PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S5

DOMADOL PLUS film-coated tablets

Tramadol hydrochloride and paracetamol

Sugar free.

Read all of this leaflet carefully before you start taking DOMADOL PLUS.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- DOMADOL PLUS 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 DOMADOL PLUS is and what it is used for

2. What you need to know before you take DOMADOL PLUS

3. How to take DOMADOL PLUS

4. Possible side effects

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1. What DOMADOL PLUS is and what it is used for

DOMADOL PLUS contains the active substances tramadol hydrochloride and paracetamol.

DOMADOL PLUS is intended for use in the treatment of moderate to severe pain when your doctor recommends that a combination of tramadol and paracetamol is needed.

2. What you need to know before you take DOMADOL PLUS

Do not take DOMADOL PLUS:

- If you are allergic to tramadol hydrochloride, paracetamol, other opiods such as codeine or any of the other ingredients of DOMADOL PLUS listed in section 6 of this leaflet.
- If you have severe liver problems.
- If you suffer from acute poisoning with alcohol, sleeping pills, pain relievers or other psychotropic medicines (medicines that affect your mood and emotions).
- If you are taking monoamine oxidase inhibitors (MAOIs) (certain medicines used for depression) or have taken them in the last 14 days before treatment with DOMADOL PLUS.
- If you are undergoing treatment for addiction to narcotic medicines.
- If you have difficulty breathing.
- If you suffer from increased pressure in the brain (possibly after a head injury or brain disease).
- If you have epilepsy that cannot be controlled by medicine.

Warnings and precautions:

DOMADOL PLUS contains paracetamol which may be fatal in overdose. If you have taken more paracetamol than you should have, even if you feel well and have no symptoms, contact your nearest doctor, hospital or poison centre immediately.

Take special care with DOMADOL PLUS:

- If you are using other medicines containing tramadol or paracetamol, as contained in DOMADOL PLUS, you should not take DOMADOL PLUS.
- If you have liver or kidney problems.
- If you have difficulty breathing.
- If you have a tendency towards epilepsy or fits.
- Tramadol works by being converted (metabolised) into its active component. If you convert (metabolise) tramadol to this active component more rapidly and completely than other

patients, you are known as an ultra-rapid metaboliser. If you are an ultra-rapid metaboliser you are more likely to have serious side effects, such as breathing difficulties, with slow or shallow breathing. If you experience these types of side effects, stop taking DOMADOL PLUS and consult with your doctor or health care provider immediately.

- If you are taking other medicines to relieve moderate to severe pain, it may increase or prolong the effects of DOMADOL PLUS.
- If you think that you are addicted to other pain relievers (opioids).
- If you recently suffered from a head injury, shock or severe headaches associated with vomiting (being sick) (see **Do not take DOMADOL PLUS**).
- If you feel that you are going to faint.
- If you experience skin rashes or any other hypersensitivity reactions, stop taking DOMADOL PLUS.
- If you are taking other sedative medicines.
- If you are going to have an anaesthetic procedure (tell your doctor that you are taking DOMADOL PLUS).
- If you are an elderly person.

Sleep-related breathing disorders

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

If any of the above-mentioned points applied to you in the past or applies to you while you are taking DOMADOL PLUS, please make sure your doctor knows. He/she can then decide whether you should continue to use DOMADOL PLUS.

Other medicines and DOMADOL PLUS:

Always tell your health care professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor or pharmacist if you are currently using:

- carbamazepine, tetrahydrocannabinol (used to treat epilepsy);
- buprenorphine, nalbuphine, pentazocine (used to treat moderate to severe pain);
- antipsychotic medicines (used to treat mental health problems);
- selective serotonin re-uptake inhibitors (SSRIs), serotonin and norepinephrine reuptake inhibitors (SNRIs) or tricyclic antidepressants (used to treat depression);
- bupropion (used to treat depression and help you stop smoking;
- fluoxetine, paroxetine, amitriptyline, mirtazapine (used to treat depression);
- cough medicines;
- benzodiazepines (used to treat anxiety and panic attacks);
- barbiturates (used to treat sleeping disorders);
- thalidomide (used to treat certain cancers);
- baclofen (used to treat muscle stiffness);
- medicines used to lower blood pressure;
- medicines to treat allergies (antihistamines);
- diflunisal (used to treat fever, pain and inflammation in your body);
- digoxin (used to treat heart failure and a fast heartbeat) or quinidine (used to treat heart rhythm disorders);
- warfarin or other blood thinning medicines (used to thin your blood and prevent blood clots from forming);
- ondansetron (used to prevent nausea and vomiting that may be caused by surgery, cancer chemotherapy or radiation treatment).

DOMADOL PLUS with food, drink and alcohol:

Do not drink alcohol while you are taking DOMADOL PLUS, as you may feel drowsier.

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other health care provider for advice before taking DOMADOL PLUS.

You should not take DOMADOL PLUS if you are pregnant or breastfeeding. If you get pregnant while taking DOMADOL PLUS, stop taking it immediately and tell your health care provider.

Driving and using machines:

DOMADOL PLUS can cause drowsiness or dizziness, which may be enhanced in conjunction with alcohol or other central nervous system (CNS) depressants. Take special care before performing tasks requiring your attention, until you know how DOMADOL PLUS will affect you.

3. How to take DOMADOL PLUS

Always take DOMADOL PLUS exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with DOMADOL PLUS will last.

Your doctor will determine the correct dose for you based on your condition.

In general, the lowest pain-relieving dose should be taken.

Take DOMADOL PLUS for as short a time as possible and no longer than your doctor has told you.

Adults and children over 16 years:

The usual dose is 1 or 2 tablets every 4 to 6 hours as needed for pain relief up to a maximum of 8 tablets per day.

Take the tablets with a sufficient quantity of liquid (e.g. one glass of water).

Do not use in children younger than 16 years of age.

Patients with kidney disease:

If your kidney abnormality is mild or moderate, your doctor may adjust your dosing to a maximin of 2 tablets every 12 hours.

DOMADOL PLUS can be taken with or without food.

If you have the impression that the effect of DOMADOL PLUS is too strong or too weak, tell your doctor or pharmacist.

If you take more DOMADOL PLUS than you should:

In the event of overdosage, consult your doctor or pharmacist without delay. If neither is available, contact the nearest hospital or poison centre. Take along any tablets that are left, including the carton, so that the hospital staff can easily tell what you have taken. This is because too much paracetamol can cause delayed, serious liver damage.

If you forget to take DOMADOL PLUS:

If you forget to take a dose, pain is likely to return.

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take DOMADOL PLUS at the next regularly scheduled time.

Do not take a double dose to make up for the forgotten individual doses.

If you stop taking DOMADOL PLUS:

People who have been using a medicine containing tramadol may become dependent on it, making it hard to stop taking it. If you have been taking DOMADOL PLUS for some time and want to stop, contact your doctor because your body may have become used to DOMADOL PLUS.

Some people may experience withdrawal symptoms after stopping

DOMADOL PLUS treatment, such as:

- panic attacks,
- feeling anxious,
- hallucinations,
- unusual perceptions such as itching, tingling and numbness,
- ringing in the ears.

If you experience any of these complaints after stopping DOMADOL PLUS, please contact your doctor.

4. Possible side effects

DOMADOL PLUS can have side effects.

Not all side effects reported for DOMADOL PLUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DOMADOL PLUS, please consult your health care provider for advice.

If any of the following happens, stop taking DOMADOL PLUS and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing;
- rash, hives or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to DOMADOL PLUS. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- fits (seizures);
- stupor (loss of consciousness or unresponsiveness);
- changes in the way your heart beats (beating faster, slower or irregular);

- chest pain;
- difficulty breathing, shortness of breath;
- blood in your stools;
- problems urinating, passing less urine than is normal;
- painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome or toxic epidermal necrolysis;
- thoughts about harming yourself (suicidal thoughts);
- yellowing of your skin and eyes, dark urine, and tiredness which may be symptoms of liver problems;
- high levels of serotonin in your body that can be potentially life-threatening (rapid heart rate, fluctuations in your blood pressure, loss of coordination, fever, coma);
- bleeding or bruising more easily than normal;
- signs of recurrent infections such as fever or sore throat.

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- changes in your mood, feeling anxious, confused or nervous;
- an unrealistic feeling of wellbeing;
- anorexia (loss of appetite);
- sleeping problems, including an inability to sleep (insomnia);
- headache or dizziness;
- sleepiness;
- tremors (involuntary trembling or shaking of hands and feet);
- hot flushes;
- nausea (feeling sick), vomiting (being sick), constipation, dry mouth, diarrhoea, pain in your stomach, indigestion, flatulence (wind);
- increased sweating;

- feeling tired, abnormal physical weakness or lack of energy.

Less frequent side effects:

- anaemia (fatigue, loss of energy, pale skin, cramps in your legs, difficulty with concentration);
- decreased body mass;
- delirium (state of severe confusion);
- feeling of unreality, sense of detachment from yourself or your body;
- feeling depressed, mood swings, abnormal thinking;
- seeing or hearing things that does not exist (hallucinations);
- nightmares;
- medicine dependence;
- amnesia (memory loss);
- inability to get or maintain an erection;
- loss of muscle co-ordination; difficulty in controlling movements, unusual muscle stiffness;
- difficulty in speaking or slurred speech;
- migraine or aggravated migraine;
- tingling or numbness of your hands and feet (pins and needles);
- vertigo (sensation of spinning or swaying);
- blurred vision, contraction of the pupil of your eye, extreme dilation/widening of your pupil, abnormal vision;
- ringing in your ears;
- high blood pressure or aggravated high blood pressure;
- low blood pressure
- difficulty in swallowing;
- swelling of your tongue;
- protein in your urine when tests are done;
- chills;
- abnormal liver test results when blood tests are done (increased transaminase).

Frequency unknown side effects:

- low blood sugar;
- a fall in blood pressure when standing up;
- increased creatinine levels when blood tests are done;
- changes in your appetite;
- changes in your activity levels (usually a decrease in your activity levels) or perception;
- worsening of asthma.

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. This includes any possible side effects not listed in this leaflet. You can also report side effects via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications:

https://www.sahpra.org.za/Publications/Index/8

By reporting side effects, you can help provide more information on the safety of DOMADOL PLUS.

5. How to store DOMADOL PLUS

- Store at or below 30 °C.
- Protect from light and moisture.
- Keep the blisters in the outer carton until required for use.
- STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
- Do not use after the expiry date printed on the carton / blister.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

Film-coated tablets: Each film-coated tablet contains 37,5 mg tramadol hydrochloride and 325 mg paracetamol.

6. Contents of the pack and other information

What DOMADOL PLUS contains:

The active substances in DOMADOL PLUS are tramadol hydrochloride and paracetamol.

Each film-coated tablet contains 37,5 mg tramadol hydrochloride and 325 mg paracetamol.

Excipients for DOMADOL PLUS:

Colloidal anhydrous silica

Magnesium stearate (E572)

Maize starch

Microcrystalline cellulose (E460(i))

Povidone

Sodium starch glycolate

Talcum.

Film coating for DOMADOL PLUS:

Opadry Yellow containing:

Hypromellose (E464)

Iron oxide yellow (colourant) (E172)

Polyethylene glycol (E1521)

Titanium dioxide (E171).

What DOMADOL PLUS looks like and contents of the pack:

Yellow, capsule shaped, biconvex, film-coated tablet, plain on one side and a break line on the other side.

Transparent, clear, PVC/PVdC aluminium blister strip containing 10 tablets packed in an outer carton.

Pack size: 30 or 60 tablets.

Holder of certificate of registration:

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