

Package Leaflet: Information for the patient

Polvolt™

Polmacoxib Capsules (2 mg)

Read all of this 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, please 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 signs of illness are the same as yours.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Polvolt™ Capsules is and what it is used for
2. What you need to know before you take Polvolt™ Capsules
3. How to take Polvolt™ Capsules
4. Possible side effects
5. How to store Polvolt™ Capsules
6. Contents of the pack and other information

1. What Polvolt™ Capsules is and what it is used for

Polvolt™ capsules contain Polmacoxib and it belongs to a class of medicines called non-steroidal anti-inflammatory drugs (NSAIDs). All non-steroidal anti-inflammatory painkillers including Polvolt™ capsules. Polmacoxib is a drug that reduces pain and inflammation caused by osteoarthritis by inhibiting the COX-2 enzyme. Pain reduction is the main function.

In addition to reducing pain and inflammation caused by osteoarthritis, drugs belonging to (NSAIDs) may, in rare cases, cause serious side effects such as myocardial infarction or stroke. To minimize the potential risk of adverse reactions, use the lowest effective dose possible. It should be used for the shortest period. Those taking long-term non-steroidal anti-inflammatory drugs and people with heart disease and heart disease may suffer from myocardial infarction or stroke.

Polmacoxib capsules are indicated for the treatment of idiopathic (primary) osteoarthritis of the hip/knee. Osteoarthritis (degenerative) is the most common disease that occurs in joints, where the ends of bones meet. Cartilage surrounds the joints and acts as a cushion. Osteoarthritis is a chronic disease that causes wear and tear and damage to joints and bones. Symptoms of degenerative arthritis include pain, stiffness, and swelling may be felt in the joint area, and as it progresses, physical dysfunction may occur. Symptoms commonly occur in weight-bearing joints like knees, hips and hand joints. Degenerative arthritis occurs with age, and obesity and is more common when there is damage to the joints. Commonly occurs more often in women than men.

2. What you need to know before you take Polvolt™ Capsules

DO NOT take Polvolt™ Capsules if you:

- If you have hypersensitivity reaction or history of hypersensitivity to the components of Polvolt™ Capsules. (listed in section 6)
- If you have an allergic reaction to sulphonamides.
- If you a history of asthma, acute rhinitis, nasal polyps, angioedema, urticaria, or allergic reactions to aspirin or other NSAIDs (including COX-2 inhibitors).
- Patients with high blood pressure that is not well controlled despite taking antihypertensive drugs.
- Patients with edema or fluid retention.
- Patients with hepatic impairment.
- Patients with renal impairment.
- Patients with active peptic ulcer or gastrointestinal bleeding.
- Patients with inflammatory bowel disease such as Crohn's disease or ulcerative colitis.
- Congestive heart failure patients (NYHA II - IV)
- Patients with established ischemic heart disease, peripheral arterial disease, and/or cerebrovascular disease.
- Women who are pregnant or may be pregnant.
- Nursing mothers.
- Treatment of pain occurring before and after coronary artery bypass surgery (CABG).
- Patients with hyperkalaemia (increased potassium levels).
- Patients with blood coagulation disorders or receiving anticoagulants.

Warnings and Precautions

Talk to your doctor or pharmacist before taking Polvolt™ Capsules.

- Patients with bronchial asthma.
- Patients with heart failure or a history of it.
- Patients with high blood pressure or a history of it.
- Patients with a history of edema.
- Patients taking diuretics or ACE inhibitors.
- Patients at risk of hypovolemia.
- Dehydrated patients.
- Elderly people.
- Patients with a history of peptic ulcer or gastrointestinal bleeding.
- People with high risk factors for adverse cardiovascular events (heart attack, stroke, etc.).
- Patients (e.g. high blood pressure, hyperlipidemia, diabetes, smoking, etc.), patients with cardiovascular disease or its history.
- Patients with difficult metabolism due to ketoconazole (CYP3A4).
- Women planning to become pregnant (taking this drug may impair female fertility).
- Diabetics.

Non-steroidal anti-inflammatory drugs can cause ulcers and bleeding in the gastrointestinal tract at any time while taking them. There are potential risks that may cause it.

The risk of ulcers and bleeding in the gastrointestinal tract appears to be higher in people who:

- Those taking “corticosteroids” and “anticoagulants”
- Long-term users of non-steroidal anti-inflammatory drugs
- Smoker
- Heavy and frequent drinkers
- Elderly people

- Unhealthy people

Medicines such as Polvolt™ Capsules 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, 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.

Serious gastrointestinal side effects such as bleeding, ulceration, and perforation can occur at any time with or without warning symptoms in patients treated with NSAIDs. If any sign of gastrointestinal bleeding occurs, Polvolt™ Capsules should be stopped immediately.

Other medicines and Polvolt™ Capsules

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

Tell your doctor if you are taking:

- Ketoconazole
- CYP enzymes
- ACE inhibitors or angiotensin II receptor antagonists
- Diuretics
- NSAIDs and Aspirin
- Lithium
- Methotrexate
- Coumarin-based anticoagulants
- Cyclosporine or Tacrolimus
- Aspirin
- Corticosteroids

Pregnancy, breast-feeding and fertility

Do not take Polvolt™ Capsules, if you are pregnant or think you may be pregnant or are planning to have a baby.

You should inform your doctor if you have problems becoming pregnant. NSAIDs may make it more difficult to become pregnant.

Polvolt™ Capsules should not be used if you are breast-feeding. It has been confirmed that Polmacoxib can be transferred to the breast milk of rats at a concentration similar to or slightly higher than that of plasma and transmitted to the fetus.

Pediatric use

The safety and effectiveness of Polmacoxib in pediatric patients under 18 years of age have not been established.

Geriatric use

Polvolt™ capsules should be administered carefully in elderly people.

Driving and using machines

Polvolt™ capsules may cause dizziness or drowsiness. So, you should not drive or operate heavy machinery if you feel dizzy or not fully alert.

3. How to take Polvolt™ Capsules

Always take Polvolt™ Capsules exactly as your doctor told you. Check with your doctor or pharmacist if you are not sure. Check the pharmacist's label for the dose recommended for you.

The recommended adult dose is **one Polvolt™ capsule (2mg) once daily** after a meal. The daily dose should not exceed 2 mg/day. Capsules should be swallowed whole and not to be opened, chewed, or crushed. Polvolt™ Capsules are not recommended for use in children.

If you take more Polvolt™ Capsules than you should-

- If you take more capsules than you should (an overdose), seek medical attention immediately. Immediately go to the emergency room of a nearby hospital.
- Symptoms of overdosage of non-steroidal anti-inflammatory painkillers generally include lethargy, drowsiness, nausea, vomiting, epigastric pain, etc. can be restored to normal with auxiliary treatment.
- Gastrointestinal bleeding may also occur, and in rare cases, hypertension, acute renal failure, respiratory depression, and coma may occur.

If you forget to take Polvolt™ Capsules-

Do not take a double dose to make up for the forgotten dose. Take your capsule as soon as you remember and continue to take your medicine as usual, but do not take more than one capsule a day.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The most commonly reported side effects of Polmacoxib were associated with GI and general disorders.

Rare but serious side effects may include:

- Myocardial infarction,
- Stroke, High blood pressure,
- Generalized edema (fluid retention) due to heart failure,
- Kidney disease, including kidney failure
- Gastrointestinal bleeding and ulcers
- Decreased red blood cells (anemia)
- Life-threatening skin reactions
- Life-threatening allergic reactions
- Liver disease, including liver failure
- Asthma

Other side effects may include: Abdominal pain, Constipation, Diarrhea, bloating, Gas, Heartburn, Nausea, Vomiting, Dizziness

If you experience any of the following symptoms, call for an emergency immediately.

- Shortness of breath or difficulty breathing.
- Chest pain
- Weakness in one part or one side of the body
- Swelling of the face or throat

If you experience the following symptoms, stop taking the drug and consult your doctor.

- Nausea
- When you feel more tired and weak than usual
- Itching
- Skin or eyes turn yellow
- Abdominal pain
- Flu-like symptoms
- Vomiting blood
- Bloody stool or black, sticky stool like tar.
- Skin rash or blisters accompanied by fever
- Abnormal weight gain
- Swelling of the arms, legs, hands, and feet

If any of the side effects become serious, or 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, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly: Website: www.zuventus.co.in and click the tab “Safety Reporting” located on the top end of the home page.

By reporting side effects, you can help provide more information on the safety of this medicine.

You can also report the side effect with the help of your treating physician

5. How to store Polvolt™ Capsules

Keep out of reach of children.

Polvolt™ Capsule should be swallowed whole and not to be opened, chewed or crushed.

6. Contents of the pack and other information

What Polvolt™ Capsule contains

Each hard gelatin capsule contains:

Polmacoxib 2 mg

Excipients q.s.

What Polvolt™ Capsules looks like and contents of the pack

Alu-Alu blister strip of 10 capsules.

Marketing Authorisation Holder

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