1.5.3 Patient Information Leaflet (PIL)

PACKAGE LEAFLET: INFORMATION FOR THE USER

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

Read all of this leaflet carefully before you start taking this medicine.
. 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 pass it on to others. It may harm them, even if their symptoms are the same as yours.
. If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

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 (hypersensitive) to tramadol hydrochloride, paracetamol or any of the other ingredients of Antalgex T listed in section 6.
- in acute poisoning with alcohol, sleeping pills, other pain relievers or other psychotropic medicines (medicines that affect mood and emotions).
- if you are also taking MAO inhibitors (certain medicines used for treatment of depression or Parkinson's disease) or have taken them in the last 14 days before treatment with Antalgex T.
- if you suffer from a severe liver disorder.
- if you have epilepsy that is not adequately controlled on your current medicine.

Warnings and precautions
Talk to your doctor before using Antalgex T:
- if you take other medicines containing paracetamol or tramadol hydrochloride.
- 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.

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.

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 hydrochloride. Tell your doctor if you are taking any other medicine containing paracetamol or tramadol hydrochloride, 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 some 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 (for migraine) or selective serotonin re-uptake inhibitors, "SSRIs" (for depression). If you experience confusion, restlessness, fever, sweating, uncoordinated movement of limbs or eyes, uncontrollable jerking of muscles or diarrhoea you should call your doctor.
- tranquillizers, sleeping pills, 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.
- medicines that can cause seizures (epilepsy), as some antidepressants, antipsychotics. The risk of epilepsy seizures might increase if you take Antalgex T concomitantly. Your doctor will tell you if Antalgex T is right for you.
- antidepressants. Antalgex T may interact with medicines and you could have symptoms as involuntary and rhythmed muscles contractions, including muscles controlling eyes movements, agitation, increased sweating, trembling, 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.

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

Taking Antalgex T with food and drink
Antalgex T may make you feel drowsy. Alcohol may make you feel drowsier, so it is best not to drink alcohol while you are taking Antalgex T.

Pregnancy, breast-feeding and fertility
As Antalgex T contains tramadol hydrochloride, 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.
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 repeatedly, you should stop breast-feeding your child.

Experience in man suggests that tramadol has no influence on 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 use tools and machines, safely.

3. HOW TO TAKE Antalgex T
Always take Antalgex T exactly as your doctor has 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 sensitivity to pain. Generally, the lowest painkiller dose should be administered.
If required, further doses may be taken, as recommended by your doctor. The shortest time 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 (aged more than 75 years), the excretion of tramadol might be delayed. If it is your case, your doctor may recommend to extend 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 to extend the interval between doses.

Method of administration:
The capsules are for oral use.

The capsules should be swallowed 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 please contact your doctor or pharmacist immediately even if you feel well. There is a risk of liver damage which 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 taking the capsules as before.

If you stop taking Antalgex T:
Generally there will be no after-effects when treatment with Antalgex T is stopped. However, on rare occasions, people who have been taking tramadol hydrochloride for some time may feel unwell if they stop treatment abruptly (see section 4. "Possible Side Effects"). If you have been taking Antalgex T for some time, you should talk to your doctor if you want to stop because your body may have become used to it.
If you have any further questions on the use of this product, 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: (more than 1 out of 10 persons treated):
- nausea,
- dizziness, drowsiness.

Common (less than 1 out of 10, but more than 1 out of 100 persons treated):
- vomiting, digestion problems (constipation, flatulence, diarrhoea), stomach pain, dry mouth,
- itching, sweating (hyperhidrosis),
- headache, trembling,
- confusion, sleep disorders, mood changes (anxiety, nervousness, euphoria).

Uncommon (less than 1 out of 100, but more than 1 out of 1,000 persons treated):
- increase in pulse or blood pressure, heart rate or heart rhythm disorders,
- tingling, numbness or feeling of pins and needles in the limbs, ringing in the ear, involuntary muscle twitching,
- depression, nightmares, hallucinations (hearing, seeing or sensing things that are not really there), memory lapse,
- difficulty breathing.
- difficulty swallowing, blood in the stools,
- skin reactions (for example rashes, hives),
- increased liver enzymes.
- presence of albumin in the urine, difficulty or pain on passing water,

- shivering, hot flushes, pain in the chest,

Rare (less than 1 out of 1,000, but more than 1 out of 10,000 persons treated):
- fits, difficulties in carrying out coordinated movements, transient consciousness loss (syncope),
- addiction,
- blurred vision, pupils contraction (miosis), impaired speech, excessive pupilliary dilation,
- impaired speech,
- excessive pupillary dilation,

Unknown frequency:
- decrease in sugar blood levels (hypoglycaemia)

The following are severe side effects which have been reported by people using medicines that contain only tramadol hydrochloride 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. phenprocoumon, 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 drop of blood pressure and fainting. <u>If this happens to you, stop treatment and see a doctor immediately. You must not take the medicine again.</u>

In rare cases, using a medicine of the type of tramadol hydrochloride may make you become dependent on it, making it hard to stop taking it.
On rare occasions, people who have been taking tramadol hydrochloride 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. Very 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 complaints after stopping Antalgex T, please consult your doctor.
In exceptional cases blood tests may reveal certain abnormalities, for instance, low counts of blood platelets, which may result in nose bleeds or bleeding 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.

5. HOW TO STORE Antalgex T
Keep 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

Exphar s.a.
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Manufacturer

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