PATIENT INFORMARION LEAFLET: INFORMATION FOR THE USER

TDRONA PLUS

(Paracetamol & Tramadol Hydrochloride Tablets)

Read all of this leaflet carefully before you start TDRONA PLUS using

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your health care provider.
- 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 becomes serious, or if you notice any side effects not listed in this leaflet, please tell your health care provider.

In this leaflet:

1. WHAT TDRONA PLUS AND WHAT IT IS USED FOR

Tramadol hydrochloride/Paracetamol is positioned as a step II analgesic.

TDRONA PLUS is indicated for:

Tramadol hydrochloride/Paracetamol tablets are indicated for the symptomatic treatment of moderate to severe pain.

The use of Tramadol hydrochloride/Paracetamol should be restricted to patients whose moderate to severe pain is considered to require a combination of tramadol and paracetamol.

2. BEFORE YOU TAKE TDRONA PLUS

Do not take TDRONA PLUS

If you are having hypersensitivity to Paracetamol, Tramadol Hydrochloride or any allergic reaction to excipients used in manufacturing of TDRONA PLUS Tablets.

Take special care with TDRONA PLUS

In patients with severe hepatic impairment Tramadol hydrochloride/Paracetamol should not be used. The hazards of paracetamol overdose are greater in patients with non-cirrhotic alcoholic liver disease. In moderate cases prolongation of dosage interval should be carefully considered.

Taking other medicines

- *Non-selective MAO Inhibitors*: risk of serotoninergic syndrome (diarrhoea, tachycardia, sweating, trembling, confusion, even coma).
- *Selective-A MAO Inhibitors*: extrapolation from non-selective MAO inhibitors, risk of serotoninergic syndrome (diarrhoea, tachycardia, sweating, trembling, confusion, even coma).
- *Selective-B MAO Inhibitors*: central excitation symptoms evocative of a serotoninergic syndrome (diarrhoea, tachycardia, sweating, trembling, confusion, even coma).

In case of recent treatment with MAO inhibitors, a delay of two weeks should occur before treatment with tramadol.

Pregnancy and Lactation

Pregnancy

Since Tramadol hydrochloride/Paracetamol is a fixed combination of active ingredients including tramadol, it should not be used during pregnancy.

Paracetamol

Epidemiological studies in human pregnancy have shown no ill effects due to paracetamol used in the recommended dosage, but patients should follow the advice of their doctor regarding its use.

Tramadol

There are no adequate data from the use of tramadol in pregnant women. Tramadol crosses the placental barrier and chronic use during pregnancy can cause withdrawal symptoms in the new-born baby. Therefore, it should not be used during pregnancy.

Tramadol administered before or during birth does not affect uterine contractility. In neonates it may induce changes in respiratory rate which are not usually clinically relevant.

Lactation

Since Tramadol hydrochloride/Paracetamol is a fixed combination of active ingredients including tramadol, it should not be ingested during breast feeding.

Paracetamol

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data on paracetamol does not contraindicate it for breast feeding.

Tramadol

Tramadol and its metabolites are found in small amounts in human breast milk. An infant could ingest 0.1% of the dose given to the mother. Tramadol hydrochloride should not be administered during breast feeding.

Driving and using machines

Must not drive vehicles when taken TDRONA PLUS.

3. HOW TO TAKE TDRONA PLUS

Adults and adolescents (12 years and older)

The use of Tramadol hydrochloride/Paracetamol should be restricted to patients whose moderate to severe pain is considered to require a combination of tramadol and paracetamol.

The dose should be individually adjusted according to intensity of pain and response of the patient.

An initial dose of two tablets of Tramadol hydrochloride/Paracetamol is recommended. Additional doses can be taken as needed, not exceeding 8 tablets (equivalent to 300 mg tramadol and 2600 mg paracetamol) per day.

The dosing interval should not be less than six hours.

Tramadol hydrochloride/Paracetamol should under no circumstances be administered for longer than is strictly necessary. If repeated use or long term treatment with Tramadol hydrochloride/Paracetamol is required as a result of the nature and severity of the illness, then careful, regular monitoring should take place (with breaks in the treatment, where possible), to assess whether continuation of the treatment is necessary.

Children

The effective and safe use of Tramadol hydrochloride/Paracetamol has not been established in children below the age of 12 years. Treatment is therefore not recommended in this population.

Elderly patients

The usual dosages may be used although it should be noted that in volunteers aged over 75 years the elimination half life of tramadol was increased by 17% following oral administration. In patients over 75 years old, it is recommended that the minimum interval between doses should be not less than 6 hours, due to the presence of tramadol.

Method of Administration:

Oral administration

If you forget to take TDRONA PLUS

Pls do not take a double dose to make up for a forgotten tablet.

If you stop taking TDRONA PLUS

If you have any further questions on the use of this product, ask your health care provider.

4. POSSIBLE SIDE EFFECTS

The most commonly reported undesirable effects during the clinical trials performed with the paracetamol/tramadol combination were nausea, dizziness and somnolence, observed in more than 10% of the patients.

Cardiac disorders:

- Uncommon: hypertension, palpitations, tachycardia, arrythmia.

Nervous system disorders:
- Very common: dizziness, somnolence
- Common: headache trembling
- Uncommon: involuntary muscular contractions, paraesthesia, tinnitus
- Rare: ataxia, convulsions.

Psychiatric disorders:
- Common: confusion, mood changes (anxiety, nervousness, euphoria), sleep disorders
- Uncommon: depression, hallucinations, nightmares, amnesia
- Rare: drug dependence.

5. HOW TO STORE TDRONA PLUS

Keep out of the reach and sight of children.
Do not store above 30ºC, Store in the original carton. Protect from light, heat and moisture.
Do not use TDRONA PLUS after the expiry date which is stated on the blister & carton.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What TDRONA PLUS contains:

- The active pharmaceutical ingredient(s) are Paracetamol & Tramadol Hydrochloride.
- The other ingredient(s) are Maize starch, Microcrystalline cellulose, PVP K-30, Sodium methyl paraben, Sodium propyl paraben, Sodium starch glycolate, Purified talc, Aerosil, Magnesium stearate.

What TDRONA PLUS looks like and contents of the pack: White colored capsule shaped uncoated tablets, having break line on one side and plain on other side.

10 Tablets are packed in a ALU-PVC blister such blister is placed in a monocarton with package insert. And Such 10 monocarton are placed in outer carton 10 x 01 x 10 Tablets.

Manufacturer

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