

## Notice: User information

**Redomex 10 mg film-coated tablets**  
**Redomex 25 mg film-coated tablets**

amitriptyline

**Please read this leaflet carefully before taking this medicine because it contains important information for you.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not give it to others. It may harm them, even if their signs of illness are the same as yours.
- If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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## 1. WHAT IS REDOMEX AND WHAT IS IT USED FOR?

Redomex belongs to a group of medicines called tricyclic antidepressants.

This medicine is used to:

- Treating depression in adults (major depressive episodes)
- Relieving neuropathic pain in adults
- Prophylaxis of tension headaches in adults
- Background treatment of migraine in adults
- To treat nocturnal bedwetting in children 6 years of age and older, only when organic causes, such as spina bifida and related disorders, have been excluded and there has been no response to all other pharmacological and nonpharmacological treatments, including muscle relaxants and desmopressin. This medication should only be prescribed by physicians experienced in the management of persistent bedwetting.

## 2. WHAT YOU NEED TO KNOW BEFORE TAKING REDOMEX?

### Never take Redomex:

- if you are allergic to amitriptyline or any of the other ingredients of this medicine (listed in section 6)
- if you have recently had a heart attack (myocardial infarction)
- if you have had heart problems such as rhythm disturbances detected on an electrocardiogram (ECG), heart block, or coronary insufficiency
- if you are taking medicines called monoamine oxidase inhibitors (MAOIs)
- if you have taken MAOIs in the last 14 days
- if you took moclobemide the day before
- if you suffer from severe liver disease.

If you are being treated with Redomex, you must stop taking this medicine and wait 14 days before starting treatment with an MAOI.

This medicine should not be used in children under 6 years of age.

### Warnings and precautions

Talk to your doctor or pharmacist before taking Redomex.

Heart rhythm disturbances and low blood pressure may occur if you take a high dose of amitriptyline. This could also occur at unusual doses if you have pre-existing heart disease.

#### QT Prolongation

A heart problem called "QT prolongation or long QT" (seen on an electrocardiogram, ECG) and heart rhythm disturbances (fast or irregular heartbeat) have been reported with Redomex.

Tell your doctor if:

- you have a slow heart rate,
- you have or have had a heart problem in which the heart does not pump enough blood to the body (heart failure),
- you are taking any other medication that could cause heart problems, or
- you have a problem that causes low potassium or magnesium levels in your blood, or high potassium levels in your blood,
- surgery is planned, as it may be necessary to stop amitriptyline treatment before giving you anesthetics. In case of emergency surgery, the anesthesiologist must be informed of the amitriptyline treatment,
- you have an overactive thyroid gland or are receiving medication for thyroid disorders.

#### Suicidal thoughts and worsening depression

If you are depressed, you may have thoughts of self-harm or suicide. This may be increased when you first start taking antidepressants because these medications take time to work, usually about two weeks, but sometimes longer.

You will be more likely to have these types of thoughts if:

- you have ever had thoughts of suicide or self-harm.
- You are a young adult. Information from clinical trials has shown an increased risk of suicidal behavior in young adults (under 25 years old) with psychiatric conditions and treated with antidepressants.

If you have thoughts of suicide or self-harm at any time, contact your doctor or go to the hospital immediately.

It may be helpful to tell a family member or friend that you are depressed and ask them to read this leaflet. You could ask them if they find your depression or anxiety worsening, or if they notice any changes in your behavior.

#### Manic Episodes

Some patients with manic-depressive disorder may enter a manic phase. This is characterized by abundant and highly changeable ideas, exaggerated cheerfulness, and excessive physical activity. In such cases, it is important to contact your doctor, who will likely change your treatment.

#### Serious skin reactions

Serious skin reactions, including drug reaction with eosinophilia and systemic symptoms (DRESS), have been reported with Redomex treatment. Stop using Redomex and seek medical help immediately if you notice any of the symptoms associated with these serious skin reactions described in section 4.

Tell your doctor if you have, or have had in the past, any medical problems, especially:

- narrow-angle glaucoma (loss of vision due to abnormally high pressure in the eye)
- epilepsy, history of seizures or convulsive fits
- difficulty urinating
- enlarged prostate
- thyroid disease
- bipolar disorder

- schizophrenia
- severe liver disease
- severe heart disease
- pyloric stenosis (narrowing of the end of the stomach) and paralytic ileus (intestinal obstruction)
- diabetes because you may need to adjust the dosage of your antidiabetic medication.

If you are using antidepressants such as selective serotonin reuptake inhibitors (SSRIs), your doctor may consider changing the dose of your medicine (see also section 2 "Other medicines and Redomex" and section 3).

Older people are more likely to experience certain side effects, such as dizziness when standing up due to low blood pressure (see also section 4 "Possible side effects").

### Children and adolescents

*Depression, neuropathic pain, prevention of chronic tension headaches and prophylaxis of migraines*

Do not administer this medicine to children and adolescents under 18 years of age for these conditions because its safety and efficacy have not been established for this age group.

### Nocturnal enuresis

- An ECG should be performed before initiating amitriptyline treatment to exclude long QT syndrome.
- These medicines should not be taken at the same time as an anticholinergic medicine (see also section 2 "Other medicines and Redomex")
- Suicidal thoughts and behaviors may also occur early in antidepressant treatment for conditions other than depression; the same precautions as with patients treated for depression should, therefore, be followed when treating patients with enuresis.

### Other medicines and Redomex

Some medicines can affect the way other medicines work and this can sometimes cause serious side effects.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, such as:

- monoamine oxidase inhibitors (MAOIs), e.g. phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine (for depression) or selegiline (for Parkinson's disease). These medicines should not be taken at the same time as Redomex (see section 2 "Do not take Redomex")
- adrenaline, ephedrine, isoprenaline, noradrenaline, phenylephrine, and phenylpropanolamine (these may be present in cough and cold medicines, and in some anesthetics)
- medicines for high blood pressure, e.g., calcium channel blockers (e.g., diltiazem and verapamil), guanethidine, betanidine, clonidine, reserpine, and methyldopa
- anticholinergic drugs such as some drugs to treat Parkinson's disease and gastrointestinal disorders (e.g., atropine, hyoscyamine)
- thioridazine (for schizophrenia)
- buprenorphine, tramadol (strong pain reliever)

Concomitant use of these medicinal products with amitriptyline may cause serotonin syndrome, which may be life-threatening (see section 4 "Possible side effects").

- medicines for fungal infections (e.g., fluconazole, terbinafine, ketoconazole, and itraconazole)
- sedatives (e.g. barbiturates)
- antidepressants (e.g., SSRIs (fluoxetine, paroxetine, fluvoxamine), duloxetine, and bupropion)
- medications for certain heart conditions (e.g., beta-blockers and antiarrhythmics)
- cimetidine (for stomach ulcers)
- methylphenidate (for ADHD)
- ritonavir (for HIV)
- rifampicin (for infections)
- phenytoin and carbamazepine (for epilepsy)
- St. John's wort ( *Hypericum perforatum* ), a plant used to treat depression
- thyroid medications
- valproic acid.

You should also tell your doctor if you are taking or have recently taken any medication that may affect your heart rhythm, e.g.:

- medicines to treat irregular heart rhythms (e.g. quinidine and sotalol)
- astemizole and terfenadine (for allergies and hay fever)
- medications used for certain mental illnesses (e.g., pimozide and sertindole)

- cisapride (for certain types of indigestion)
- halofantrine (against malaria)
- methadone (for pain relief and detoxification)
- diuretics (e.g. furosemide).

If you are going to have an operation and local or general anesthesia, you must inform your doctor that you are taking this medicine.

Likewise, you should inform your dentist that you are taking this medication if you are going to receive local anesthesia.

#### **Redomex with alcohol**

It is not advisable to drink alcohol while taking this medicine as it may increase the sedative effect.

#### **Pregnancy and breastfeeding**

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

Amitriptyline is not recommended during pregnancy unless your doctor considers it clearly necessary and only after careful consideration of the benefit/risk ratio. If you have taken this medicine during the latter part of pregnancy, the newborn may experience withdrawal symptoms such as irritability, increased muscle tension, tremors, irregular breathing, poor feeding, intense crying, urinary retention and constipation.

Your doctor will advise you whether you can start/continue/should stop breastfeeding or should stop taking this medicine, taking into account the benefit of breastfeeding for your child and the benefit of treatment for you.

#### **Driving and using machines**

This medicine may cause drowsiness and dizziness, especially at the beginning of treatment. If you experience these symptoms, do not drive or operate any tools or machines.

#### **Redomex contains lactose and sodium.**

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

This medicine contains less than 1 mmol (23 mg) sodium per tablet, that is to say essentially 'sodium-free'.

### **3. HOW TO TAKE REDOMEX?**

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are unsure.

Not all dosage regimens can be achieved with all pharmaceutical forms/strengths. The appropriate formulation/dose must be selected for initial doses and all subsequent dose increases.

#### **Depression**

##### *Adults*

The recommended starting dose is 25 mg twice daily.

Depending on your response to the medication, your doctor may gradually increase the dose to 150 mg daily divided into two doses.

##### *Elderly (over 65 years) and patients with cardiovascular disease*

The recommended starting dose is 10 mg to 25 mg per day.

Depending on your response to the medication, your doctor may gradually increase your dose to a total daily dose of 100 mg divided into two doses. If you receive doses between 100 mg and 150 mg, your doctor may need to monitor you more frequently.

##### *Use in children and adolescents*

This medicine should not be given to children or adolescents for the treatment of depression. See section 2 for further information.

#### **Neuropathic pain, prevention of tension headaches and basic treatment of migraine**

Your doctor will adjust the dosage of the medication based on your symptoms and response to treatment.

##### *Adults*

The recommended starting dose is 10 mg to 25 mg in the evening.

The recommended daily dose is 25 mg to 75 mg.

Depending on your response to the medication, your doctor may gradually increase the dose. If you receive doses above 100 mg, your doctor may need to monitor you more frequently. Your doctor will explain whether you should take the doses once a day or divide them into two doses.

##### *Elderly people (over 65 years) and people with cardiovascular disease*

The recommended initial dose is 10 mg to 25 mg in the evening.

Depending on your response to the medication, your doctor may gradually increase the dose. If you are receiving doses above 75 mg per day, your doctor may need to monitor you more frequently.

##### *Use in children and adolescents*

This should not be given to children or adolescents for the treatment of neuropathic pain, for the prophylaxis of chronic tension-type headaches, or for

the prophylaxis of migraines. For further information, see section 2.

### **Bedwetting**

*Use in children and adolescents*

Recommended doses for children:

- aged under 6 years: see section 2 "Do not take Redomex"
- 6 to 10 years of age: 10 mg to 20 mg daily. An appropriate dosage form should be used for this age group.
- aged 11 years and over: 25 mg – 50 mg.

The dosage should be increased gradually.

Take this medicine 1 to 1.5 hours before bedtime.

Before starting treatment, your doctor will perform an ECG of your heart to check for any signs of unusual heart rhythms.

Your doctor will reassess your treatment after 3 months and, if necessary, perform a new ECG.

Do not stop treatment without first consulting your doctor.

### **Patients at particular risk**

Patients with liver disease or people who are so-called "poor metabolisers" usually take lower doses.

Your doctor may order blood tests to determine the concentration of amitriptyline in your blood (see also section 2).

### **How and when to take Redomex?**

This medication can be taken with or without food.

Swallow the tablets with a glass of water. Do not chew them.

### **Duration of treatment**

Do not change the dose of the medicine or stop taking the medicine without first consulting your doctor.

### **Depression**

As with other medications for depression, it may take a few weeks before you feel any improvement.

In the treatment of depression, the duration of treatment is determined on a case-by-case basis and generally lasts at least 6 months. The duration of treatment is decided by your doctor.

Continue to take this medicine for as long as your doctor recommends.

The underlying condition may persist for a long time. If you stop treatment too early, your symptoms may return.

### **Neuropathic pain, tension headache prevention and migraine treatment**

It may take a few weeks before you feel pain relief.

Talk to your doctor about the length of treatment and continue taking this medicine for as long as your doctor recommends.

### **Bedwetting**

Your doctor will assess whether treatment should be continued after 3 months.

### **If you take more Redomex than you should**

If you take too much Redomex, immediately contact your doctor or the nearest hospital emergency room or the Poison Control Center (070/245.245), even if there are no signs of discomfort or poisoning. Take the box of this medicine with you if you go to a doctor or hospital.

Symptoms of overdose include:

- dilated pupils
- fast or irregular heartbeat
- difficulty urinating
- dry mouth and tongue
- intestinal obstruction
- convulsive seizures
- fever
- huddle
- confusion
- hallucinations
- uncontrolled movements
- drop in blood pressure, weak pulse, pallor
- difficulty breathing

- blue skin discoloration
- slowing of the heart rate
- drowsiness
- loss of consciousness
- coma
- various cardiac symptoms, such as: heart block, heart failure, hypotension, cardiogenic shock, metabolic acidosis, hypokalemia.

An overdose of amitriptyline can have serious consequences in children. Children are particularly susceptible to coma, cardiac symptoms, difficulty breathing, seizures, low blood sodium levels, lethargy, drowsiness, nausea, vomiting, and high blood sugar levels.

**If you forget to take Redomex**

Take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Redomex**

Your doctor will decide when and how to stop your treatment to avoid unpleasant symptoms that could occur if you stop the medicine suddenly (e.g. headache, general feeling of being unwell, insomnia and irritability).

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

## 4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you develop any of the following side effects, you should consult your doctor immediately:

- Intermittent attacks of blurred vision, rainbow vision, and eye pain.

You must consult an ophthalmologist immediately before continuing treatment with this medicine. These symptoms may be a sign of acute glaucoma. This is a very rare side effect, which may affect up to 1 in 10,000 people.

- A heart problem called QT prolongation (seen on an electrocardiogram, ECG). A common side effect, which may affect up to 1 in 10 people.
- Constipation, distended stomach, fever, and vomiting. These symptoms may be due to paralysis of parts of the intestines. Rare side effect, which may affect up to 1 in 1,000 people.
- Yellowing of the skin and whites of the eyes (jaundice). Your liver may be affected. Rare side effect, may affect up to 1 in 1,000 people.
- Persistent bruising, bleeding, pallor, or sore throat and fever. These symptoms may be the first signs that your blood or spinal cord is affected.

Effects on the blood may include a decrease in the number of red blood cells (which carry oxygen around the body), white blood cells (which fight infection), and platelets (which help the blood clot). This is a rare side effect that may affect up to 1 in 1,000 people.

- Suicidal thoughts or behavior. Rare side effect, may affect up to 1 in 1,000 people.
- Involuntary rhythmic muscle contractions, including those of the muscles that control eye movements, agitation, hallucinations, coma, excessive sweating, tremor, exaggerated reflexes, increased muscle tension, body temperature above 38°C (signs of serotonin syndrome, a potentially life-threatening condition). Unknown side effects, the frequency of which cannot be estimated from the available data.
- Stop using Redomex and seek immediate medical attention if you notice any of the following symptoms: generalized skin rash, high body temperature, and swollen lymph nodes (Drug Reaction with Eosinophilia or DRESS). Unknown side effects whose frequency cannot be estimated from the available data.

The following side effects have been reported, at the frequencies indicated:

Very common: may affect more than 1 in 10 people

- drowsiness/sleepiness
- tremors of the hands or other parts of the body
- dizziness
- headaches
- irregular, pounding, or rapid heartbeat
- dizziness when standing up due to low blood pressure (orthostatic hypotension)
- dry mouth
- constipation

- nausea
- excessive sweating
- weight gain
- slow articulation or slurred speech
- assault
- stuffy nose.

Common: may affect up to 1 in 10 people

- confusion
- sexual disorders (decreased libido, erectile dysfunction)
- attention deficit disorder
- taste disturbances
- numbness or tingling in the arms or legs
- coordination disorders
- dilated pupils
- heart block
- fatigue
- low sodium level in the blood
- hush
- urinary disorders (trouble urinating)
- feeling of thirst.

Uncommon: may affect up to 1 in 100 people

- euphoria, anxiety, sleep disturbances, nightmares
- convulsions
- tinnitus
- high voltage
- diarrhea, vomiting
- skin rash, hives, swelling of the face and tongue
- difficulty urinating
- increased milk production or milk production in the absence of breastfeeding
- increased pressure in the eye
- cardiovascular collapse
- worsening of liver failure
- impaired liver function (e.g., cholestatic liver disease).

Rare: may affect up to 1 in 1,000 people

- loss of appetite
- delirium (especially in elderly patients), hallucinations
- abnormalities in heart rhythm or heartbeat pattern
- swelling of the salivary glands
- hair loss
- increased sensitivity to sunlight
- breast enlargement in men
- fever
- weight loss

- abnormal liver function test results.

Very rare: may affect up to 1 in 10,000 people

- heart muscle disease
- feeling of restlessness and a strong need to be constantly on the move
- peripheral nerve disorder
- acute increase in pressure in the eye
- special forms of abnormal heart rhythm (torsades de pointes)
- allergic inflammation of the pulmonary alveoli and lung tissue.

Frequency not known: cannot be estimated from the available data

- absence of appetite
- increase or decrease in blood sugar levels
- paranoia
- movement disorders (involuntary movements or decreased movement)
- allergic inflammation of the heart muscle
- hepatitis
- hot flashes
- dry eye.

An increased risk of bone fractures has been observed in patients taking this type of medication.

#### **Reporting of side effects**

If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

#### **Belgium**

Federal Agency for Medicines and Health Products

[www.afmps.be](http://www.afmps.be)

Vigilance Division:

Website: [www.notifieruneffetindesirable.be](http://www.notifieruneffetindesirable.be)

e-mail: [adr@fagg-afmps.be](mailto:adr@fagg-afmps.be)

#### **Luxembourg**

Regional Pharmacovigilance Centre of Nancy or Pharmacy and Medicines Division of the Health Directorate

Website: [www.guichet.lu/pharmacovigilance](http://www.guichet.lu/pharmacovigilance)

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. HOW TO STORE REDOMEX**

Keep out of sight and reach of children.

Do not use this medicine after the expiry date shown on the label after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage precautions.

Do not dispose of any medications via wastewater or household waste. Ask your pharmacist how to dispose of medications you no longer use. These measures will help protect the environment.

## 6. CONTENTS OF THE PACKAGE AND OTHER INFORMATION

### What Redomex contains

- The active substance is amitriptyline.

Each Redomex 10 mg film-coated tablet contains 10 mg of amitriptyline as hydrochloride.  
Each Redomex 25 mg film-coated tablet contains 25 mg of amitriptyline as hydrochloride.

- The other components are:

Maize starch, lactose monohydrate, colloidal anhydrous silica, microcrystalline cellulose, copovidone, croscarmellose sodium, magnesium stearate.  
Coating: Macrogol 400.  
Colour: Opadry OY-S-9470 red-brown (E171, E172).

### Appearance of Redomex and contents of the outer packaging

Red-brown, round, biconvex film-coated tablets.

This medicine is available in polyethylene pill boxes in the following presentations:  
10 mg: 50 tablets or 100 tablets.  
25 mg: 30 tablets, 50 tablets, 100 tablets and 250 tablets.

Not all presentations may be marketed.

### Marketing Authorisation Holder and Manufacturer

#### *Marketing Authorisation Holder*

Lundbeck sa - Stephanie Square Centre - Avenue Louise 65/11 – 1050 Brussels

#### *Manufacturer*

H. Lundbeck A/S, Ottiliavej 9, 2500 Valby, Denmark

### Marketing Authorisation Numbers:

BE:

10 mg: BE048736

25 mg: BE048465

LU:

10mg: 2011091255

25mg: 2011091256

**Delivery method:** On medical prescription.

**This medicine is authorized in the member states of the European Economic Area under the following names:**

Austria, Denmark, Sweden: Saroten

Belgium, Luxembourg: Redomex

Norway: Sarotex

**The last date this notice was approved is 02/2025.**