

## **Package leaflet: Information for the patient**

### **NURODOL FORTE**

Caffeine, Ibuprofen and Paracetamol Tablets

Please read this leaflet carefully before using this medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

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#### **1. What NURODOL FORTE Tablets is and what it is used for?**

NURODOL FORTE Tablets contain Caffeine, Ibuprofen and Paracetamol.

Paracetamol works to stop the pain messages from getting through to the brain.

Ibuprofen belongs to a group of medicines called non-steroidal anti-inflammatory drugs (or NSAIDs). It relieves pain and reduces inflammation (swelling, redness or soreness).

Caffeine works as a mild stimulant that causes wakefulness and increased mental activity. Caffeine acts to further help the effectiveness of Paracetamol.

NURODOL FORTE Tablets are used for short-term symptomatic treatment of mild to moderate pain.

Ask your doctor or pharmacist if you have any questions about this medicine.

You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

#### **2. Before you take NURODOL FORTE Tablets**

Do not take NURODOL FORTE Tablet

- If you are allergic to the active substance(s) or any of the other ingredients of this medicine (listed in section 6);
- If you have a history with gastrointestinal bleeding or perforation, related to previous NSAIDs therapy; - you have an active or recurrent peptic ulcer (i.e. stomach or duodenal ulcer), or bleeding (two or more distinct episodes of proven ulceration or bleeding); - if you regularly drink large quantities of alcohol

- If you have severe heart failure, hepatic failure or renal failure - if you have cerebrovascular or other active bleeding
- If you have blood-formation disturbances
- If you have asthma, urticaria or allergic-type reactions after taking acetylsalicylic acid or other NSAIDs - during the last three months of pregnancy
- If you are under the age of 18 years

## **Warnings and precautions**

Talk to your doctor or pharmacist before taking NURODOL FORTE Tablet.

Anti-inflammatory/pain-killer medicines like Ibuprofen may be associated with a small increased risk of heart attack or stroke, particularly when used at high doses. Do not exceed the recommended dose or duration of treatment.

You should discuss your treatment with your doctor or pharmacist before taking NURODOL FORTE Tablet if you:

- Have heart problems including heart failure, angina (chest pain), or if you have had a heart attack, bypass surgery, peripheral artery disease (poor circulation in the legs or feet due to narrow or blocked arteries), or any kind of stroke (including ‘mini-stroke’ or transient ischaemic attack “TIA”).
- Have high blood pressure, diabetes, high cholesterol, have a family history of heart disease or stroke, or if you are a smoker.

*Tell your doctor or pharmacist if:*

You have liver disease, hepatitis, kidney disease or difficulty urinating; you are a drug user;

You are pregnant or intend to become pregnant; you are breast-feeding or plan to breast-feed; you currently have an infection;

You plan to have surgery;

You have or have had other medical conditions including:

- Heartburn, indigestion, stomach ulcer or any other stomach problems;
- Vomiting blood or bleeding from back passage;
- Severe skin reactions such as exfoliative dermatitis, toxic epidermal necrolysis and stevens-Johnson syndrome;
- Asthma;
- Vision problems;
- Tendency to bleed or other blood problems;

- Bowel or intestinal problems such as ulcerative colitis or Crohn's disease;
- Swelling of ankles or feet;
- Diarrhoea;
- Inherited genetic or acquired disorder of certain enzymes that manifest with either neurological complications or skin problems or occasionally both i.e. porphyria;
- Smallpox;
- Autoimmune disease such as lupus erythematosus or other connective tissue disorders.

**In order to avoid the risk of overdose,**

Check that other medicines do not contain paracetamol,

Observe the maximum recommended doses (see section 3).

Do not drink alcoholic beverages when taking this medication. Combining alcohol with NURODOL FORTE Tablet may lead to liver damage.

The product belongs to a group of medicines (NSAIDs) which may impair the fertility in women. This effect is reversible on stopping the medicine.

The prolonged use of analgesics can result in headache which must not be treated by increasing the dose of the medicine.

Taking this medicine may interfere with the results from the urine analysis test for 5-hydroxyindoleacetic acid (5HIAA), causing false-positive results. To avoid false results do not take this medicine or other paracetamol containing products for several hours before or during the collection of the urine specimen.

**Children and adolescents**

This product is contraindicated in children under 12 years.

**Other medicines and NURODOL FORTE Tablet**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

NURODOL FORTE Tablet may affect or be affected by some other medicines. For example:

Medicines that are anti-coagulants (i.e. thin blood/prevent clotting e.g. aspirin/acetylsalicylic acid, warfarin, ticlopidine)

Medicines that reduce high blood pressure (ACE-inhibitors such as captopril, beta-blockers such as atenolol medicines, angiotensin-II receptor antagonists such as losartan)

Medicines to treat epilepsy or fits

Chloramphenicol, an antibiotic used to treat ear and eye infections probenecid, a medicine used to treat gout

Zidovudine, a medicine used to treat HIV (the virus that causes acquired immunodeficiency disease) medicines used to treat tuberculosis such as isoniazid

Salicylates or other NSAID medicines diuretics, also called fluid tablet/capsule

Lithium, a medicine used to treat some types of depression

Methotrexate, a medicine used to treat arthritis and some types of cancer corticosteroids, such as prednisone, cortisone

Metoclopramide, propantheline, antidepressants with anticholinergic properties, and narcotic analgesics cholestyramine, a medicine used to reduce raised serum lipid levels

Tacrolimus or ciclosporin, immunosuppressive drugs used after organ transplant sulphonylureas, a medicine used to treat diabetes

Some antibiotics (such as quinolone antibiotics or co-trimoxazole) cardiac glycosides, medicines to strengthen the heart.

Some other medicines may also affect or be affected by the treatment of NURODOL FORTE Tablet. You should therefore always seek the advice of your doctor or pharmacist before you use NURODOL FORTE Tablet with other medicines.

Your doctor and pharmacist will have more information on these and other medicines to be careful with or avoid while taking this medicine.

### **NURODOL FORTE Tablet with food and drink**

The tablet may be taken either before or after a meal.

### **Pregnancy, breast-feeding and fertility**

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

Do not take this medicine during the last 3 months of your pregnancy. Take special care when taking this medicine if you are in the first 6 months of pregnancy.

You should use the lowest possible dose that reduces your pain and use it for the shortest time possible. Contact your doctor or midwife if the pain is not reduced or if you need to take the medicine more often. This product may impair female fertility and is not recommended in women attempting to conceive.

## **Driving and using machines**

Be careful driving or operating machines until you know how NURODOL FORTE Tablet affect you.

### **3. How to take NURODOL FORTE Tablet?**

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

**Adults & Children over 12 years:** 2 to 3 tablets total daily dose. If gastrointestinal complaints occur, administer Nurodol Forte tablet with meal.

You should avoid drinking too much coffee, tea or fizzy drinks when taking this medicine as it contains Caffeine.

### **If you take more NURODOL FORTE Tablet than you should**

Talk to a doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you have taken more NURODOL FORTE Tablet than you should, or if children have taken this medicine by accident always contact a doctor or nearest hospital to get an opinion of the risk and advice on action to be taken.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), headache, ringing in the ears, confusion and shaky eye movement. At high doses, drowsiness, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), weakness and dizziness, blood in urine, cold body feeling, and breathing problems have been reported.

### **If you forget to take NURODOL FORTE Tablet**

If it is almost time for your next dose, skip the missed dose and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, and then go back to taking your tablet as you would normally.

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

If you are not sure whether to skip the dose, talk to your doctor or pharmacist.

#### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most frequent type of adverse reaction occurring with this preparation due to presence of Ibuprofen is gastrointestinal. Nausea, epigastric pain, heartburn, diarrhea, abdominal distress, nausea, vomiting, indigestion, constipation, abdominal cramps or Pain, fullness of GI tract (bloating and flatulence) Dizziness, headache, nervousness, rash (including maculopapular type), pruritus edema, fluid retention are common adverse effects. Due to presence of Paracetamol, in rare cases hypersensitivity reactions, predominantly skin allergy (itching and rash), may appear. Long-term treatment with high doses may cause a toxic hepatitis with following initial symptoms: nausea, vomiting, sweating and discomfort. Occasionally a gastrointestinal discomfort may be seen. Caffeine occasionally causes marked cerebral congestion, insomnia and embarrassment of respiration.

If any side effects become serious or if you notice any side effects that are not listed in this leaflet, please tell your doctor or pharmacist.

#### **5. How to store NURODOL FORTE Tablet?**

- Keep NURODOL FORTE Tablet and all the medicines out of reach and sight of children.
- Store NURODOL FORTE Tablet below 30°C, protected from sunlight.
- Throw away NURODOL FORTE Tablet that is no longer needed or expired (out of date).
- Keep NURODOL FORTE Tablet in the container that it came in and keep the container tightly closed.
- Do not use NURODOL FORTE Tablet if the original seal over the container opening is broken or missing.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

#### **6. Further information**

##### **What NURODOL FORTE Tablet contains:**

##### **Active substance:**

Each uncoated tablet contains: Caffeine 30 mg, Ibuprofen 400 mg and Paracetamol 500 mg.

**Other ingredients:**

Microcrystalline Cellulose, Maize Starch, Povidone K-30, Methyl Paraben, Propyl Paraben, Tartrazine Supra Colour, Colloidal Anhydrous Silica, Croscarmellose Sodium, Purified Talc, Polacrillin Potassium, Sodium Starch Glycolate.

**What NURODOL FORTE Tablet looks like and contents of the pack:**

A light yellow coloured, capsule shaped, biconvex, uncoated tablet having break line on one side supplied in carton of 10 x 1 x 10 Tablets.

**Supplier and Manufacturer**

**CENTURION LABORATORIES PVT. LTD.**

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**Date of publication or revision**

Feb 2020