'Do not take MIRELLE').
The risk of venous or arterial blood clots (e.g. deep venous thrombosis, pulmonary embolism, heart attack) or stroke increases:

- with age
- if you are overweight
- if anyone in your immediate family has ever had a blood clot (thrombosis in the leg, lung 'pulmonary embolism', or elsewhere), a heart attack or a stroke at a young age, or if you or any of your relatives are known or suspected of having a hereditary blood clotting disorder increasing your risk for developing blood clots. In this case you should see a specialist before deciding about using any combined oral contraceptive. Certain blood factors that may suggest you have tendency for venous or arterial thrombosis include activated protein C (APC) resistance, hyperhomocysteinaemia, antithrombin-III deficiency, protein C deficiency, protein S deficiency, antiphospholipid antibodies (anticardiolipin antibodies, lupus anticoagulant).
- with prolonged immobilisation (for example, when you have your leg or legs in plaster or splints), major surgery, any surgery to the legs, or major trauma. In these situations it is better to stop taking the pill (if the surgery is planned you should stop at least four weeks beforehand) and not to start again until two weeks after you are fully on your feet again
- if you smoke (the risk increases the more you smoke and the older you get, especially in women over 35 years of age). When using the pill you should stop smoking, especially if you are older than about 35 years of age.

- if you or someone in your immediate family has or has ever had high blood levels of cholesterol or triglycerides (fatty substances)
- if you have high blood pressure . If you develop high blood pressure while using the pill, you may be told to stop using it.
- if you suffer from migraine
- if you have a heart valve disorder or a certain heart rhythm disorder

Directly after giving birth, women are at an increased risk of blood clots so you should ask your doctor how soon after delivery you can start taking a combined pill.

MIRELLE and cancer

Breast cancer has been observed slightly more often in women using combined pills, but it is not known whether this is caused by the treatment itself. For example, it may be that more tumours are detected in women on combined pills because they are examined by their doctor more often. The risk of breast tumours becomes gradually less after stopping the combined hormonal contraceptive. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In rare cases, **benign liver tumours**, and in even fewer cases **malignant liver tumours** have been reported in contraceptive pill users. In isolated cases, these tumours have led to life-threatening internal bleeding. Contact your doctor if you have unusually severe abdominal pain.

The most important risk factor for cervical cancer is persistent Human Papilloma Virus (HPV) infection. Some studies suggest that long-term use of the pill increases a woman's risk of developing **cervical cancer**. However, it is not clear to what extent sexual behaviour or other factors such as Human Papilloma Virus increases this risk.

The above mentioned tumours may be life-threatening or may have a fatal outcome.

MIRELLE and depression

Some women using hormonal contraceptives including MIRELLE have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts. If you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Bleeding between periods

With all Pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods. You may need to use sanitary protection, but continue to take your tablets as normal. Irregular vaginal bleeding usually stops once your body has adjusted to the Pill (usually after about 3 tablet-taking cycles). If it continues, becomes heavy or starts again, tell your doctor.

What to do if no bleeding occurs

If you have taken all the tablets correctly, have not had any vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant. Continue to take MIRELLE as usual.
If you have taken the tablets incorrectly, or, if you have taken the tablets correctly but the expected bleeding does not happen twice in a row, you may be pregnant. Contact your doctor immediately. Do not start the next pack until you are sure that you are not pregnant. In the meantime, use non-hormonal contraceptive measures. See also ‘General notes’.

Additional information on special populations

Use in children
MIRELLE is not intended for use in females whose periods have not yet started.

Use in older women
MIRELLE is not intended for use after the menopause.

Women with liver impairment
Do not take MIRELLE if you suffer from liver disease. See also sections 'Do not take MIRELLE' and 'Warnings and precautions'.

Women with kidney impairment
Talk to your doctor. Available data do not suggest a need to change the use of MIRELLE.

Other medicines and MIRELLE

Always tell your health care provider if you are taking any other medicine. This includes complementary or traditional medicines. They can tell you if you need to take additional contraceptive precautions (for example condoms) and if so, for how long, or, whether the use of another medicine you need must be changed.

Some medicines
- can have an influence on the blood levels of MIRELLE
- can make it less effective in preventing pregnancy
- can cause unexpected bleeding.

These include:
- medicines used for the treatment of:
  - epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate)
  - tuberculosis (e.g. rifampicin)
  - HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors)
  - fungal infections (griseofulvin, azole antifungals, e.g. itraconazole, voriconazole, fluconazole)
  - bacterial infections (macrolide antibiotics, e.g. clarithromycin, erythromycin)
  - certain heart diseases, high blood pressure (calcium channel blockers, e.g. verapamil, diltiazem)
  - arthritis, arthrosis (etoricoxib)
- the herbal remedy St. John's wort
- grapefruit juice

MIRELLE may **influence the effect** of other medicines, e.g.
- lamotrigine
- ciclosporin
- melatonin
- midazolam
- theophylline
- tizanidine

Laboratory tests

If you need a blood test or other laboratory tests tell your doctor or the laboratory staff that you are taking the Pill because oral contraceptives can affect the results of some tests.

Pregnancy and breastfeeding

Do not take MIRELLE if you are pregnant, or, if you think you may be pregnant. If you become pregnant while taking MIRELLE, stop taking it immediately and contact your doctor. If you want to become pregnant, you can stop taking MIRELLE at any time (see also 'If you stop taking MIRELLE').

MIRELLE is not recommended for use during breastfeeding. If you want to take the Pill while you are breastfeeding, you should contact your doctor.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor or pharmacist for advice before taking this medicine.

Driving or using machines

No studies on the effects of the ability to drive and use machines have been performed.

MIRELLE contains
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking MIRELLE.

3. How to take MIRELLE

Do not share medicines prescribed for you with any other person.

The MIRELLE pack contains 28 tablets. Take your tablet at about the same time each day, with some liquid if necessary. Follow the direction of the arrows until all 28 tablets have been taken. Usually a period will start on day 2-3 after the last hormone-containing pale yellow MIRELLE tablet (i.e. while you are taking the last 4 hormone-free white tablets). Do not leave a gap between packs, i.e. start taking your next pack on the day after you have finished the current one, even if your period continues. This means that you will always start new packs on the same day of the week, and also that you have your withdrawal bleed on about the same days every month.

When can you start with the first pack?

If you have not used a contraceptive with hormones during the previous month

Start taking MIRELLE on the first day of the cycle (that is, the first day of your period). Then follow the days in order. MIRELLE will work immediately, it is not necessary to use an additional contraceptive method. You may also start on days 2-5 of your cycle, but in that case make sure you also use an additional contraceptive method (barrier method) for the first 7 days of taking the tablets in the first cycle.

Changing from another combined hormonal contraceptive pill, or combined contraceptive vaginal ring or patch.

You can start taking MIRELLE the day after you take the last tablet from your present Pill pack (this means no tablet-free break). If your present Pill pack also contains hormone-free tablets you can start MIRELLE on the day after taking the last tablet containing hormones (if you are not sure which this is, ask your doctor or pharmacist). You can also start later, but never later than the day following the tablet-free break of your present Pill (or the day after the last hormone-free tablet of your present Pill). In case you have used a vaginal ring or transdermal patch, start using MIRELLE preferably on the day of removal of the last ring or patch of a cycle pack, but at the latest when the next application would have been due. If you follow these instructions, it is not necessary to use an additional contraceptive method.

Changing from a progestogen-only-method (progestogen-only pill, injection, implant or a progestogen-releasing 'IUS', intrauterine system).

You may switch from the progestogen-only pill any day (from an implant or the IUS on the day of its removal, from an injectable when the next injection would be due) but in all of these cases you must use extra protective measures (for example, a condom) during the first 7 days of MIRELLE use.

After a miscarriage.

Follow the advice of your doctor.

After having a baby

If you have just had a baby, your doctor may tell you to wait until after your first normal period before you start taking MIRELLE. Sometimes it is possible to start sooner. Your doctor will advise you.

If, after having a baby, you have had sex before starting MIRELLE, be sure that you are not pregnant or wait until the next menstrual period.

If you want to start MIRELLE after having a baby and are breastfeeding, discuss this first with your doctor.

Ask your doctor what to do if you are not sure when to start.

If you take more MIRELLE than you should

There are no reports of serious harmful effects of taking too many MIRELLE tablets.
If you take several hormone-containing tablets at once, you may feel sick or vomit or may bleed from the vagina. Even girls who have not yet started to menstruate but have accidentally taken this medicine may experience such bleeding.
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take MIRELLE

Depending on the day of the cycle on which one tablet has been missed, you may need to take additional contraceptive precautions, for example a barrier method such as a condom. Take the tablets according to the following principles. See also the 'missed pill chart' for details. In case of doubt, contact your doctor.

- If you forgot to take any of the 4 hormone-free white tablets (the last 4 tablets in the blister), you are still protected against pregnancy because they do not contain any hormones. However, to make sure that you do not change your pill taking rhythm, which is important for the

contraceptive reliability of your Pill, you should proceed with your next tablet at the normal time and discard the forgotten hormone-free white film-coated tablet(s) to avoid any confusion. If you forgot the last hormone-free white tablet of your current pack it is important that you still take the first tablet from the next pack at the correct time.

The following advice refers to the pale yellow tablets (those containing hormones) (tablets 1-24 of your blister):

- If you are **less than 12 hours late** when taking a tablet, the protection against pregnancy is not reduced. Take the tablet as soon as you remember and then continue taking the tablets again at the usual time.
- If you are **more than 12 hours late** in taking any of pale yellow tablets your protection against pregnancy may be reduced. The more pale yellow tablets you have forgotten, the greater the risk that the protection from pregnancy is reduced. There is a particularly high risk of becoming pregnant if you miss tablets at the beginning of the pack or at the end (the last of the 24 pale yellow tablets). Therefore, you should follow the rules given below (see also the diagram below).
- **More than one tablet forgotten in a pack**
  Contact your doctor.

Do not take more than 2 tablets on a given day, to make up for missed pills.

If you have forgotten tablets in a pack, and you do not have the expected bleeding that should start at the end of the blister (while taking the last 4 hormone-free white tablets), you may be pregnant. Contact your doctor before you start the next pack.

1 tablet missed during day 1-7

If you have forgotten to start a new pack, or if you have missed tablet(s) during the first 7 days of your pack, there is a risk that you are already pregnant (if you had sex in the 7 days before forgetting the tablet). In that case, contact your doctor before you start the next pack. See also the 'missed pill chart' for details.
If you had no sex in the 7 days before the oversight, take the missed pale yellow tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time. Use extra contraceptive precautions (barrier method) for the next 7 days.

1 tablet missed during day 8-14

Take the missed pale yellow tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next tablets at the usual time. The reliability of the Pill is maintained. You need not use extra contraceptive precautions.

1 tablet missed during day 15-24

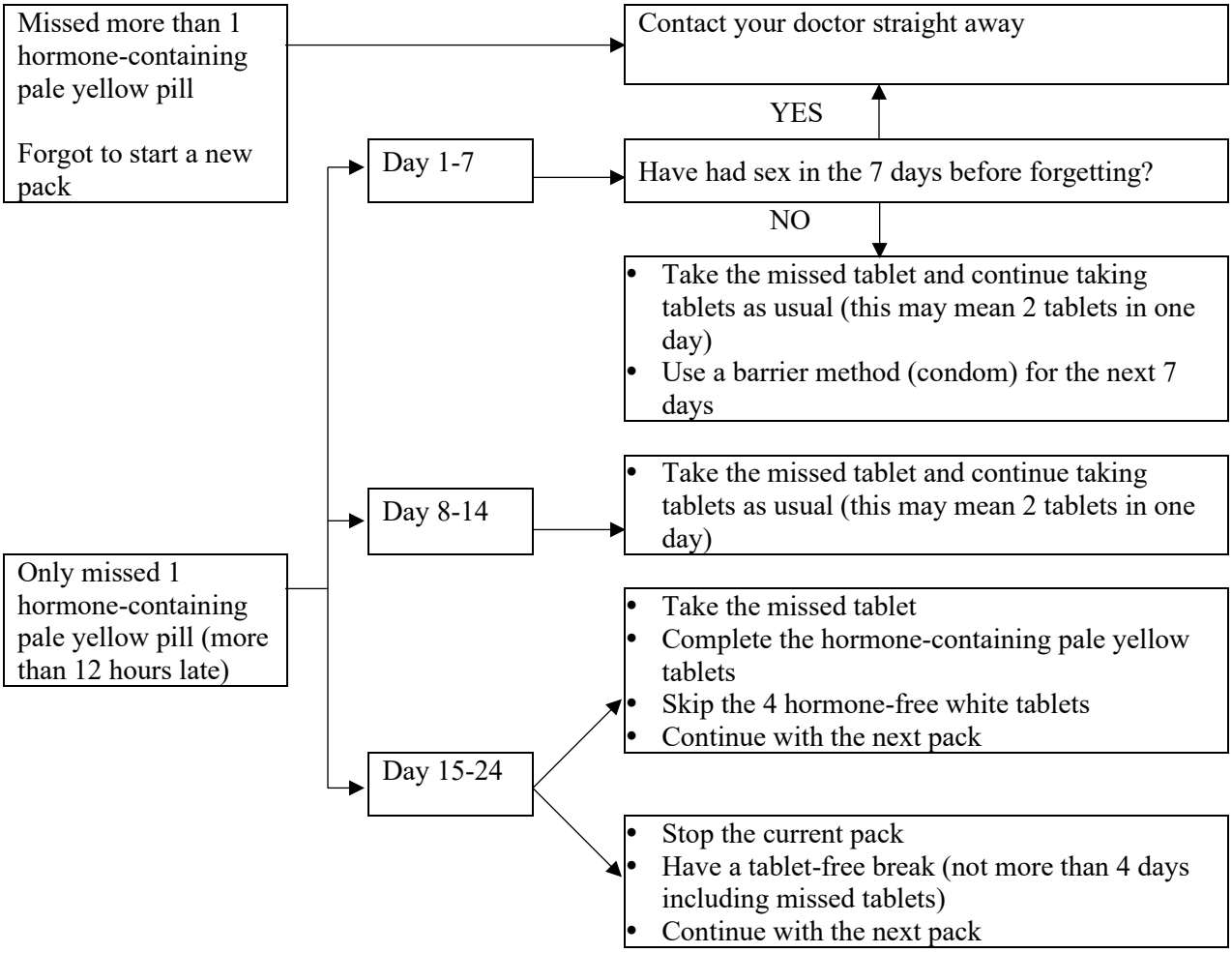
You may choose either of the following options, without the need for extra contraceptive precautions.

1. Take the missed pale yellow tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next pale yellow tablets at the usual time (unless there are no pale yellow tablets left in the current pack). Discard your current pack as soon as the pale yellow tablets are finished (do not take the remaining 4 white hormone-free tablets) and start the next pack so that no gap is left between packs. You may not have a withdrawal bleed until you have finished the pale yellow tablets of the second pack but you may have spotting or breakthrough bleeding while taking the tablets.

or

2. Stop taking tablets from your current pack, have a tablet-free break of 4 days or less (also count the day you missed your tablet) and continue with the next pack.

Missed Pill Chart



What to do if you vomit or have severe diarrhoea

If you vomit or have severe diarrhoea after taking any of the pale yellow coated tablets, the active ingredients in that tablet may not have been completely absorbed. If you vomit within 3 to 4 hours after taking your tablet, this is like missing a tablet. Therefore, follow the advice under 'If you forget to take MIRELLE'. If you have severe diarrhoea, please contact your doctor. Vomiting or diarrhoea while taking the 4 hormone-free white tablets at the end of your blister does not have an influence on the contraceptive reliability.

If you stop taking MIRELLE

You can stop taking MIRELLE at any time. If you do not want to become pregnant, ask your doctor for advice about other reliable methods of birth control. If you want to become pregnant, stop taking MIRELLE and wait for a menstrual period before starting to try to become pregnant. You will be able to calculate the expected delivery date more easily.

If you want to delay a period

To delay a period you should continue with another pack of MIRELLE without taking the remaining hormone-free white tablets from your current pack and the hormone-free white tablets from the silver section of your next pack. Start with the pale yellow coated tablets from your next pack as soon as the pale yellow coated tablets from your current pack are finished. The extension can be carried on for as long as wished, until the end of the second pack. During the extension you may experience breakthrough bleeding or spotting. Regular intake of MIRELLE is then resumed after the hormone-free white tablet phase.

4. Possible side effects

MIRELLE can have side effects.
Not all side effects reported for MIRELLE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking MIRELLE, please consult your health care provider for advice.

Tell your doctor if you notice any of the following:

Frequent side effects:
- nausea
- abdominal pain
- weight gain
- headache
- depressed or altered mood
- breast pain including breast tenderness

Less frequent side effects:
- vomiting
- diarrhoea
- fluid retention
- migraine
- reduced interest in sex
- breast enlargement
- rash
- urticaria (hives)
- contact lens intolerance
- allergic reactions (hypersensitivity)
- weight loss
- increased interest in sex
- vaginal discharge
- breast discharge
- erythema nodosum or multiforme (skin disorders)
- venous and arterial thromboembolic events*

* Estimated frequency, from epidemiological studies encompassing a group of combined oral contraceptives. The term venous and arterial thromboembolic events covers the following: any blockage or clot in a deep peripheral vein, clots which travel through the venous blood system (e.g. to the lung known as pulmonary embolism or as pulmonary infarction), heart attack caused by blood clots, stroke caused by blockage of the blood supply to or in the brain

Description of selected adverse reactions

Adverse reactions with very low frequency or with delayed onset of symptoms which are considered to be related to the group of combined oral contraceptives are listed below (see also sections 'Do not take MIRELLE' and 'Warnings and precautions'):

Tumours
- The frequency of diagnosis of breast cancer is very slightly increased among users of oral contraceptives. 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. It is not known whether there is a direct link to users of combined oral contraceptives.
- liver tumours (benign and malignant)

Other conditions
- women with hypertriglyceridemia (increased blood fats resulting in an increased risk of pancreatitis when using combined oral contraceptives)
- high blood pressure
- occurrence or worsening of conditions for which a link to combined oral contraceptives is not definite: jaundice and/or itching related to cholestasis (blocked bile flow); gallstone formation; a metabolic condition called porphyria; systemic lupus erythematosus (a chronic autoimmune disease); haemolytic uremic syndrome (a blood clotting disease); a neurological condition called Sydenham's chorea; herpes gestationis (a type of skin condition that occurs during pregnancy); otosclerosis-related hearing loss
- In women with hereditary angioedema (characterised by sudden swelling of e.g. the eyes, mouth, throat etc.) external estrogens may induce or worsen symptoms of angioedema
- disturbed liver function
- changes in glucose tolerance or effect on peripheral insulin resistance
- Crohn's disease, ulcerative colitis (chronic inflammatory bowel disease)
- chloasma (golden brown pigment patches, so-called "pregnancy patches", especially on the face)

Interactions
Unexpected bleeding and/or contraceptive failure may result from interactions of other medicines with oral contraceptives (e.g. the herbal remedy St. John's wort, or medicines for epilepsy, tuberculosis, HIV infections and other infections). See section 'Other medicines and MIRELLE').

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za.Publications/Index/8. By reporting side effects, you can help provide more information on the safety of MIRELLE.

5. How to store MIRELLE

Keep out of the reach and sight of children.
Store at or below 25 °C.
Protect from light.
Store in the blister in the outer carton.

6. Contents of the pack and other information

What MIRELLE contains
24 pale yellow tablets containing ethinylestradiol (0,015 mg) and gestodene (0,06 mg). 4 white hormone-free tablets.
The other ingredients are ferric oxide red, ferric oxide yellow, hydroxypropyl cellulose, hypromellose, lactose monohydrate, macrogol 1450, magnesium stearate, microcrystalline cellulose, polacrilin, potassium, polyethylene glycol, titanium dioxide, wax E

What MIRELLE looks like and contents of the pack

MIRELLE is presented as a blister pack containing 24 coated tablets containing hormones and 4 hormone-free coated tablets.
The tablet containing hormones is pale yellow, round with convex faces.
The hormone-free tablet is white, round with convex faces.

MIRELLE tablets are contained in blister packs consisting of transparent films made of polyvinyl chloride and metallic foils made of aluminium. The blister is packed in a cardboard carton.

Holder of Certificate of Registration

Bayer (Pty) Ltd
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27 Wrench Road
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