Zorvolex®

18 mg and 35 mg capsules
Diclofenac

Read all of this leaflet carefully before you start taking this medicine.
- 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. It may harm them even if their symptoms are the same as yours.
  If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. WHAT ZORVOLEX IS AND WHAT IT IS USED FOR

Zorvolex 18 mg and 35 mg capsules belong to a group of medicines called non-steroidal anti-inflammatory drugs (NSAIDs), which are used to reduce pain and inflammation in different conditions.
Zorvolex contains diclofenac submicron particles of approximately 200 – 800 nanometers in size which increases the total surface area. Increased surface area leads to faster dissolution which allows for the dose to be lowered without delaying the rate of absorption while maintaining the therapeutic efficacy of the drug.
Zorvolex is indicated for treatment of mild to moderate acute pain and osteoarthritis pain.

2. BEFORE YOU TAKE ZORVOLEX

Do not take Zorvolex if:
- you are allergic to diclofenac or any of the other ingredients of this medicine (listed in section 6)
- you have a peptic ulcer (ulcer in your stomach or duodenum) or bleeding in your stomach, or have had two or more episodes of peptic ulcers, stomach bleeding or perforation
- you have previously had a reaction (asthma, hives or a cold) caused by an allergy to salicylates (e.g. aspirin) or other non-steroidal pain killers
- you suffer from severe kidney, heart or liver failure
  you are pregnant, and in the last three months (last trimester) of pregnancy

Take special care with Zorvolex
Talk to your doctor before taking Zorvolex, if you:
- have a history of gastrointestinal disease e.g. ulcerative colitis or Crohn's disease
  have reduced heart, kidney, or liver function
  suffer from hypertension
- suffer from any blood clotting disorder
  have or have had asthma
  suffer from liver porphyria (disorder of the red blood pigment)
  have had or need to have surgery
- are elderly (over 65)
  if you are being treated with diuretic (water tablets) or COX-2 inhibitors such as celecoxib

Medicines such as diclofenac may be associated with a small increased risk of heart attack (myocardial infarction) or stroke. Any risk is more likely with high doses and prolonged treatment. Do not exceed the recommended dose or duration of treatment.

If you have heart problems, have had a previous stroke or think that you might be at risk of these conditions (for example if you have high blood pressure, diabetes or high cholesterol or are a smoker) you should discuss your treatment with your doctor or pharmacist.

Whilst you are taking these capsules, your doctor may want to give you a check-up from time to time.

If you have a history of stomach problems when you are taking NSAIDs, particularly if you are elderly, you must tell your doctor straight away if you notice any unusual symptom.

Taking other medicines, herbal or dietary supplements
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.
Especially:
- anticoagulants (e.g. warfarin); these may increase the risk of bleeding
- diuretics (water tablets); the effect of these may be decreased
- lithium (medicine to treat depression); the blood levels of these medicines may be increased if taken with Zorvolex
- cytotoxic medicines (e.g. methotrexate to treat cancers); the blood levels of these medicines may be increased if taken with Zorvolex
  ciclosporin; this may harm kidney function
  other NSAIDs (e.g. aspirin); these may increase the risk of side effects
- medicines to treat high blood pressure (ACE-inhibitors, beta blockers): the blood pressure lowering effect may be reduced.

Taking Zorvolex with food and drink
Always take Zorvolex capsules exactly as your doctor has told you. If you are unsure, check with your doctor or pharmacist. Zorvolex must not be taken long-term, blood tests should be carried out if taken for more than a few days.
To minimize side-effects, you should take the lowest effective dose for the shortest time necessary to relieve your symptoms. Taking Zorvolex with food may cause a reduction in effectiveness compared to taking Zorvolex on an empty stomach.

Pregnancy and breastfeeding
Pregnancy
It is not recommended that you take Zorvolex during the first 30 weeks of pregnancy. However, your doctor may prescribe Zorvolex for you during the first six months of pregnancy if he/she feels the benefit to you outweighs the risk. You must not however take Zorvolex past 30 weeks of pregnancy as damage to the fetus and reduced labour may occur.

Breastfeeding
You should only use Zorvolex whilst breastfeeding if advised by your doctor.
Ask your doctor or pharmacist for advice before taking any medicine.

3. HOW TO TAKE ZORVOLEX

Always take Zorvolex capsules exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
Adults:
The dosage for acute pain is 18 mg or 35 mg orally three times a day.
The dosage for osteoarthritis pain is 35 mg orally three times a day.
To minimize side-effects, you should take the lowest effective dose for the shortest time necessary to relieve your symptoms. Zorvolex capsules are not interchangeable with other formulations of oral diclofenac even if the milligram strength is the same.
Children:
The safety and effectiveness of Zorvolex in pediatric patients has not been established.

If you take more Zorvolex than you should
Contact your doctor, emergency room or pharmacist if you have taken more Zorvolex capsules than stated in this leaflet or more than what your doctor has prescribed (and you feel unwell).

If you forget to take Zorvolex
Do not take a double dose to make up for forgotten dose. Continue the treatment as advised by your doctor.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Zorvolex can cause side effects, although not everybody gets them.
If you suffer from any of the following at any time during your treatment, **STOP TAKING** the medicine and seek immediate medical help:
  pass blood in your feces (stools / bowel motions)
- pass black tarry stools
  vomit any blood or dark particles that look like coffee ground
  an allergic reaction such as itching, low blood pressure, swelling of the face, lips, tongue, mouth and throat, which may cause shortness of breath or difficulty swallowing
  yellowing of the skin or the whites of your eyes
  stomach pain. indigestion, heartburn, nausea (feeling sick), vomiting (being sick) or other abnormal stomach symptoms

Most common adverse reactions in clinical trials (incidence ≥2% in Zorvolex 18 mg or 35 mg group) include: swelling (edema), nausea, headache, dizziness, vomiting, constipation, severe itching of the skin (pruritus), diarrhea, flatulence, pain in extremity, abdominal pain, sinusitis, increased alanine aminotransferase (ALAT), increased blood creatinine, hypertension, and indigestion (dyspepsia).

Adverse reactions reported for diclofenac and other NSAIDs:
In patients taking other NSAIDs, the most frequently reported adverse reactions occurring in approximately 1%-10% of patients are:
  Gastrointestinal experiences including: abdominal pain, constipation, diarrhea, dyspepsia, flatulence, gross bleeding/perforation, heartburn, nausea, GI ulcers (gastric/duodenal) and vomiting.
- Abnormal renal function, anemia, dizziness, edema, elevated liver enzymes, headache, increased bleeding time, pruritus, rashes and tinnitus.

Additional adverse reactions reported occasionally include:
- Body as a Whole: fever, infection, sepsis
- Cardiovascular System: congestive heart failure, hypertension, tachycardia, syncope
- Digestive System: dry mouth, esophagitis, gastric/peptic ulcers, gastritis, gastrointestinal bleeding, glossitis, hematemesis, hepatitis, jaundice
- Hemic and Lymphatic System: ecchymosis, eosinophilia, leukopenia, melena, purpura, rectal bleeding, stomatitis, thrombocytopenia
- Metabolic and Nutritional: weight changes
  Nervous System: anxiety, asthenia, confusion, depression, dream abnormalities, drowsiness, insomnia, malaise, nervousness, paresthesia, somnolence, tremors, vertigo
- Respiratory System: asthma, dyspnea
  Skin and Appendages: alopecia, photosensitivity, sweating increased
  Special Senses: blurred vision
- Urogenital System: cystitis, dysuria, hematuria, interstitial nephritis, oliguria/polyuria, proteinuria, renal failure.

Other adverse reactions, which occur rarely are:
  Body as a Whole: anaphylactic reactions, appetite changes, death
  Cardiovascular System: arrhythmia, hypotension, myocardial infarction, palpitations, vasculitis
  Digestive System: colitis, eructation, fulminant hepatitis with and without jaundice, liver failure, liver necrosis, pancreatitis
- Hemic and Lymphatic System: agranulocytosis, hemolytic anemia, aplastic anemia, lymphadenopathy, pancytopenia
  Metabolic and Nutritional: hyperglycemia
- Nervous System: convulsions, coma, hallucinations, meningitis
- Respiratory System: respiratory depression, pneumonia
  Skin and Appendages: angioedema, toxic epidermal necrolysis, erythema multiforme, exfoliative dermatitis, Stevens-Johnson syndrome, urticaria
- Special Senses: conjunctivitis, hearing impairment

Medicines such as Zorvolex may be associated with a small increased risk of heart attack ("myocardial infarction") or stroke.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE ZORVOLEX

Keep out of reach and sight of children.
Do not store above 30°C.
Store in the original package in order to protect from moisture.
Do not use Zorvolex after the expiry date which is stated on the carton and blister. The expiry date refers to the last day of that month.
Do not use any Zorvolex pack that is damaged or shows signs of tampering.
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 protect the environment.

6. FURTHER INFORMATION

What Zorvolex contains
- The active substance is Diclofenac 18 mg or 35 mg.
- The other ingredients are: Lactose monohydrate, sodium lauryl sulfate, microcrystalline cellulose, croscarmellose sodium, sodium stearyl fumarate

What Zorvolex looks like and contents of the pack
Zorvolex 18 mg: Capsule size 2 consisting of a blue body with "IP-203" imprinted in white ink and a light green cap with "18 mg" imprinted in white ink.
Zorvolex 35 mg: Capsule size 1 consisting of a blue body with "IP-204" imprinted in white ink and a green cap with "35 mg" imprinted in white ink.

Zorvolex is available in blister packs of 20 capsules.

This is a medicament
- A medicament is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold you the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.

Keep all medicaments out of reach of children.

Council of Arab Health Ministers
Union of Arab pharmacists

Manufactured by
Catalent CTS, LLC, Kansas City, USA

Packaged by
ALGORITHM S.A.L. Zouk Mosbeh, Lebanon.
Under license from Iroko Pharmaceuticals Inc. Tortola, British Virgin Islands

P15793-03
Rev. No. 04/2016