SELECT THE REQUIRED INFORMATION

PROFESSIONAL INFORMATION

PATIENT INFORMATION LEAFLET

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Read all of this leaflet carefully before you start taking MELODENE.

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

SCHEDULING STATUS: **S3**

PROPRIETARY NAME AND DOSAGE FORM:

MELODENE

Tablets

1. WHAT MELODENE CONTAINS:

The active substances are ethinylestradiol (0,02 mg) and gestodene (0,075 mg).
The other ingredients are: calcium carbonate, ferric oxide pigment (red), ferric oxide pigment (yellow), glycerol 85%, lactose monohydrate, macrogol 6000, magnesium stearate, maize starch, montanglycol wax, povidone 25 000, povidone 700 000, sucrose, talc, titanium dioxide.

2. WHAT MELODENE IS USED FOR:

- MELODENE is used to prevent pregnancy.
- Each of the 21 white coated tablets contains a small amount of the female hormones ethinyloestradiol and gestodene.
- Contraceptive pills that contain two hormones are called ‘combined pills’ or ‘combined oral contraceptives’.

3. BEFORE YOU TAKE MELODENE:

3.1 Do not take MELODENE:

If you are hypersensitive (allergic) to gestodene or ethinylestradiol or any of the other ingredients of MELODENE.

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

- If you have, or have ever had a disorder affecting the blood circulation: in particular, those conditions relating to thrombosis (the formation of a blood clot) in the blood vessels of the legs (deep vein thrombosis), the lungs (pulmonary embolism), the heart (heart attack), or other parts of the body.
- If you have or have had a stroke (caused by a blood clot or a rupture of a blood vessel in the brain).
- If you have or have ever had a condition that may be a first sign of a heart attack (such as angina pectoris or chest pain) or stroke (such as transient ischaemic attack or small reversible stroke).
- If you have a history of migraine accompanied by e.g. visual symptoms, speech disability, or weakness or numbness in any part of your body.
- If you have diabetes mellitus with blood vessel damage.

- If you have or have had pancreatitis (an inflammation of the pancreas) associated with high levels of fatty substances in your blood.
- If you have jaundice (yellowing of the skin) or severe liver disease.
- If you have or have 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 had a benign or malignant liver tumour.
- If you have any unexplained vaginal bleeding.
- If you are pregnant or think you might be pregnant.

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

3.2 Take special care with MELODENE:

Before taking MELODENE tell your doctor if:

- you have an inflammation of your veins (superficial phlebitis);
- you have varicose veins;
- anyone in your immediate family has had a thrombosis, a heart attack or a stroke;
- you have a heart valve disorder or a certain heart rhythm disorder;
- you suffer from migraine;
- you suffer from epilepsy;
- you smoke;
- you have diabetes;
- you are overweight;
- you have high blood pressure;
- you or someone in your immediate family has or has had high blood levels of cholesterol or triglycerides (fatty substances);
- anyone in your immediate family has had breast cancer;
- you have liver or gall bladder disease;
- you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- you have systemic lupus erythematosus (SLE; a disease affecting the skin all over the body);
- you have haemolytic uremic syndrome (HUS; a disorder of blood coagulation causing failure of the kidneys);
- you have sickle cell disease;
- 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, a neurological disease called Sydenham's chorea);
- you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation;
- you have hereditary angioedema; exogenous oestrogens may induce or exacerbate symptoms of angioedema. You should see your doctor immediately if you experience symptoms of angioedema such as swollen face, tongue and/or pharynx and/or difficulty swallowing or hives together with difficulty breathing.

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

MELODENE and thrombosis:
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).
If this blood clot breaks away from the veins where it is formed, it may reach and block the arteries of the lungs, causing a so-called "pulmonary embolism". Deep venous thrombosis is a rare occurrence. The risk for venous thromboembolism is highest during the first year a woman ever uses MELODENE.
Overall the risk for venous thromboembolism in users of low oestrogen dose (< 50 µg ethinyloestradiol) pills, such as MELODENE, is higher than for non-users of combined oral contraceptives.

Blood clots can also occur in the blood vessels of the heart (causing a heart attack) or the brain (causing a stroke). Extremely rarely blood clots can occur in the liver, gut, kidney or eye. Very occasionally thrombosis may cause serious permanent disabilities or may even be fatal.

When using MELODENE you should stop smoking, especially if you are older than about 35 years of age.

If you develop high blood pressure while using MELODENE, you may be told to stop using it. The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilisation (for example, when you have your leg or legs in plaster or splints). In women who use MELODENE, the risk may be yet higher. Tell your doctor you are using MELODENE well in advance of any expected hospitalisation or surgery. Your doctor may tell you to stop taking MELODENE several weeks before surgery or at the time of immobilisation. Your doctor will also tell you when you can start taking MELODENE again after you are back on your feet. If you notice possible signs of a thrombosis, stop taking MELODENE and consult your doctor immediately.

MELODENE and cancer:
An increased risk of cervical cancer in long-term users of combined oral contraceptives, such as MELODENE, has been reported in epidemiological studies.
In rare cases benign liver tumours and even more rarely, malignant liver tumours have been reported in users of MELODENE. These tumours may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your abdomen.

3.3 Pregnancy and breastfeeding:

MELODENE and pregnancy:
MELODENE must not be used by women who are pregnant, or who think they may be pregnant. If you suspect that you are pregnant while you are already using MELODENE, you should consult your doctor as soon as possible.

MELODENE and breastfeeding:
MELODENE is not recommended for use during breastfeeding. If you wish to take MELODENE while breastfeeding, please seek the advice of your doctor.

Additional information on special populations:
Use in children:
MELODENE is not intended for use in females whose periods have not yet started.
Use in older women:
MELODENE is not intended for use after the menopause.
Women with liver impairment:
Do not take MELODENE if you suffer from liver disease. See also “Before you take MELODENE”.
Women with kidney impairment:
Talk to your doctor. Available data do not suggest a need to change the use of MELODENE.

3.4 Taking other medicines with MELODENE:

- If you are taking other medicines on a regular basis, including complementary, traditional medicines or any medicines that you obtained without a prescription, the use of MELODENE with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.
- If you are taking any of the following medicines please consult your healthcare professional: these include medicines used for the treatment of epilepsy (e.g. primidone, phenytoin, barbiturates, carbamazepine, oxcarbazepine, topiramate, felbamate); tuberculosis (e.g. rifampicin, rifabutin) and HIV infections (e.g. ritonavir, nevirapine); antibiotics (e.g. penicillins, tetracyclines, griseofulvin) for some other infectious diseases; and the herbal remedy St. John’s wort (primarily used for the treatment of depressive moods).
- MELODENE may also interfere with the working of other medicines, e.g. medicines containing cyclosporin, or the anti-epileptic lamotrigine.

3.5 Important information about some ingredients of MELODENE:

MELODENE contains **lactose**. If you are intolerant to some types of sugar contact your doctor before taking it.

4. HOW TO TAKE MELODENE:

Always take MELODENE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
MELODENE, when taken correctly, has a failure rate of approximately 1 % per year. The failure rate may increase when pills are missed or taken incorrectly.

When and how to take the 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 to 3 after the last active MELODENE tablet (i.e. while you are taking tablets from the last row of your pack). 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, each month.

Starting your first pack of MELODENE:

When no hormonal contraceptive has been used in the past month:
Start taking MELODENE on the first day of your cycle, i.e. the first day of menstrual bleeding. Then follow the days in order. You may also start on days 2 to 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 tablet-taking in the first cycle.

When changing from a combined Pill, vaginal ring, or transdermal (contraceptive) patch:
You can start taking MELODENE 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 inactive tablets you can start MELODENE on the day after taking the last **active** tablet (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 inactive tablet of your present Pill).
In case you have used a vaginal ring or transdermal patch, you should start using MELODENE preferably on the day of removal, 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.

When changing from a progestogen-only pill (minipill):
You can stop taking the minipill any day and start taking MELODENE the next day, at the same time. But make sure you also use an additional contraceptive method (a barrier method) for the first 7 days of tablet-taking when having intercourse.

When changing from an injectable, an implant, or a progestogen-releasing intrauterine device (IUD):
Start using MELODENE when your next injection is due or on the day that your implant or your IUD is removed. But make sure you also use an additional contraceptive method (a barrier method) for the first 7 days of tablet-taking when having intercourse.

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 MELODENE. Sometimes it is possible to start sooner. Your doctor will advise you. If you are breast-feeding and want to take MELODENE, you should discuss this first with your doctor.

After a miscarriage or an abortion:
Your doctor will advise you.

For how long should you take MELODENE:

MELODENE must be taken for as long as you want to prevent pregnancy. You can stop taking MELODENE at any time you want. If you stop because you want to get pregnant, it is generally recommended that you wait until you have had a natural period before trying to conceive. This helps you to work out when the baby will be due. If you do not want to become pregnant, ask your doctor about other methods of birth control.

If you take more MELODENE than you should:

Symptoms that may occur in case of taking an overdose are: nausea, vomiting and in young girls; slight vaginal bleeding. There have been no reports of serious effects from overdose noted. In the event of overdosage, consult your doctor or pharmacist. If neither is unavailable, seek help at the nearest hospital or poison control centre.

What should you do if you have taken too few MELODENE tablets or have forgotten to take a dose:

Management of missed tablets:
The pink tablets are inactive tablets and missing these can be disregarded. However, they should be discarded to avoid unintentionally prolonging the inactive tablet phase. The following advice only refers to missed active tablets.

If the user is ***less than 12 hours*** late in taking any active 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:
1. Active tablet-taking must never be discontinued for longer than 7 days;
2. 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:

First 7 days of active tablet-taking:
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 intercourse took place in the preceding 7 days, the possibility of a pregnancy should be considered. The more tablets that are missed and the closer they are to the inactive tablet phase, the higher the risk of a pregnancy.

Second 7 days of active tablet-taking:
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. Provided that the woman has taken her tablets correctly in the 7 days preceding the first missed tablet, there is no need to use extra contraceptive precautions. However, if this is not the case, or if she missed more than 1 tablet, the woman should be advised to use extra precautions for 7 days.

Third 7 days of active tablet-taking:
The risk of reduced reliability is imminent because of the forthcoming inactive tablet phase. However, by adjusting the tablet-intake schedule, reduced contraceptive protection can still be prevented. If either of the following two options is adhered to, there is no need to use extra contraceptive precautions, provided that in the 7 days preceding the first missed tablet the woman has taken all tablets correctly. If this is not the case, the woman should be advised to follow the first of these two options, and also to use extra precautions for the next 7 days as well.
1. 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 until the active tablets are used up. The 7 inactive tablets must be discarded. The next pack must be started right away. The user is unlikely to have a withdrawal bleed until the end of the active tablets section of the second pack, but she may experience spotting or breakthrough bleeding on active tablet-taking days.

2. The woman may also be advised to discontinue active tablet-taking from the current pack. She should then have a tablet-free interval of up to 7 days, including the days she missed tablets, and subsequently continue with the next pack, starting in the silver section with the tablet for the appropriate day of the week.

If the woman missed active tablets and subsequently has no withdrawal bleed in the inactive tablet phase, the possibility of a pregnancy should be considered.

What should you do if you want to interrupt the treatment or stop using MELODENE before the end of the course:

You should always consult your doctor before deciding to interrupt the course of treatment or stop taking MELODENE altogether.

5. POSSIBLE SIDE EFFECTS:

Not all side effects reported for MELODENE are included in this leaflet. Should your general health worsen while taking MELODENE, please consult your doctor, pharmacist or other health care professional for advice.
If any of these side effects continue, are severe or bother you, tell your doctor or pharmacist.
Serious reactions associated with the use of MELODENE, as well as the related symptoms, are described in the following sections: *"MELODENE and thrombosis/MELODENE and cancer"*. Please read these sections for additional information and consult your doctor at once where appropriate.

The following common side effects have been reported by users of combined oral contraceptives (COCs), such as MELODENE. These side effects may occur in the first few months that you are using MELODENE and usually improves with time: nausea, abdominal pain, weight increased, headache, depressed mood, mood altered, breast pain, breast tenderness.

6. STORING AND DISPOSING OF MELODENE:

Store at or below 30 ºC.
STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.
Return unused or expired medicines to your pharmacist for safe disposal.

7. PRESENTATION OF MELODENE:

Cartons with one or three calendar blister packs each containing 28 tablets.

8. IDENTIFICATION OF MELODENE:

21 small white, round coated hormonal tablets and 7 large pink, round coated non-hormonal tablets.

9. REGISTRATION NUMBER:

31/18.8/0462

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Bayer (Pty) Ltd
Reg. No.: 1968/011192/07
27 Wrench Road
Isando
1609

11. DATE OF PUBLICATION:

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