**PACKAGE LEAFLET: INFORMATION FOR THE PATIENT**

**ANTALGEX T 37.5 mg/325 mg capsules**
Tramadol hydrochloride/Paracetamol

**Read all of this leaflet carefully before you start 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 only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet (see section 4).

What is in this leaflet:



**1. What ANTALGEX T is and what it is used for**
ANTALGEX T is a combination of two analgesics, tramadol hydrochloride and paracetamol, which act together to relieve your pain.
ANTALGEX T is intended for use in the treatment of moderate to severe pain when your doctor recommends that a combination of tramadol hydrochloride and paracetamol is needed.
ANTALGEX T should only be taken by adults and adolescents over 12 years.

**2. What you need to know before you take ANTALGEX T**
**Do not take ANTALGEX T**
- if you are allergic to tramadol, paracetamol or any of the other ingredients of ANTALGEX T listed in section 6.-,
- in case of acute alcohol poisoning, of sleeping pills, of other pain relievers or psychotropic medicines (medicines that affect mood and emotions),
- if you are also taking Monoamine Oxidase Inhibitors (or MAOIs, these medicines are used in the treatment of depression or Parkinson's disease) or if you have taken them in the last two weeks before treatment with ANTALGEX T,
- if you suffer from a severe liver disorder,
- if you have epilepsy that is not adequately controlled by your current medicine.

## Warnings and precautions
Talk to your doctor before using ANTALGEX T:
- if you take other medicines containing paracetamol or tramadol,
- if you have liver problems or a liver disease or if you notice your eyes and skin turning yellow. This may suggest jaundice or problems with your bile ducts,
- if you have kidney problems,
- if you have severe difficulties in breathing for example asthma or severe lung problems,
- if you have epilepsy or have already experienced fits or seizures,
- if you have recently suffered from a head injury, shock or severe headaches associated with vomiting,

- if you are dependent on any medicines including those used to relieve pain, for example morphine,
- if you take other medicines to treat pain that contain buprenorphine, nalbuphine or pentazocine,
- if you are going to have an anaesthesia. Tell your doctor or dentist that you are taking ANTALGEX T.

Sleep-related breathing disorders
ANTALGEX T contains an active substance that belongs to the group of opioids. Opioids can cause sleep-related breathing disorders, for example central sleep apnea (shallow/ pause of breathing during sleep) and sleep-related hypoxemia (low level of oxygen in blood).
The risk of experiencing central sleep apnea is dependent on the dose of opioids. Your doctor may consider decreasing your total opioid dosage if you experience central sleep apnea.

Tramadol is transformed in the liver by an enzyme. Variations of this enzyme exists in some patients, which can have consequences in people in different ways. In some people, they may not get enough pain relief whereas others would be more likely to get serious side effects. If you notice any of the following side effects, you must stop taking this medicine and seek immediate medical advice: slow or shallow breathing, confusion, sleepiness, small pupils, feeling or being sick, constipation, lack of appetite.
If any of the above-mentioned points applied to you in the past or applies to you while you are taking ANTALGEX T, please make sure your doctor knows. He/she can then decide whether you should continue to use this medicine.

**Children and adolescents**
Use in children with breathing problems:
Tramadol is not recommended in children with breathing problems, since the symptoms of tramadol toxicity may be worse in these children.

**Other medicines and ANTALGEX T**
Please tell your doctor or pharmacist if you are taking or have recently taken or could take any other medicines.
**Important: This medicine contains paracetamol and tramadol. Tell your doctor if you are taking *any other medicine containing paracetamol or tramadol*, so that you do not exceed the maximum daily doses.**

You **must not** take ANTALGEX T together with Monoamine Oxidase Inhibitors (MAOIs) (see section "Do not take ANTALGEX T").

ANTALGEX T is not recommended to be taken with the following:
- carbamazepine (a medicine commonly used to treat epilepsy or other types of pain such as severe pain attacks in the face called trigeminal neuralgia).
- buprenorphine, nalbuphine or pentazocine (opioid-type pain relievers). The pain-relieving effect may be reduced.

The risk of side effects increases if you also take:
- triptans (treatment for migraines) or selective serotonin re-uptake inhibitors, "SSRIs" (treatment for depression). If you experience confusion, restlessness, fever, sweating, uncoordinated movements of limbs or eyes, uncontrollable jerking of muscles or diarrhoea you should call your doctor.
- other pain relievers such as morphine and codeine (also as cough medicine), baclofen (a muscle relaxant) medicines used to lower blood pressure or medicines to treat allergies. You may feel drowsy or feel faint. If this happens, tell your doctor.

Concomitant use of ANTALGEX T and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible. However, if your doctor prescribes ANTALGEX T together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.

Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. If could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

- medicines that can cause seizures (epilepsy), as some antidepressants, or antipsychotics. The risk of epilepsy seizures might increase if you take ANTALGEX T at the same time. Your doctor will tell you whether ANTALGEX T is suitable for you.
- certain antidepressants. ANTALGEX T may interact with medicines and you could have symptoms as involuntary and rhythmed muscles contractions, including muscles controlling eyes movements, agitation, an excessive sweating, tremor, exaggerated reflexes, increased muscular tension, increased body temperature above 38 °C.
- warfarin or phenprocoumon (for blood thinning). The effectiveness of such medicines may be altered and bleeding may occur. Any prolonged or unexpected bleeding should be reported to your doctor immediately.

The effectiveness of ANTALGEX T may be altered if you also take:

- metoclopramide, domperidone or ondansetron (medicines used to treat nausea and vomiting/being sick)
- cholestyramine (medicine used to reduce level of cholesterol in the blood)

Your doctor will tell you which medicines are safe to take with ANTALGEX T.

**ANTALGEX T with food, drink and alcohol**
ANTALGEX T may make you feel drowsy. Alcohol may make you feel drowsier, it is better not to drink alcohol while you are taking ANTALGEX T.

**Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, if you think you may be pregnant or currently planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

As ANTALGEX T contains tramadol, you should not take this medicine during pregnancy or breast-feeding. If you become pregnant during treatment with ANTALGEX T, please consult your doctor before taking any further capsules.

Breast-feeding
Small amounts of tramadol may pass into the breast milk. Therefore, ANTALGEX T should not be taken more than once during breast-feeding, if you take ANTALGEX T more than once, you should stop breast-feeding your child.
Human experience suggests that tramadol does not influence man or woman fertility. There is no data concerning the influence of the combination of tramadol and paracetamol on fertility.

Ask your doctor or pharmacist for advice before taking any medicine.

**Driving and using machines**
ANTALGEX T may make you feel drowsy and this may affect your ability to drive, or to use tools and machines.

**3. How to take ANTALGEX T**
Always take ANTALGEX T exactly as your doctor or your pharmacist have told you. You should check with your doctor or pharmacist if you are not sure.
You should take ANTALGEX T for as short a time as possible.
The use in children below the age of 12 years is not recommended.
The dosage should be adapted to the intensity of your pain and to your individual pain sensitivity. In general, the lowest painkiller relieving dose should be administered.

The recommended starting dose, unless otherwise prescribed by your doctor, is 2 capsules for adults and adolescents over 12 years old.
If required, further doses may be taken, as recommended by your doctor. Interval between doses must be at least 6 hours.

**Do not take more than 8 ANTALGEX T capsules per day.**
Do not take ANTALGEX T more often than your doctor has told you.

*Elderly patients*
In elderly patients (over 75 years old), the excretion of tramadol might be delayed. If it is your case, your doctor may recommend extending the interval between doses.

*Patients with a severe liver or kidney disease (failure)/ dialysis patients*
Patients with severe hepatic and/or kidney failure should not take ANTALGEX T. If your failure is mild to moderate, it is likely that your doctor recommends extending the interval between doses.

**Method of administration:**
The capsules are for oral use.
The capsules should be swallowed whole with a sufficient amount of beverage.
If you think that the effect of ANTALGEX T is too strong (i.e. you feel very drowsy or have difficulty breathing) or too weak (i.e. you have inadequate pain relief), contact your doctor.

**If you take more ANTALGEX T than you should:**
In such cases contact your doctor or pharmacist immediately even if you feel well. There is a risk of liver damage which symptoms may only show later.

**If you forget to take ANTALGEX T:**
If you forget to take the capsules, pain is likely to return. Do not take a double dose to make up for forgotten individual doses, simply continue following your treatment as before.

**If you stop taking ANTALGEX T:**
You should not suddenly stop taking this medicine unless your doctor tells you to. If you want to stop taking your medicine, discuss this with your doctor first, particularly if you have been taking it for a long time. Your doctor will advise you when and how to stop, which may be by lowering the dose gradually to reduce the chance of developing unnecessary side effects (withdrawal symptoms). If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

**4. Possible side effects**
Like all medicines, ANTALGEX T can cause side effects, although not everybody gets them.

*Very common (may affect more than 1 in 10 people):*
- nausea,
- dizziness, drowsiness.

*Common (may affect up to 1 in 10 people):*
- vomiting (being sick), digestion problems (constipation, flatulence, diarrhoea), stomach pain, dry mouth,
- itching, sweating (hyperhidrosis),
- headache, tremor,
- confusion, sleep disorders, mood changes (anxiety, nervousness, euphoria).

*Uncommon (may affect up to 1 in 100 people):*
- increase in pulse or blood pressure, heart rhythm disorders,
- prickling, numbness or tingling in the limbs, ringing in the ear, involuntary muscle twitching,

- depression, nightmares, hallucinations (hearing, seeing or sensing things that are not the reality), amnesia,
- difficulty breathing.
- difficulty swallowing, blood in the stools,
- skin reactions (for example rashes, hives),
- increased liver enzymes.
- presence of albumin in urine, difficulties or pain on passing urine,
- shivering, hot flushes, pain in the chest,

*Rare (may affect up to 1 in 1000 people):*
- fits, difficulties in carrying out coordinated movements, transient consciousness loss (syncope),
- drug dependence,
- delirium,
- blurred vision, pupils' contraction (miosis),
- impaired speech,
- excessive pupillary dilation (mydriasis),

*Undetermined frequency (unknown frequency):*
- decrease in sugar blood levels (hypoglycaemia)

The following side effects which have been reported by people using medicines that contain only tramadol or only paracetamol. However, if you experience any of these while taking ANTALGEX T, you should tell your doctor:
- feeling faint when getting up from a lying or sitting position, slow heart rate, fainting, changes in appetite, muscle weakness, slower or weaker breathing, mood changes, changes in activity, changes in perception, worsening of existing asthma.
- use of ANTALGEX T together with medicines used to thin the blood (e.g. phenorocoumon, warfarin) may increase the bleeding risk. Any prolonged or unexpected bleeding should be reported to your doctor immediately.
- in some rare cases a skin rash, indicating an allergic reaction, may develop with sudden swelling of the face and neck, difficulties breathing or a drop of blood pressure and fainting. If this happens to you, stop treatment and see a doctor immediately. You must not take this medicine again.

In rare cases, using a medicine of the type of tramadol may make you become dependent on it, making it hard to stop taking it.
On rare occasions, people who have been taking tramadol for some time may feel unwell if they stop treatment abruptly. They may feel agitated, anxious, nervous or shaky. They may be hyperactive, have difficulty sleeping and have stomach or bowel disorders.
Few people may also get panic attacks, hallucinations, unusual perceptions such as itching, tingling and numbness, and noise in the ears (tinnitus). If you experience any of these symptoms after stopping ANTALGEX T, please consult your doctor.
In exceptional cases, blood tests may reveal certain abnormalities including low counts of blood platelets, which may result in bleeding in nose or gums.
Very rare cases of severe skin reactions have been reported with paracetamol.
Very rare cases of respiratory depression have been reported with tramadol.

**Reporting of side effects**
If you get 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 the national reporting system.
By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store ANTALGEX T

Keep this medicine out of the sight and reach of children.
Do not use ANTALGEX T after the expiry date which is stated on the carton and the aluminium strip. The expiry date refers to the last day of that month.
Do not store above 30º C.
Do not throw away any medicines via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6. Content of the pack and other information**
**What does ANTALGEX T contain**
The active substances are: tramadol hydrochloride and paracetamol.
One capsule contains 37.5 mg tramadol hydrochloride and 325 mg paracetamol.
The other ingredients are: Dibasic calcium phosphate, magnesium stearate.

**What ANTALGEX T looks like and contents of the pack**
ANTALGEX T capsules are off-white. The capsules are packed in PVC/Aluminium blisters.
ANTALGEX T is available in boxes of 20 capsules.

**ANTALGEX T® is a trademark**
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Exphar s.a.
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