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PROFESSIONAL INFORMATION

PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: S3

MELODENE® 0,02 mg/0,075 mg coated tablet
Ethinylestradiol/gestodene
Contains sugar (lactose monohydrate and sucrose)

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.

What is in this leaflet

1. What MELODENE is and what it is used for

- MELODENE is used to prevent pregnancy.
- Each of the 21 white coated tablets 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 MELODENE

General notes
Before you can begin taking MELODENE, 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 MELODENE, or where the reliability of MELODENE 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 MELODENE alters the monthly changes of body temperature and cervical mucus.

MELODENE does not protect against HIV infection (AIDS) or any other sexually transmitted disease.

Do not take 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 are hypersensitive (**allergic**) to gestodene or ethinylestradiol or any of the other ingredients of MELODENE (listed in section 6).
- If you have or have 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 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, 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 a high risk of venous or arterial blood clots (see "*MELODENE and thrombosis*". Consult your doctor who will decide whether you may use MELODENE.
- 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 jaundice** (yellowing of the skin) or **severe liver disease**.
- if you are taking any antiviral medicines which contain ombitasvir, paritaprevir, 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 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.

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 "*Do not take MELODENE*" and "*Warnings and precautions*".

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

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

- 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 had a thrombosis (blood clot in your leg, lung 'pulmonary embolism', or elsewhere), a heart attack or a stroke at a young age;
- if you suffer from migraine;
- if you suffer from epilepsy (see "*Other medicines and MELODENE*");
- if you or someone in your immediate family has or has had high blood levels of cholesterol or triglycerides (fatty substances);
- if anyone in your immediate family has had breast cancer;
- if you have liver or gall bladder disease;
- if you have Crohn's disease or ulcerative colitis (chronic inflammatory bowel disease);
- if you have systemic lupus erythematosus (SLE; a disease affecting the skin all over the body);
- if you have haemolytic uremic syndrome (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, a neurological disease called Sydenham's chorea);
- if 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;
- if you have hereditary angioedema; exogenous estrogens 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 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.

Overall, the risk for venous thromboembolism in users of low estrogen dose (< 50 µg ethinylestradiol) 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.

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 discoloration 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 MELODENE'*).

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 MELODENE 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 MELODENE, 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 MELODENE.

MELODENE and cancer

Breast cancer has been observed slightly more often in women using combined pills such as MELODENE, 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.

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.

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.

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

Melodene and depression

Some women using hormonal contraceptives including MELODENE 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

You can have irregular vaginal bleeding (spotting or breakthrough bleeding) between your periods for the first few months using MELODENE. 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 MELODENE (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 MELODENE 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*'.

Other medicines and MELODENE

Always tell your health care provider if you are taking other medicine. This includes all complementary or traditional medicines.

Some medicines
- can have an influence on the blood levels of MELODENE
- 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

MELODENE 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.

Pregnancy and breastfeeding

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

Driving and using machine

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

MELODENE contains lactose.

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

3. How to take MELODENE

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

Always take MELODENE exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

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 hormone-containing white MELODENE tablet (i.e. while you are taking tablets from the last 7 hormone-free pink 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, each month.

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.

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 hormone-free tablets you can start MELODENE on the day after taking the last hormone-containing 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 hormone-free 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 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.

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.

If you take more MELODENE than you should

There have been no reports of serious effects from overdose noted.
If you take several white 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 unavailable, seek help at the nearest hospital or poison control centre.

If you forget to take MELODENE

If you forgot to take any of the 7 hormone-free pink tablets (the last 7 tablets in the blister), you are still protected against pregnancy because they do not contain any hormones. However, they should be discarded to avoid unintentionally prolonging the hormone-free phase.

The following advice only refers to missed hormone-containing white tablets.

- If you are ***less than 12 hours*** late in taking any tablet, contraceptive protection is not reduced. Take the tablet as soon as you remember and continue taking the tablets at the usual time.

- If you are ***more than 12 hours*** late in taking any of the white tablets, contraceptive protection against pregnancy may be reduced. The more white 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 21 white 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 7 hormone-free pink tablets), you may be pregnant. Contact your doctor before you start the next pack.

1 tablet missed during the first 7 days

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 sexual intercourse 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 sexual intercourse in the 7 days before missing one tablet, take the missed white 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 the second 7 days

Take the missed white 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 do not need to use extra contraceptive precautions.

1 tablet missed during the third 7 days

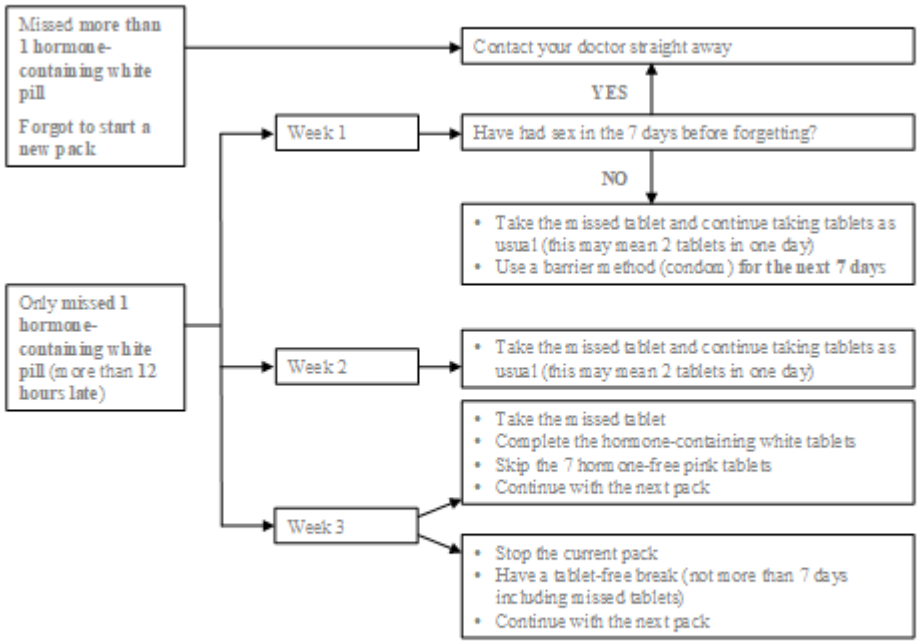
You may choose either of the following options, without the need for extra contraceptive precautions.

1. Take the missed white tablet as soon as you remember (even if this means taking two tablets at the same time) and take the next white tablet at the usual time (unless there are no white tablets left in the current pack). Complete taking all of the white tablets and discard the 7 pink hormone-free tablets and start the next pack right away so that there is no gap left between packs). You may not have a withdrawal bleed until the you have finished the white tablets of the second pack, but you may experience spotting or breakthrough bleeding while taking the tablets.

OR

2. Stop taking tablets from the current pack, have a tablet-free break of up to 7 days (also count the day you missed your tablet) and continue with the next pack, starting in the silver section with the tablet for the appropriate day of the week.

<u>Missed Pill Chart</u>



What to do if you vomit or have severe diarrhoea

If you vomit or have severe diarrhoea after taking any of the white 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 MELODENE*' If you have severe diarrhoea, please contact your doctor. Vomiting or diarrhoea while taking the 7 hormone-free pink coated tablets at the end of your blister does not have an influence on the contraceptive reliability.

If you stop taking MELODENE

You can stop taking MELODENE at any time you want. 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 MELODENE and wait for a menstrual period before trying to become pregnant. This helps you to work out when the baby will be due
You should always consult your doctor before deciding to interrupt the course of treatment or stop taking MELODENE altogether.

If you want to delay a period

You can delay your period if you start with your next pack of MELODENE immediately after having finished the white tablets of your current blister (do not take the 7 hormone-free pink coated tablets at the end of your blister). You can continue with the second pack for as long as you wish, e.g. until this pack is empty, to get a period approx. 3 weeks later than usual. If you wish your period to begin earlier than that, just stop taking white tablets from the second pack, discard the pack and have a pill-free interval of a maximum of 7 days and then start a new pack. In this case, approx. 2-3 days after you take the last white tablet from the second pack you should get your period. While using the second pack you may have some breakthrough bleeding or spotting on tablet-taking days.

4. Possible side effects

MELODENE can have side effects.

Not all side effects reported for MELODENE are included in this leaflet. Should your general health worsen or if you experience any untoward effects 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*" and "*MELODENE and cancer*". Please read these sections for additional information and consult your doctor at once where appropriate.

Tell you 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 or increased interest in sex
- breast enlargement
- rash
- urticaria (hives)
- allergic reaction (hypersensitivity)
- contact lens intolerance
- weight loss
- 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 MELODENE*' 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
- chloasma

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 MELODENE'.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

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/Plublications/Index/8. By reporting side effects, you can help provide more information on the safety of MELODENE.

5. How to store MELODENE

Store all medicines out of the reach of children.
Store at or below 30 ºC.
Return unused or expired medicines to your pharmacist for safe disposal.

6. Contents of the pack and other information

What MELODENE contains

21 white coated tablets containing ethinylestradiol (0,02 mg) and gestodene (0,075 mg).
7 pink non-hormonal coated tablets.

The other ingredients are lactose monohydrate, maize starch, povidone 25 000, magnesium stearate, sucrose, povidone 700 000, macrogol 6 000, calcium carbonate, talc, montanglycol wax, ferric oxide red, ferric oxide yellow, glycerol 85 % (w/w), titanium dioxide.

What MELODENE looks like and contents of the pack

MELODENE is presented as a blister pack containing 21 small white round coated hormonal tablets and 7 large pink round coated non-hormonal tablets.

MELODENE tablets are contained in blister packs consisting transparent films made of PVC and aluminium foil. Blister packs are contained within a cardboard carton.

Holder of Certificate of Registration

Bayer (Pty) Ltd
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