

Patient Information Leaflet : user information

ALFENAC[®]-P tablet

Aceclofenac and Paracetamol

Please read this leaflet completely before taking this medicine as it contains important information:

- Keep this leaflet, as you may need to read it again.
- Ask your doctor or pharmacist if you have further questions.
- This medicine was prescribed for you only. Do not give it to others. It may harm them, even if their symptoms are identical to yours.
- If you have any side effects, including some that are not listed in this leaflet, inform your doctor or pharmacist.

What is in this leaflet:

1. What is Alfenac[®]-P and when to use it
2. What you need to know before taking Alfenac[®]-P
3. How to take Alfenac[®]-P
4. Possible side effects
5. How to store Alfenac[®]-P
6. Pack content and other information

1. What is Alfenac[®]-P and when to use it

ALFENAC[®]-P is indicated for the treatment of acute painful inflammatory conditions with or without associated fever.

2. What you need to know before taking Alfenac[®]-P

Do not take ALFENAC[®]-P

- If you have hypersensitivity to Paracetamol or any component of the tablet (see section 6);
- If you are the patients who take substances with a similar action (like aspirin or other NSAIDs), precipitate attacks of asthma, bronchospasm, acute rhinitis or urticarial or patients are hypersensitive to these drugs.
- If you suffer from severe heart failure;
- If you suffer from severely impaired hepatic or renal organ function;
- If you are in the last three months of pregnancy.

Precautions with ALFENAC[®]-P

- Inform your doctor or pharmacist before taking **ALFENAC[®]-P** if
 - you have symptoms indicative of gastrointestinal disorders, with a history suggestive of gastrointestinal ulceration, with ulcerative colitis or with Crohn's disease, bleeding diathesis or haematological abnormalities.
 - If you are pregnant or planning to become pregnant or breastfeeding.
- Do not take **ALFENAC[®]-P** for more than the recommended doses or without the advice of a doctor
- May cause blurred vision, dizziness, drowsiness and therefore may seriously influence the ability to drive and operate machinery.
- Do not take with any other NSAIDs and corticosteroids that may cause some other serious side effects.

Concomitant use of ALFENAC®-P with other medicines

Inform your doctor or pharmacist before taking **ALFENAC®-P** if you are taking any of the following medicines which may have drug interactions associated with Aceclofenac and Paracetamol

Aceclofenac

- Other analgesics including cyclooxygenase-2 selective inhibitors : Avoid concomitant use of two or more NSAIDs (including aspirin)
- Anti-hypertensives : NSAIDs may reduce the effect of anti-hypertensives.
- Diuretics: Diuretics can increase the risk of nephrotoxicity of NSAIDs.
- Cardiac glycosides : NSAIDs may exacerbate cardiac failure, reduce GFR (glomerular filtration rate) and increase plasma glycoside levels.
- Lithium and digoxin: Several NSAID drugs inhibit the renal clearance of lithium, resulting in increased serum concentrations of both.
- Methotrexate: Decreased elimination of methotrexate. When combination therapy has to be used, the renal function should be monitored.
- Mifepristone: NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effect of mifepristone.
- Corticosteroids: Increased risk of gastrointestinal ulceration or bleeding.
- Anti-coagulants: NSAIDs may enhance the effects of anti-coagulants, such as warfarin.
- Quinolone antibiotics: Patients taking NSAIDs and quinolones may have an increased risk of developing convulsions.
- Anti-platelet agents and selective serotonin reuptake inhibitors (SSRIs): Increased risk of gastrointestinal bleeding.
- Cyclosporine, Tacrolimus: During combination therapy, carefully monitor renal function.
- Zidovudine: Increased risk of haematological toxicity when NSAIDs are given with zidovudine.
- Anti-diabetic agents: With Aceclofenac, consideration should be given to adjustment of the dosage of hypoglycaemic agents.

Paracetamol

- Cholestyramine: The speed of absorption of paracetamol is reduced by cholestyramine.
- Metoclopramide and Domperidone: The absorption of paracetamol is increased by metoclopramide and domperidone.
- Warfarin: The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.
- Chloramphenicol: Increased plasma concentration of chloramphenicol.

Pregnancy and breast-feeding

NSAIDs like Aceclofenac should not be used during pregnancy or labour unless the potential benefit to the patient outweighs the potential risk to the foetus.

In limited studies so far available, NSAIDs like aceclofenac can appear in breast milk in very low concentrations.

ALFENAC®-P should, if possible, be avoided when breastfeeding.

Driving and using machines

Undesirable effects such as dizziness, vertigo, drowsiness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

3. How to take ALFENAC®-P

Always respect the dosage recommended by your doctor. In case of doubt, consult your doctor or pharmacist.

Dosage and administration

The recommended dose of **Alfenac-P** : 1 tablet twice daily.

Generally, no dose adjustment is necessary in elderly patients and those with mild renal impairment.

Do not give to children aged under 6 years.

Oral administration.

To be taken preferably with or after food.

Keep out of reach of children.

If you have taken more ALFENAC®-P than prescribed

Contact your doctor immediately.

If you have any other questions pertaining to the use of this medicine, ask your doctor or pharmacist for more information.

If forget to take ALFENAC®-P

Take your dose as soon as possible. If it is almost time for the next dose, just skip that dose and take the next one as per the schedule. If in doubt, please contact your doctor or pharmacist. Do not take a double dose to make up for a forgotten dose.

If you stop taking ALFENAC®-P

You should always take the complete treatment as described by the doctor. Never stop the treatment on your own.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Most of the adverse events are minor and reversible with treatment discontinuation. The majority of side effects are related to gastrointestinal system (dyspepsia, abdominal pain, nausea and diarrhoea), most frequent being dyspepsia, abdominal pain and rise in hepatic enzymes. Other rare side-effects include dizziness, constipation, vomiting, ulcerative stomatitis, rash, dermatitis, headache, fatigue, allergic reactions, anaemia, granulocytopenia, thrombocytopenia, neutropenia, oedema, palpitation, leg cramps, flushing, purpura, paraesthesia, tremors, gastrointestinal bleeding, gastrointestinal ulceration, pancreatitis, interstitial nephritis, depression, abnormal dreaming, somnolence, insomnia, vasculitis, hypoglycaemia, rise in blood urea, serum creatinine and serum potassium. As with other NSAIDs, severe muco-cutaneous skin reactions may occur.

5. How to store ALFENAC®-P

Store in a cool, dry place. Protect from light.

Keep out of reach and sight of children.

Do not use after the expiry date.

6. Pack content and other information

What is the composition of ALFENAC®-P

Each film coated tablet contains :

Paracetamol 500 mg

Aceclofenac 100 mg

Excipients q.s.

Excipients: Maize Starch, Gelatin, Methyl Paraben, Propyl Paraben, Purified Talc, Magnesium Stearate, Sodium Starch Glycolate, Aerosil, Wincoat WT-01076 Orange, Isopropyl Alcohol, Dichloromethane.

Aspect of ALFENAC®-P and pack content

ALFENAC®-P is packed in Blister (Aluminium/PVC foil) of 10 tablets in a carton along with package insert.

Manufacturer

BLISS GVS PHARMA LTD.

102, Hyde Park,

Saki Vihar Road, Andheri (East)

Mumbai – 400 072, INDIA

Tel. : (+91) (22) 42160000 / 28505387

Fax : (+91) (22) 28563930

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