

Package Leaflet: Information for the Patient

HABIDIP FORTE TABLET

(Paracetamol, Diclofenac sodium and Chlorzoxazone Tablets)

(Invented) Name Strength Pharmaceutical Form: HABIDIP FORTE TABLET

(Paracetamol, Diclofenac sodium and Chlorzoxazone Tablets)

COMPOSITION:

Each uncoated tablet contains:

Paracetamol BP.....500 mg

Diclofenac sodium BP50 mg

Chlorzoxazone USP250 mg

Colour: Sunset Yellow (In House)

Excipients: (Paracetamol BP, Diclofenac Sodium BP, Chlorzoxazone USP, Microcrystalline Cellulose BP, Starch Maize BP, Methyl Paraben BP, Propyl Paraben BP, P.V.P.K 30 BP, Sodium Starch Glycolate BP, Colloidal Silicon dioxide BP, Magnesium Stearate BP, Talcum Powder BP, Colour Sunset Yellow IHs, Sodium Lauryl Sulphate BP, and Cross Povidone BP)

Read all of this leaflet carefully before you start using this medicine because it contains.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your Health care provider, Pharmacist, Nurse.
- 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, Pharmacist, Nurse.

In this leaflet:

1. What HABIDIP FORTE TABLET is and what it is used for
2. Before you take or use HABIDIP FORTE TABLET
3. How to take or use HABIDIP FORTE TABLET
4. Possible side effects
5. How to store HABIDIP FORTE TABLET
6. Further information

1. What HABIDIP FORTE TABLET is and what it is used for

HABIDIP FORTE TABLET is combination of Paracetamol, Diclofenac sodium & Chlorzoxazone. Paracetamol, Diclofenac sodium & Chlorzoxazone Tablet is a medicine that is used for the treatment of Back pain, Sprains and strains, Febrility, Headache, Cold, Fever, Arthralgia and other conditions.

What HABIDIP FORTE TABLET is used for

HABIDIP FORTE TABLET are used in the treatment of inflammatory and degenerative forms of rheumatism; rheumatoid arthritis, ankylosing spondylitis, osteoarthritis and spondylarthritis, Painful post - traumatic and post-operative inflammation and swelling. Toothache, pain after dental procedures/tooth extraction, pain after vaccination and the discomfort from colds, Influenza and sore throats.

2. Before you take or use HABIDIP FORTE TABLET

Do not use HABIDIP FORTE TABLET

- If you are allergic or hypersensitive to any of the active substance or any other ingredients used in the formulation, check with your Healthcare provider, Pharmacist or Nurse if you think this applies to you.

Warnings and precautions:

Talk to your doctor, nurse or pharmacist before you are given this Habidip Forte Tablet:

HABIDIP FORTE TABLET should be given with care to patients with impaired kidney or liver function. Large doses should be avoided in patients with hepatic impairment. Do not exceed recommended dose it should be given with care to patients with alcohol dependence.

Pregnancy & Lactation:

The use of HABIDIP FORTE TABLET in pregnant women has not been studied. Therefore, it should not be used during the first two trimesters of pregnancy unless the potential benefit to the mother out weights the risk to the foetus. As with other NSAIDs, use of Diclofenac during third trimester of pregnancy is contraindicated owing to the possibility of the uterine inertia and / or premature closure of the ductus arteriosus.

HABIDIP FORTE TABLET passes into the breast milk in small amounts. Therefore it should not be administered during breast feeding in order to avoid undesirable effects in the infant.

Taking or Using other medicines:

Please tell your health care provider if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

HABIDIP FORTE TABLET may interact with oral anticoagulants, corticosteroids and other non-steroidal anti-inflammatory drugs, Aspirin, Methotrexate, Lithium, digoxin, Anti-Hypertensive drugs, Diuretics and Anti – Platelet drugs.

3. How to Take or Use HABIDIP FORTE TABLET

Always take or use HABIDIP FORTE TABLET 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 follows: One tablet daily or as directed by the physician.

If you take or use more HABIDIP FORTE TABLET than you should, If you forget to take or use HABIDIP FORTE TABLET

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

Overdosage: Toxic symptoms include vomiting, abdominal pain, hypotension and sweating. The most serious adverse effect of acute overdosage of HABIDIP FORTE TABLET is a dose-dependent, potentiality fatal hepatic necrosis, vomiting, gastrointestinal hemorrhage, diarrhoea, dizziness, tinnitus or convulsions. In the event of significant poisoning, acute renal failure and liver damage are possible.

Treatment: In cases of overdose, methods of reducing the absorption of ingested drug are important. Gastric lavage is essential even if several hours have elapsed. Supportive measures and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastrointestinal disorder, and respiratory depression.

If you stop taking or using HABIDIP FORTE TABLET

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, **HABIDIP FORTE TABLET** can cause side effects, although not everybody gets them.

Cardiac Disorders:

Very Rare: Palpitations, chest pain, cardiac failure, myocardial infarction.

Vascular Disorders:

Very Rare: vasculitis.

Respiratory, thoracic and mediastinal disorders:

Rare: Asthma (including dyspnea)

Very Rare: Pneumonitis

Gastrointestinal Disorders:

Common: Nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia.

Rare: Gastritis, gastrointestinal haemorrhage, haematemesis, diarrhoea haemorrhagic, malaena, gastrointestinal ulcer (with or without bleeding or perforation).

Very Rare: Colitis (including haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, oesophageal disorder, diaphragm – like intestinal strictures, pancreatitis.

Hepatobiliary disorders:

Common: Transaminases increased.

Rare: Hepatitis, jaundice, liver disorder.

Very Rare: Hepatic necrosis, Hepatic failure.

Skin and subcutaneous tissue disorders:

Common: Rash.

Rare: Urticaria.

Very Rare: Eczema, Erythema, Erythema multiforme, Stevens – Johnson purpura, allergic purpura, pruritus.

Renal and Urinary disorders:

Very Rare: Acute renal failure, haematuria. Proteinuria, nephrotic syndrome, interstitial nephritis, renal papillary necrosis.

5. How to store HABIDIP FORTE TABLET

Do not store above 30 °C. Protect from Light.

Keep out of the reach and sight of children.

Do not use HABIDIP FORTE TABLET after the expiry date which is stated on the label or carton or bottle.

Do not use HABIDIP FORTE TABLET if you notice any deterioration or visible signs in the formulation.

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 MALAHARP TABLET contains:

The active pharmaceutical ingredients are Paracetamol BP, Diclofenac Sodium BP, Chlorzoxazone USP.

- The other ingredients are Microcrystalline Cellulose BP, Starch Maize BP, Methyl Paraben BP, Propyl Paraben BP, P.V.P.K 30 BP, Sodium Starch Glycolate BP, Colloidal Silicon dioxide BP, Magnesium Stearate BP, Talcum Powder BP, Colour Sunset Yellow IHs, Sodium Lauryl Sulphate BP, and Cross Povidone BP)

What HABIDIP FORTE TABLET looks like and contents of the pack:

HABIDIP FORTE TABLET is Orange coloured, capsule shaped uncoated tablets with a break line on one side and an embossing of HABIDIP FORTE on other side of each tablet.

Alu-PVC Blister Pack of 10 tablets in a carton with pack inserts.

Manufacturer:

ASTAMED HEALTHCARE (I) PVT. LTD.

Plot No.: 2, 3, Phase-II, Genesis Ind.

Complex, Kolgaon, Palghar,

Thane - 401404, Maharashtra, India.

This leaflet was last revised in 14/2020