

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
This medicine is dispensed with a doctor's prescription only

Melodil 25, 50

Film-coated tablets

Composition:

Each film-coated **Melodil 25** tablet contains:

Maprotiline HCl 25 mg

Each film-coated **Melodil 50** tablet contains:

Maprotiline HCl 50 mg

For the list of inactive ingredients, please see section 6.

Read this leaflet carefully in its entirety before using the medicine. It is recommended that you have someone close to you read this leaflet. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

Therapeutic activity: For treatment of states of depression, and states of anxiety accompanied by depression.

Therapeutic group: This medicine belongs to the group of tetracyclic antidepressants.

2. BEFORE USING THE MEDICINE

❗ Do not use the medicine if:

- You are sensitive (allergic) to maprotiline HCl, to any of the other ingredients contained in the medicine (see section 6: "Further Information") or to other medicines from the same pharmacological class (tetracyclic antidepressants).
- You are suffering, or have suffered in the past, from convulsions (epilepsy) or if there is suspicion of this disease.
- Do not use the medicine during the acute stage of a myocardial infarction (MI).
- You are being concomitantly treated with medicines from the monoamine oxidase inhibitors group (for depression) or are within 14 days of having discontinued treatment with them.

Special warnings regarding use of the medicine:

❗ Before treatment with Melodil, inform the doctor if:

- you are pregnant, planning to become pregnant, or breastfeeding.
- you have suffered a myocardial infarction (MI) in the past, or if you are suffering, or have suffered in the past, from heart and/or vascular diseases.
- you are suffering from increased intraocular pressure, from glaucoma or have a history of glaucoma, a history of urinary retention.
- you are suffering, or have suffered in the past, from impaired function of: the respiratory system (e.g., asthma), the liver, the kidney/urinary system, digestive system (e.g., ulcer), thyroid, blood system (e.g., clotting, etc.), nervous system, from prostatic hyperplasia, from alcoholism, and if you are receiving electroconvulsive therapy (ECT).
- you are being treated with phenothiazine antipsychotics, as taking Melodil together with these medicines increases the risk of convulsions.
- you are suffering, or have suffered in the past, from bipolar disorder (manic depression), or if you have a family history of suicide, bipolar disorder and/or depression.
- you are due to undergo surgery (including dental) or any other procedure requiring anesthesia.

This medicine may cause a decrease in the number of white

blood cells; therefore, blood counts should be performed in patients suffering from fever or from sore throats during treatment with Melodil.

This medicine may cause particular sensitivity upon exposure to the sun; therefore, avoid exposure to the sun and take care to have proper protection (long clothes, hat, sunscreens, etc.).

An increase in suicidal thoughts and actions and hostility have been observed in children, adolescents and young adults up to the age of 24 who took antidepressants, especially at the beginning of treatment or when the dosage was changed. Nevertheless, your doctor can prescribe this medicine when he thinks it is for your benefit. If the doctor prescribed this medicine and you are interested in discussing it with him – refer to the doctor again. Inform your doctor immediately if any of the detailed side effects occur or worsen.

❗ Information for families and care-givers: Relatives and care-givers must monitor if the child or patient shows signs of behavioral changes, such as: unusual anxiety, restlessness, panic attacks, trouble sleeping, irritability, hostility, aggressiveness, impulsivity, agitation, excitement/overexcitement, mania or hypomania, or other unusual changes in behavior; exacerbation of the depressive state or suicidal thoughts. This recommendation should be adhered to avoid strictly in patients aged 18-24. Report such signs to the attending doctor immediately; assess such signs on a daily basis, especially during the early stages of the antidepressant treatment and when the dose is increased or lowered, as these changes can be sudden. Such signs may be associated with increased risk of suicidal thoughts or suicidal behavior, and can indicate the need for close monitoring and possibly for a change of the medicine.

❗ If you are taking, or have recently taken, other medicines, including nonprescription medicines and nutritional supplements, inform the doctor or pharmacist. Especially inform the doctor or pharmacist if you are taking:

- Medicines which affect the central nervous system (e.g., sedatives, hypnotics, medicines for Parkinson's, epilepsy, anti-allergics, surgical anesthetics and narcotic analgesics).
- Anticholinergics or medicines with anticholinergic activity (e.g., preparations for abdominal spasms) or sympathomimetics (e.g., cough and cold medicines).
- Thyroid medicines.
- Antihypertensives.
- The risk of convulsions may rise when concomitantly used with phenothiazine antipsychotics, or when lowering the dose of benzodiazepines (sedatives or hypnotics).
- Liver enzyme inhibitors, such as cimetidine (for ulcer) or fluoxetine (antidepressant) – concomitant use of these medicines with Melodil may increase the Melodil levels in the blood.
- Medicines which lead to increased activity of liver enzymes, such as barbiturates, phenytoin (for convulsions). The doctor may adjust the Melodil dosage in such cases.
- Do not take concomitantly and within 14 days of completing treatment with monoamine oxidase inhibitors (for depression).

❗ Use of the medicine and food – This medicine can be taken with or without food.

❗ Use of the medicine and alcohol consumption – Do not drink wines or alcoholic beverages during the course of treatment with this medicine.

❗ Pregnancy and breastfeeding – Do not use this medicine without consulting a doctor before commencing treatment if you are planning to become pregnant, are pregnant or breastfeeding.

❗ Use in children and adolescents below the age of 18 – This medicine is not usually intended for use in children and adolescents below the age of 18. When used in children of this age group, the doctor will weigh the risk versus the benefit in taking this medicine.

❗ Driving and use of machines – Use of this medicine may impair alertness and therefore, caution must be exercised when driving a car, operating dangerous machinery and when engaging in any activity requiring alertness. Children must be warned about riding bicycles or playing near the road, and the like.

❗ Important information regarding some of the ingredients of the medicine – This medicine contains lactose which may cause an allergy among people sensitive to lactose. Each **Melodil 25** tablet contains 24 mg lactose. Each **Melodil 50** tablet contains 29 mg lactose.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure. The dosage and the treatment regimen will be determined by the doctor only.

The usual dosage is generally:

Adults: The recommended starting dosage is 75 mg **Melodil** per day, given 1-3 times a day. However, in some patients, especially in the elderly, the starting dosage may be 25 mg. After about two weeks, the doctor may gradually increase the dosage.

For most patients, a maintenance dosage of 75-150 mg a day will be effective. In severe cases, the doctor may increase the dosage to a maximal dosage of 225 mg per day.

Elderly patients: The dosage of the medicine may be lower in patients above the age of 60; the recommended dosage is 50-75 mg per day.

Do not exceed the recommended dose.

Swallow the medicine with water. Do not chew! If necessary, the tablet can be crushed for immediate use. **Melodil 25** – do not halve the tablet.

If you accidentally take too high a dosage, or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you. The symptoms of overdose may include: changes in heart rhythm, decreased blood pressure, convulsions, nervous system depression (including coma), changes in the EKG, drowsiness, rapid heart rate, involuntary movements, vomiting, cyanosis, shock, restlessness, nervousness, high fever, muscle rigidity, uncontrollable movements of the limbs and dilated pupils.

If you forget to take this medicine at the required time, take a dose as soon as you remember, but if it is almost time for the next dose, skip the forgotten dose and take the next dose at the regular time. Never take two doses together!

Adhere to the treatment as recommended by the doctor. A few weeks may pass until you begin to feel better. Continue taking this medicine even if it takes time until your feeling improves. The effect of the medicine is sometimes only apparent after a few weeks.

Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the doctor; do not change the dosage without consulting the doctor and even then, gradually.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Melodil may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Refer to a doctor immediately if you experience: spasms in the muscles of the jaw, neck or back; slowed speech

or difficulty speaking; dragging the legs when walking; uncontrollable tremor in different parts of the body; fever, chills, sore throat or flu-like symptoms; difficulty breathing or swallowing; rash; yellowing of the skin and eyes; irregular heartbeat.

Additional side effects

Side effects which occur frequently: Nervousness, anxiety, trouble sleeping, agitation; sleepiness, dizziness, tremor; dry mouth, constipation, blurred vision; nausea, weakness, fatigue, headache.

Side effects which occur rarely: Hypotension, hypertension, rapid heartbeat, palpitations, arrhythmia, cardiac arrest, fainting; confusion (especially among the elderly), hallucinations, disorientation, false thoughts (delusions), restlessness, nightmares, hypomania, mania, exacerbation of psychosis, decrease in memory, loss of grip on reality; numbness, stinging, motor hyperactivity, inability to stand or sit still, convulsions, changes in the EEG, tinnitus, extrapyramidal symptoms, involuntary movements, speech disturbances; problems focusing eyes, dilated pupils, urinary retention, difficulty passing urine; rash, petechia, itching, photosensitivity, edema, fever; vomiting, esophageal irritation, diarrhea, bitter taste in the mouth, abdominal pain, difficulty swallowing; increased or decreased sexual desire (libido), impotence; increased or decreased blood sugar levels; changes in liver functions, jaundice, increased or decreased weight, excessive sweating, flushing, urinary frequency, oversaturation, nasal congestion, hair loss.

Side effects of unknown frequency: Bone marrow depression (including reduction of white blood cells and platelets), heart attack, peripheral neuropathy, sublingual adenitis, blackening of the tongue, stomatitis, intestinal obstruction, enlarged breasts in men, breast enlargement and galactorrhea in women, testicular swelling, pneumonia (associated in some cases to the reduction in white blood cells and increase in liver enzymes), Stevens-Johnson syndrome and toxic epidermal necrolysis (life-threatening skin effects).

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إسكاس، تشوش الرؤية؛ غثيان، ضعف، إرهاق، صداع. أعراض جانبية تظهر بأوقات نادرة: انخفاض ضغط الدم، فرط ضغط الدم، نبض سريع، خفقان القلب، اضطرابات في نظم القلب، سكتة قلبية، إغماء؛ أعراض خارج الهرمية، حركات لا إرادية، هوس أفكار وهمية (delusions)، قلة هدوء، كوابيس في الليل، هوس خفيف، هوس، تفاعم في الذهان، انخفاض في الذاكرة، انفصال عن الواقع؛ قلة الإحساس، وخز، فرط نشاط حركي، قلة القدرة على الوقوف أو الجلوس براحة، تشنجات، تغيرات في EEG، طنين في الأذنين، أعراض خارج الهرمية، حركات لا إرادية، اضطرابات في الكلام، مشاكل في تمرکز العينين، توسع الحدقتين، احتباس البول، صعوبات في التبول؛ طفح، بقع زرقاء على الجلد، حكة، حساسية للضوء، وذمة، سخونة؛ تقيؤات، تهيج في المريء، إسهال، مذاق مر في الفم، ألم بطن، صعوبة في البلع؛ ارتفاع أو انخفاض في الرغبة الجنسية (libido)، عجز جنسي؛ ارتفاع أو نقصان بمستويات السكر في الدم؛ تغيرات في وظائف الكبد، بقران، انخفاض أو زيادة بالوزن، تعرق زائد، تورم، وتيرة تبول مرتفعة، زيادة إفراز اللعاب، احتقان في الأنف، تساقط شعر.

أعراض جانبية شيوها غير معروفة: تشييط نخاع العظم (يشمل انخفاض في تعداد خلايا الدم البيضاء وفي الصفائح الدموية)، نوبة قلبية، اعتلال عصبي محيطي، التهاب في الغدد تحت اللسان، إسوداد اللسان، التهاب في الأغشية المخاطية في الفم (stomatitis)، انسداد الأمعاء، كبر الشيين لدى الرجال، تشييط الشيين وإفراز الطيب لدى النساء، تورم الخصيتين، التهاب الرتتين (يتعلق في بعض الحالات بانخفاض في تعداد خلايا الدم البيضاء، وارتفاع بآثريمات الكبد)، متلازمة Stevens-Johnson وToxic epidermal necrolysis (أعراض جلدية تشكل خطراً على الحياة).

إذا تفاقت إحدى الأعراض الجانبية، أو عندما تعاني من عرض جانبي لم يذكر في هذه النشرة، عليك استشارة الطبيب.

5 كيفية تخزين الدواء؟

• تجنب التسمم؛ يجب حفظ هذا الدواء في مكان مغلق بعيداً عن متناول أيدي الأطفال وأو الرضع، وذلك لتفادي إصابتهم بالتسمم. لا تسبب التقيؤ بدون تعليمات صريحة من الطبيب.

• لا يجوز إستعمال الدواء بعد إنتهاء تاريخ الصلاحية (exp. date) الذي يظهر على ظهر العبوة. يشير تاريخ الصلاحية إلى اليوم الأخير من نفس الشهر.

• يجب تخزين الدواء في درجة حرارة دون ٢٥ درجة مئوية وفي مكان محمي من الضوء.

• Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.

• Store the medicine at a temperature below 25°C and in a place protected from light.

6 FURTHER INFORMATION
In addition to the active ingredient, the medicine also contains: Lactose, maize starch, pregelatinized starch, talc, tricalcium phosphate, magnesium stearate, opadry.

كيف يبدو الدواء وما هو محتوي العبوة:
ميلوديل معبأ ضمن شرائح ألومينيوم (بليستر) يتم إدخالها لداخل عبوة كرتون. تحتوي كل عبوة ميلوديل على ٢٠ قرصاً.

ميلوديل ٢٥ هي أقراص مغطاة، مدورة، ممدودة، ممدودة من كلا الطرفين بلون وردي.

ميلوديل ٥٠ هي أقراص مغطاة، مدورة، ممدودة من كلا الطرفين مع خط شطر من أحد الأطراف، بلون برتقالي.

اسم صاحب الامتياز: أونيفارم م.ض.ص.ب. ٢٩ ٢١٤ تل-أبيي. اسم المنتج وعنوانه: تريما م.ض.، كيبوت مااباروت.

أقرت وزارة الصحة صيغة هذه النشرة ومحتواها فحص ورُخص في تاريخ: تموز ٢٠١٣.

رقم سجل الدواء في سجل الأدوية الحكومي في وزارة الصحة: ميلوديل ٢٥: ٠٠ ٢٢٦٥٥ ٥٧ ٠٣٢
ميلوديل ٥٠: ٠٠ ٢٢٦٥٤ ٤٧ ٠٣٢

من أجل سهولة وتسهيل القراءة، تمت صياغة هذه النشرة بصيغة المذكور. على الرغم من ذلك، فإن الدواء مخصص لكلا الجنسين.

معلومات هامة عن بعض مركبات الدواء - يحتوي هذا الدواء على لاكتوز الذي قد يسبب الرجيا لدى أشخاص يعانون من حساسية للاكتوز. كل قرص من ميلوديل ٢٥ يحتوي ٢٤ ملغ لاكتوز. كل قرص من ميلوديل ٥٠ يحتوي ٢٩ ملغ لاكتوز.

٣ كيفية إستعمال الدواء؟
يجب الإستعمال حسب تعليمات الطبيب دائماً. عليك الإستيخاض من الطبيب أو الصيدلي إذا لم تكن واثقاً. الجرعة الدوائية وطريقة العلاج يحددان من قبل الطبيب فقط. المقدار الدوائي الإعتيادي عادة هو:

بالغين: الجرعة الإبتدائية الإعتيادية هي ٧٥ ملغ ميلوديل لليوم، والتي تعطى ٣-١ مرات في اليوم. لكن، لدى بعض المعالجين، خاصة المسنين، قد تكون الجرعة الإبتدائية ٢٥ ملغ، بعد نحو أسبوعين، قد يزيد الطبيب الجرعة تدريجياً.

بالنسبة لكبار السن، الجرعة دافعة بمقدار ٧٥-١٥٠ ملغ لليوم تكون ناجحة. في حالات صعبة قد يزيد الطبيب الجرعة حتى جرعة قصوى قدرها ٢٢٥ ملغ في اليوم.

معالجين مسنين: قد تكون جرعة الدواء أخفض لدى معالجين فوق عمر ٦٠ سنة. الجرعة الإعتيادية هي ٥٠-٧٥ ملغ لليوم. لا تتجاوز الجرعة الموصى بها.

يجب بلع الدواء مع ماء. لا يجوز المضغ! إذا كان هناك حاجة يمكن سحق القرص للاستعمال الفوري. ميلوديل ٢٥ - لا يجوز شطر القرص إلى نصفين.

إذا تناولت بالخطأ جرعة أعلى من اللازم، أو إذا بلع طفل بالخطأ من الدواء، توجه فوراً إلى الطبيب أو للمستشفى واحضر عبوة الدواء معك. قد تشمل أعراض الجرعة المفرطة: تغيرات في نظم القلب، انخفاض في ضغط الدم، تشنجات، تشييط جهاز الأعصاب (حتى غيبوبة)، تغيرات في الـ EKG، نغاس، نظم قلب سريع، حركات لا إرادية، تقيؤ، زرقعة الجلد أو الانسجة المخاطية، صدمة، قلة الهدوء، عصبية، سخونة مرتفعة، تصلب العضلات، حركات من دون سيطرة في الأطراف وتوسع الحدقتين.

إذا نسيت تناول هذا الدواء في الوقت المحدد، يجب تناول جرعة حال تذكرك، لكن إذا كان وقت تناول الجرعة التالية قريباً، عليك تفويت الجرعة المنسية وتناول الجرعة التالية في الوقت المعتاد. لا يجوز بأي حال من الأحوال تناول جرعتين سوياً!

يجب المواظبة على العلاج كما وصفه الطبيب. قد تمر بضعة أسابيع حتى تبدأ الشعور بتحسن أفضل. يجب الإستمرار بتناول الدواء حتى لو يستغرق بعض الوقت ليحسن الشعور. في بعض الأحيان يلاحظ تأثير الدواء بعد عدة أسابيع.

لا يجوز التوقف عن العلاج بالدواء بدون إستشارة الطبيب، حتى ولو طرأ تحسن على وضك الصحي، لا يجوز تغيير الجرعة بدون إستشارة طبيب، وحتى حينئذ بشكل تدريجي.

لا تتناول الأدوية في العتمة؛ يجب تشخيص طابع الدواء والتأكد من المقادير الدوائية في كل مرة تتناول فيها دواء. ضع النظارات الطبية إذا لزم الأمر ذلك.

إذا تفرقت لديك أسئلة إضافية حول إستعمال الدواء، إستشر الطبيب أو الصيدلي.

٤ الأعراض الجانبية
كما بكل دواء، إن إستعمال ميلوديل قد يسبب أعراضاً جانبية عند بعض المستعملين. لا تتدهش من قائمة الأعراض الجانبية. من الجائز ألا تعاني أياً منها.

يجب التوجه حالاً إلى الطبيب في حال أنك تشعر ب: تشنجات في عضلات الفك، العتق أو الظهر؛ تباطؤ أو صعوبة في النطق؛ المشي مع جر القدمين؛ إرتجاف خارج عن السيطرة في أجزاء مختلفة من الجسم؛ سخونة قشعريرة؛ ألم في المحجرة أو أعراض تشبه الإنفلونزا؛ صعوبات في التنفس أو البلع؛ طفح؛ إصفرار الجلد والعينين؛ نبض غير منظم.

أعراض جانبية إضافية
أعراض جانبية تظهر بأوقات متقاربة: عصبية، قلق، مشاكل في النوم، عدم الهدوء؛ نغاس، دوام، إرتجاف؛ جفاف في الفم،