PACKAGE LEAFLET

ZERO-P 100 mg Film Coated Tablets
Taken by mouth.

Active substance: Each film coated tablet contains 100 mg flurbiprofen
Excipients: Lactose monohydrate (produced from cow milk), magnesium stearate, microcrystalline cellulose pH 101, microcrystalline cellulose pH 102, colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl methylcellulose, Opadry II blue 32K20439 [lactose monohydrate (produced from bovine milk), hydroxypropyl methylcellulose, titanium dioxide, triacetin, FD&C blue #2 indigo carmine aluminum lake, yellow iron oxide].

Read all of this PACKAGE LEAFLET carefully before you start taking this medicine because it contains important information for you.
- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you. Do not pass it on to others.*
- *While you are taking this medicine, tell your doctor that you use this medicine, when you go to doctor or hospital.*
- *Exactly comply with what is written in this leaflet. Do not take either a **higher** or **lower** dose other than recommended to you.*

In this leaflet:

1. WHAT ZERO-P IS AND WHAT IT IS USED FOR

ZERO-P is a blue colored film coated tablet. Each film coated tablet contains 100 mg flurbiprofen. It is presented in blister packs of 15 or 30 tablets.

ZERO-P belongs to the medicine group known as non-steroidal anti-inflammatory drugs (NSAIDs), which are used to treat or relieve many types of pain.

ZERO-P is used for the treatment of
- A long lasting (chronic) disease causing pain, swelling and deformation in the joints (rheumatoid arthritis)
- A degenerative joint disease and usually known as calcification (osteoarthritis)
- A long-term (chronic) disease causing pain, swelling and deformation in the joints (ankylosing spondylitis)
- Acute musculoskeletal pain
- Acute gout arthritis
- Menstrual pain (dysmenorrhea)

2. WHAT YOU NEED TO KNOW BEFORE YOU USE ZERO-P

Do not use ZERO-P, if

- You are hypersensitive to any of the ingredients of ZERO-P,
- You have ever had asthma, urticaria or any other allergic-type reactions after taking aspirin or any other non-steroidal anti-inflammatory drugs,
- You have pain soon just before or after having coronary artery bypass surgery,
- You have severe liver failure,
- You have severe kidney failure,
- You have severe heart failure,
- You currently have or have ever had a peptic ulcer,
- You have a history of bleeding or perforation in your stomach or bowels due to NSAID use,
- You have bleeding in your stomach or bowels, brain bleeding or any other bleeding,
- You are in the late stage of pregnancy (from the 6th month).

Take special care with ZERO-P, if

- You have a disease of heart or blood vessels (cardiovascular). In this case, your doctor will give you the lowest effective dose. Even if you have not experienced cardiovascular symptoms before, you and your doctor should be alert to the occurrence of such events, your doctor will inform you about what to do in such a case.
- You have a high blood pressure (hypertension). Your doctor will closely monitor your blood pressure during the initiation of ZERO-P treatment and throughout the course of therapy.
- You have fluid retention and edema,
- You have a disease characterized by respiratory failure, edema, enlarged liver due to pre-existing heart failure,
- You have inflammation, bleeding and perforation in your stomach or bowels,
- You are elderly, have a disease of heart and blood vessels, using concurrently aspirin or you have ulceration, bleeding in your stomach-bowel tract, or you have or had an inflammatory disease like stomach-bowel disease,
- You have a pre-existing asthma,
- You have anemia or have disorders with blood clotting,
- You are planning to become pregnant,
- You have systematic lupus erythematosus (SLE) or other connective tissue disorders,
- You have heart failure, liver cirrhosis and advanced kidney disease. If you have kidney dysfunction, your doctor will give you a lower dose of flurbiprofen.
- Skin rash, mucosal lesions or any other sign of hypersensitivity develop. In such a case, your doctor will stop your treatment.
- You have complaints with your eyes. In such a case, consult an ophthalmologist.

Do not use concomitantly with other similar pain killers.

Serious skin reactions, including exfoliative dermatitis, inflammation characterized by swelling, redness and blood accumulation in the skin and around the eyes (Stevens-Johnson syndrome) and toxic epidermal necrolysis, some of which can be fatal, may occur very rarely in association with flurbiprofen. You are most at risk for these events early in your treatment, with the majority of cases onset occurring within the first month of treatment.

If these warnings apply to you, even at any time in the past, please consult your doctor.

Pregnancy
Consult your doctor or pharmacist before taking this medicine.

ZERO-P should not be used during pregnancy unless it is necessary.
ZERO-P should not be used in late stage of pregnancy (after 6th month). Its use is not recommended during pregnancy unless advised by your doctor.

If you realize you are pregnant during your treatment, immediately consult your doctor or pharmacist.

Breast-feeding
Do not breastfeed while taking this medicine. Because it passes into your milk, it can harm your baby.

Consult your doctor or pharmacist before taking this medicine.

Driving and using machines
ZERO-P may cause side effects such as dizziness, restlessness, tremor and drowsiness. If you experience these side effects, do not drive or operate machinery.

Important information about some of the ingredients of ZERO-P
This medicinal product contains 104.8 mg lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Concomitant use with other medicines
Following medicines may interact with ZERO-P. Tell your doctor if you are using any of these:
- ACE inhibitors or angiotensin II antagonists (used to treat high blood pressure)
- Aspirin (pain killer, blood-thinning medicine)
- Anti-coagulants (used to prevent blood clots)
- Beta-blockers (used to treat high blood pressure)
- Diuretics (water tablets)
- Corticosteroids (used for treatment of allergy and hormone replacement)
- Zidovudine, ticlopidine and tacrolimus and cyclosporine (used in organ transplant)
- Lithium and selective serotonin reuptake inhibitors (psychiatric medicines)
- Methotrexate (used to treat cancers)
- Digoxin (used for heart failure)
- Oral hypoglycemic agents (medicines which are used for treatment of diabetes)
- Antibiotics called quinolones (used to treat some infections)
- Antiplatelet agents (used for treatment of thrombosis)
- Cimetidine, ranitidine, antacids (used for some stomach disorders)
- Any other pain medicine belonging to the group of non-steroidal anti-inflammatory drugs (NSAIDs)

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

3. HOW TO TAKE ZERO-P

Instructions for proper use and dose/administration frequency:
The recommended daily dose is 200 mg in divided doses.
This will be two tablets per day. Depending on the severity of the symptoms of your disease, the dose can be increased up to 300 mg per day.

For relief of the symptoms of rheumatoid arthritis (inflammation of the joints and sometimes surroundings tissues) and osteoarthritis (a non-inflammatory joint disease, which is seen mostly in older persons, in which the joints become damaged, painful and stiff), the recommended ZERO-P dose is 200 mg to 300 mg per day, divided for administration two or three times a day.

For menstrual pain, you should initially take 100 mg, i.e. 1 tablet. Following this, you can take 100 mg every 4-6 hours.

If you will take more than one ZERO-P daily, single dose should not exceed 100 mg.

Route and method of administration:
Take the tablets after meals with adequate liquid (a glass of water).

Different age groups
Use in children
It should not be used in children, as its efficiency and safety have not been established.

Use in elderly
As elderly patients are more at risk of severe side effects, the lowest dose should be used.

Use in special conditions
Kidney/liver impairment
Long-term therapy should not be used in patients, especially those with renal or hepatic impairment, as it may cause kidney damage.

It should not be used by patients with severe kidney impairment. It should be used with caution if there is a sign of kidney impairment.

Please talk to your doctor or pharmacist if you think that effect of ZERO-P is too strong or too weak.

If you use more ZERO-P than you should
Please talk to your doctor or pharmacist if you have taken more ZERO-P than you should

If you have taken more ZERO-P than you should; generally, drowsiness, nausea, vomiting and abdominal pain occur. In such cases, appropriate management should be applied in emergency department. The use of oral activated charcoal is useful within 4 hours of ZERO-P ingestion. Your doctor or pharmacist will help you for this situation.

If you forget to use ZERO-P
If you forget to take your tablet on time, take it when you remember. If the time to take your next tablet is approaching, continue your normal treatment without taking an additional dose.

Do not take a double dose to make up for a forgotten dose, this may be too much for you.

Tell your doctor if you miss more than one dose.

4. POSSIBLE SIDE EFFECTS

Like all medicines, side effects may occur in people with sensitivity to ingredients of ZERO-P.

If you notice any of the followings, stop taking ZERO-P and contact your doctor IMMEDIATELY or go to the nearest hospital emergency department:

Very common : may occur in at least one 1 in 10 patients
Common : may occur in less than one in 10 patients, but more than one in 100 patients.
Uncommon : may occur in less than one in 100 patients, but more than one in 1000 patients.
Rare : may occur in less than one in 1000 patients, but more than one in 10,000 patients.
Very rare : may occur in less than one in 10,000 patients.
Not known : cannot be estimated from the available data.

Common:
- Nasal inflammation (rhinitis)
- Urinary tract infection
- Body weight changes
- Anxiety
- Depression
- Sleeplessness
- Nervousness
- Forgetfulness (amnesia)
- Dizziness
- Headache
- Reflexes increased
- Sleepiness (somnolence)
- Tremor
- Changes in vision
- Ringing in the ears (tinnitus)
- Abdominal pain
- Constipation
- Diarrhea
- Indigestion (dyspepsia)
- Flatulence
- Bleeding in the stomach and intestine (gastrointestinal bleeding)
- Nausea
- Vomiting
- Skin rash
- Weakness (asthenia)
- Fluid retention in the body, such as swelling in the ankles (edema)
- Malaise, feeling sick
- Elevated liver enzymes

Uncommon:
- Anemia (iron deficiency anemia)
- Increased level of uric acid in the blood (hyperuricemia)
- Liquid retention
- Blurring of consciousness (confusion)
- Muscle coordination disorder (ataxia)
- Decrease in blood flow to the brain (cerebrovascular ischemia)
- Numbness (paresthesia)
- Smell disorder (parosmia)
- Inflammation of the eye (conjunctivitis)
- Heart failure
- Vessel diseases
- Widening of blood vessels (vasodilatation)
- High blood pressure (hypertension)
- Asthma
- Nose bleeding (epistaxis)
- Bloody diarrhea
- Esophageal disease
- Inflammation of stomach (gastritis)
- Vomiting blood (hematemesis)
- Wound in stomach or small intestine (peptic ulcer)
- Mouth inflammation (stomatitis)
- Wound in gastrointestinal tract (gastrointestinal ulcer)
- Inflammation of liver (hepatitis)
- A type allergic reaction (angioedema)
- Eczema
- Itching
- Hives (urticarial)
- Twitching
- Blood in urine (hematuria)
- Kidney failure
- Chills
- Fever
- Alteration in some test results (decrease in levels of hemoglobin and hematocrit)

Rare:
- Serious allergic reactions (anaphylactic reactions)
- Heart attack (myocardial infarction)
- Perforation in the stomach-bowel tract (gastrointestinal perforation)
- Inflammation of the kidney (glomerulonephritis)
- Tissue death of the kidney (renal papillary necrosis)
- Functional disorder of nephron which is the smallest structural unit of the kidney (nephrotic syndrome)

Not known:
- Inhibition of blood clotting (inhibition of platelet aggregation)

The following side effects are mainly derived from worldwide post-marketing experience and literature. Precise frequency estimation is often not possible.

- Anemia (aplastic anemia, hemolytic anemia)
- Decrease of platelet in blood (thrombocytopenia)
- Allergic shock (anaphylaxis)
- Large bowel inflammation (colitis)
- Exacerbation of inflammatory bowel disease
- Small bowel inflammation with loss of blood and protein
- Jaundice
- A type of skin inflammation (exfoliative dermatitis)
- Sensitivity to light (photosensitivity)
- Skin diseases (Stevens-Johnson syndrome, toxic epidermal necrosis)
- Inflammation of brain membrane (aseptic meningitis)
- Inflammation of the kidney accompanied by vomiting (interstitial nephritis)

If you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects
If you get any side effects including any possible side effects not listed in this leaflet, talk to your doctor, pharmacist or nurse. You can also report side effects directly via the national reporting system. By reporting side effects, you can help provide more information on the safety of this medication.

5. HOW TO STORE ZERO-P

Keep ZERO-P out of the reach and sight of children and in its original package.
Store at room temperature below 25°C.

Use it in accordance with the expiry date.
Do not use ZERO-P after the expiry date, which is stated on the pack.

Do not use ZERO-P if you notice any damage on the product and/or its package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

Marketing Authorization Holder
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