PATIENT INFORMARION LEAFLET: INFORMATION FOR THE USER

PARAFENAC DS

(Diclofenac Sodium & Paracetamol Capsules)

Read all of this leaflet carefully before you start PARAFENAC DS 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 PARAFENAC DS IS AND WHAT IT IS USED FOR

Diclofenac Sodium & Paracetamol Capsules combination medicine which helps in relieving pain.

PARAFENAC DS is indicated in the treatment of painful rheumatic disorders such as rheumatoid arthritis, osteoarthritis, ankylosing spondylitis and acute gout. Acute musculoskeletal disorders and soft tissue inflammation such as periarthritis, sprains, strains, tenosynovitis, bursitis, pain in fractures and dislocation. Relief of pain and inflammation associated with orthopaedic, dental, gynaecological and other minor surgical procedures.

2. BEFORE YOU TAKE PARAFENAC DS

Do not take PARAFENAC DS

If you are having hypersensitivity to Paracetamol, Diclofenac sodium or any allergic reaction to excipients used in manufacturing of PARAFENAC DS capsules.

Take special care with PARAFENAC DS

Previous hypersensitivity reactions (eg asthma, urticaria, angioedema or rhinitis) in response to Ibuprofen, aspirin or other non-steroidal anti-inflammatory drugs.

• Severe hepatic, renal and cardiac failure.

• During the last trimester of pregnancy.

• Active, or history of recurrent peptic ulcer/haemorrhage (two or more distinct episodes of proven ulceration or bleeding).

• History of gastrointestinal bleeding or perforation, related to previous NSAIDs therapy.

• Established congestive heart failure (NYHA II-IV), ischemic heart disease, peripheral arterial disease and/or cerebrovascular disease.

Taking other medicines

Other analgesics including cyclo-oxygenase-2 selective inhibitors: Avoid concomitant use of two or more NSAIDs (including aspirin) as this may increase the risk of adverse effects .

Diuretics and Anti-hypertensive: Reduced diuretic and anti-hypertensive effect may be seen

The combination should be administered with caution, and patients, especially older people, should have their blood pressure monitored. Patients should be adequately hydrated and renal function monitored after initiation of concomitant therapy and periodically thereafter, particularly for those patients on diuretics and ACE inhibitors, due to the increased risk of nephrotoxicity.

Diuretics can increase the risk of nephrotoxicity of NSAIDs. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels, hence serum potassium should be monitored.

Pregnancy and breast-feeding

Diclofenac Sodium

Pregnancy:

Inhibition of prostaglandin synthesis may adversely affect the pregnancy and/or the embryo/foetal development. Data from epidemiological studies suggest an increased risk of miscarriage and of cardiac malformation and gastroschisis after use of a prostaglandin synthesis inhibitor in early pregnancy. The absolute risk for cardiovascular malformation was increased from less than 1%, up to approximately 1.5 %. The risk is believed to increase with dose and duration of therapy. In animals, administration of a prostaglandin synthesis inhibitor has been shown to result in increased pre- and post-implantation loss and embryo-foetal death.

In addition, increased incidences of various malformations, including cardiovascular malformations, have been reported in animals given a prostaglandin synthesis inhibitor during the organogenetic period. During the first and second trimester of pregnancy, Motifene should not be given unless absolutely necessary. If Motifene is used by a woman when attempting to conceive, or during the first and second trimester of pregnancy, the dose and durations should be kept as low and as short as possible.

During the third trimester of pregnancy, all prostaglandin synthesis inhibitors may cause the following in the foetus:

- cardiopulmonary toxicity (with premature closure of the ductus arteriosus and pulmonary hypertension);

- renal dysfunction, which may progress to renal failure with oligo-hydroamniosis;

In the mother and the neonate, at the end of pregnancy:

- an anti-aggregating effect which may occur even at very low doses leading to possible prolongation of bleeding times;

- inhibition of uterine contractions resulting in delayed or prolonged labour.

Consequently, Motifene is contraindicated during the third trimester of pregnancy.

Breast-feeding:

In limited studies so far available, NSAIDs can appear in breast milk in very low concentrations. NSAIDs should, if possible, be avoided when breast-feeding.

Paracetamol

Pregnancy

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. A large amount of data on pregnant women indicate neither malformative, nor feto/neonatal toxicity. Paracetamol can be used during pregnancy if clinically needed however it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.

Breastfeeding

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breast feeding.

Driving and using machines

Diclofenac Sodium

Diclofenac Sodium has minor or moderate influence on the ability to drive and use machines. Undesirable effects such as dizziness, drowsiness, fatigue and visual disturbances, vertigo, somnolence or other central nervous system disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

Paracetamol

Paracetamol has no influence on the ability to drive and use machines.

3. HOW TO TAKE PARAFENAC DS

Always take PARAFENAC DS exactly as your health care provider has told you. You should check with your health care provider if you are not sure. The usual dose is as per follows:

Adults, the elderly and children over 12 years of age:

1 capsule two or three times daily

Not recommended for children under 12 years of age.

Method of Administration:

Oral administration

If you forget to take PARAFENAC DS

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

If you stop taking PARAFENAC DS

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

4. POSSIBLE SIDE EFFECTS

Immune system disorders

Hypersensitivity including skin rash may occur.

Not known: anaphylactic shock, angioedema

Blood and lymphatic system disorders

Not known: blood dyscrasias including thrombocytopenia and agranulocytosis

Skin and subcutaneous disorders

Very rare cases of serious skin reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis, fixed drug eruption have been reported.

5. HOW TO STORE PARAFENAC DS

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 PARAFENAC DS 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 PARAFENAC DS contains:

- The active pharmaceutical ingredient(s) are… Paracetamol & Doclofenac Sodium
- The other ingredient(s) are ... Povidone, Isopropyl Alcohol, Purified Talc, Magnesium Stearate, Aerosil.

What PARAFENAC DS looks like and contents of the pack: Size “0” Orange / Orange Colour hard gelatin Capsules.

10 x 1 x 10 Capsules Alu-PVC blister

Manufacturer

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